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FERMENTATION PILOT PLANT  
TECHNO-ECONOMIC STUDY

DP/MYA/85/013

UNION OF MYANMAR

Technical report: Findings and recommendations\*

Prepared for the Government of the Union of Myanmar  
by the United Nations Industrial Development Organization,  
acting as executing agency for the United Nations Development Programme

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PRINCIPAL ABBREVIATIONS AND ACRONYMS USED

AMSD	Army Medical Stores Department
BPI	The Burma Pharmaceutical Industry
CMSD	Central Medical Stores Depot
DCPT	The Development Centre for Pharmaceutical Technology
GDP	Gross Domestic Product
GMP	Good Manufacturing Practice
GTZ	German Agency for Technical Cooperation Ltd.
IBRD	International Bank for Reconstruction and Development
MMTC	Medicines and Medical Equipment Trading Corporation
MPI	Myanma Pharmaceutical Industries
M <sup>2</sup>	Square Meter
SSB	Social Security Board
UNICEF	United Nations Children's Fund
UNDP	United Nations Development Programme
UNIDO	United Nations Industrial Development Organization
WHO	World Health Organization
( . )	Indicates decimals
( , )	Distinguishes thousands and millions
Gm	Gram
Kg	Kilogram
Cm	Centimeter

M	Meter
Gln	Imperial gallon (4.5 liters)
Lt	Liter
Kw	Kilo watt hour
KVA	Kilo volt ampere
BHP	Boiler Horse power
Btu	British thermal unit (unit of heat)
HP	Horse Power
°C	degrees Celcius
°F	degrees Fahrenheit
Cuft	Cubic feet
PSI	Pounds per square inch (pressure unit)
P	Density
V	Viscosity
CP	Centipoise (unit of viscosity)
AISI	American iron and steel institute (standard for steels)
PSV	Pressure safety valve
P.I.	Pressure indicator
T.I.	Temperature indicator
PHI	pH indicator
DOA	Dissolved oxygen analyzer
D	Tank diameter (MTS)
CIF	Cost insurance freight
EIRR	Economic Internal Rate of Return
F/C	Fixed Costs
Forex	Foreign Exchange
FOB	Free on Board

IRR	Internal Rate of Return
K	Kyats
Landed	Included duties at the factory
VIC	Variable cost

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## EXECUTIVE SUMMARY

### 1.0 INTRODUCTION

1.1 Modern medicines for the most part are produced by the Burma Pharmaceutical Industry(BPI) based on the imported pharmaceutical active ingredients. Partly they are also imported in the ready to use formulations by some state agencies. Most of pharmaceutical active ingredients have to be almost entirely imported. In the light of the above, the intention of the Government is to upgrade the national pharmaceutical industry, advancing, as far as feasible, from pure formulation to production of pharmaceutical active ingredients.

Before an investment decision is made it is the intention of the Government, as an interim stage, to propose the establishment of a pilot plant for fermentation based pharmaceuticals for further absorption of technology plus training as well as for the evaluation of locally available agro-based products for use in fermentation.

In this connection, UNDP support has been requested to assess the technical and economic implication of establishing a pilot plant for fermentation based pharmaceuticals.

### 1.2 THE PHARMACEUTICAL SUBSECTOR-ASSESSMENT OF DEMAND FOR PHARMACEUTICALS

In recent years, on account of scarcity of foreign exchange, the domestic production of pharmaceuticals' formulations as well as the official imports of the same have declined. In view of this these figures do not represent the actual requirements. Hence, the concerned authorities advised that the pharmaceutical requirements for the purpose of the present project be calculated based on the conventional morbidity/mortality statistics and that these figures should be taken as the upper limit and the present official supplies of pharmaceuticals through domestic production and official imports as the lower limit. In this connection, two separate studies have been carried



out during the past decade concerning the pharmaceutical requirements in Myanmar - (1) Under the auspices of the German Agency for Technical Cooperation LTD (GTZ) and (2) Under the auspices of UNDP by the International Bank for Reconstruction and Development (IBRD). The GTZ Study considered the case frequency rate of the common diseases as one of the basic elements for calculating the Population's need for drugs, taking into account the available Myanmar morbidity statistics, supplemented by its own random sampling of Primary surveys. The GTZ study also based its calculation of requirements assuming the total population of Myanmar as the target consumption group for drugs. The quantities arrived at and the demand projection made by the GTZ Study represent a comprehensive effort so far.

The IBRD Study, however, made some arbitrary assumptions in assessing the pharmaceutical requirements. For example, pharmaceuticals, which should be consumed, rather than those which were being consumed guided the estimate provided by the IBRD Study. The requirements of pharmaceuticals and the demand projection as estimated by the IBRD Study are therefore, rather arbitrary and are subject to several preconditions. In view of the above, the pharmaceutical requirements and demand projection as estimated in the GTZ Study were taken as the upper limit of pharmaceutical demand in the present project.

### 1.3 DEVELOPMENT CENTRE FOR PHARMACEUTICAL TECHNOLOGY (DCPT)

DCPT, which is one of the units within Myanma Pharmaceutical Industries of the Ministry of No. 1 Industry was established in 1982 within the frame work of Myanma/Japanese Technical Cooperation with the object of undertaking development and research in the areas of pharmaceuticals, the utilization of indigenous resources for pharmaceutical products and training. Among the different activities of DCPT, the fermentation department is engaged in the research and development in the utilization of indigenous resources to produce antibiotics by fermentation, collection of microorganisms and training in basic fermentation technology. This department has

a nucleus of well qualified and technical staff. Some standard equipment are available in this department and the laboratories are well equipped with sophisticated instrumentation. However, the equipment is limited to the laboratory and small scale operations and there is need to supplement the same with some tanks and equipment for the recovery of the Product, for which recommendations are made.

There is also need to impart practical training to the fermentation staff to enable them to carry out fermentation studies. In view of this, it is recommended that two microbiologists presently involved in Penicillin fermentation work, one fermentation supervisor, one chemical engineer and one mechanical engineer be trained for a period of six months each in actual Pilot Plant/plant operations and maintenance in a Penicillin and ampicillin plant aboard. Possible locations for such training have been suggested. In the meantime, it is desirable that all the nucleus staff are engaged in running the existing pilot plant on a continuous basis, for which raw materials need to be procured.

The development work carried out in the course of past eight years is interesting and useful. However, more intensive work has to be carried out on a continuous basis in selected areas in order to develop technology for small scale production and to replace imported agro-based materials in the fermentation process.

Bearing the above in mind, recommendation are made for further development work, which could be carried out within the capabilities of DCPT as well as outside.

With a view to motivate the nucleus technical staff for further development effort and dedication, some sort of incentives are recommended.

## 2.0 TECHNOLOGY TRANSFER AT DCPT BY UNIDO CONSULTANT

The development work on Penicillin fermentation had been initiated in view of its importance to Myanmar. Indigenous raw materials for the sporulation of the culture *P. chrysogenum* have been evaluated based on which the imported materials have been replaced by the indigenous ones. Five shake flask fermentation batches have been completed using some indigenous materials and the rated productivity of the culture strain have been obtained. Due to the non-availability of some imported raw materials, despite efforts to procure them in time, Scale up work could not be taken up. Assistance has also been given in testing and commissioning of locally fabricated 150 liter fermentor. Technology also has been transferred for the processing of local maize to obtain starch and corn steep liquor to replace the imported materials.

### 2.1 POTENTIAL FOR THE UTILIZATION OF AGRO-BASED PRODUCTS IN THE FERMENTATION PROCESS - IMPORT SUBSTITUTION

The sources of some of the raw materials were identified, places visited and discussions were held with the concerned. These included cotton seed cake, yeast, distillers solubles, barley, Palm sugar Syrup and Sugar as well as Sorghum for use in fermentation Process.

## 3.0 ASSESSMENT OF TECHNICAL AND ECONOMIC FEASIBILITY OF SMALL SCALE PRODUCTION IN VIEW OF DEMAND FOR FERMENTATION BASED PHARMACEUTICALS

The supply of pharmaceuticals through domestic production and official imports falls much short of demand. In recent years, this situation worsened due to the scarcity of foreign exchange. Apparently, the gap has been filled by receipts through illegal channels, which in their turn pose serious health hazards. Since there is no local production of fermentation based pharmaceutical active ingredients, the domestic supply fluctuates widely depending on the availability of foreign exchange.

Since pharmaceuticals are next only in importance to food, the present situation concerning supply vs demand highlights the need to set up a small scale production capacity of at least some of the essential fermentation based pharmaceuticals.

With the development work carried out by DCPT, the presence of qualified scientific and technical staff, the availability of well equipped microbiological and chemical laboratories and some standard equipment, there exists some technical base.

The implementation of the recommendations for further development work made by the United consultant will provide the necessary technical base to take up small scale production of fermentation based pharmaceuticals.

A review of the projected demand of fermentation based pharmaceuticals suggests that the quantities involved are apparently below the minimum economic size for a commercial scale production. However, there is need to set up a fermentation pilot plant to carry out further development work to improve technology, to evaluate indigenous raw materials, to produce small quantities of specific pharmaceuticals for investigation purposes, for training and finally to have the potential to meet fully the present and the demand in the year 2,000 of few essential fermentation based pharmaceuticals.

#### 4. PRELIMINARY DESIGN OF A FERMENTATION PILOT PLANT BASED ON DEMAND, WORK OF DCPT AND ASSESSMENT OF TECHNICAL AND ECONOMIC FEASIBILITY OF SMALL SCALE PRODUCTION

The design of a fermentation pilot plant is presented, which is flexible enough to carry out all the functions mentioned above. As regards the production capacity, the pilot plant can produce small quantities of special products as well as quantities of Penicillin and ampicillin or tetracycline to meet the full needs of

Myanmar. As regards technology, DCPT has some technology for Penicillin and industrial enzymes and this could be improved further. The present day antibiotics industry in the industrialized countries utilizes high yielding microbial and culture strains, which are rather expensive. For example, the technology package with a Penicillin strain with a productivity of 55,000 units per milliliter costs around US \$500,000. However, the strains of lower productivity cost much less and these could be procured for the proposed pilot plant.

#### 4.1. EQUIPMENT FOR PILOT PLANT

A list of major equipment for the pilot plant has been prepared. The fermentors vary in size from 30 liters to 20,000 liters capacity and the equipment for the recovery is geared to the individual capacities of the fermentors. The equipment provided takes into account the existing facilities at DCPT to avoid duplication, to integrate and strengthen where necessary.

Important attention has been given to the recovery of solvents used in the process as well as the treatment of effluents. Except for some carbon steel storage tanks, all the other equipment have to be imported.

#### 4.2. PREMISES

A lay out of the pilot plant is presented. The production block, which is the main building and the nerve centre of the pilot plant is a U-shaped building of reinforced cement concrete construction.

It has three floors and has a total area of 802.5 m<sup>2</sup> or 8,671 square feet. Based on the discussion with the officials of the State Public works Department, except for some items such as aluminum doors, window frames, glazed tiles, acid proof tiles and glazed stone ware pipe, all the rest of the construction materials are locally available. The Cost of the production block excluding the

imported components works out to about K 4,680,000. The Cost of the other units is extra.

The layouts and elevation of pilot plant at different levels are presented. The construction of the production block is expected to take about one year.

#### 4.3 LOCATION OF THE PLANT

Since the proposed pilot plant is complementary to DCPT and as the fermentation based pharmaceuticals produced will primarily be used by BPI; it is desirable to locate the pilot plant in the territory of DCPT adjacent to BPI.

Further, there are well laid out communication system, roads and other infrastructure available at DCPT. The required power supply is expected to be available by the time proposed pilot plant takes shape. There is also adequate space within the territory of DCPT for the location of the pilot plant.

### 5. FINANCIAL AND ECONOMIC ANALYSIS

#### 5.1 OBJECTIVES

The objectives of the proposal stress the social and economic criteria which should be recognized in determining the desirability of the project to the government and people of Myanmar. Government officials made clear however that financial feasibility was an important government consideration. Basic economic aspects of the proposal have been drawn on to provide the basis for the calculations which follow. Such aspects include:

1. The market for pharmaceutical products and effective demand.
2. The selection of products for manufacture and processing.
3. Location, infrastructure and services.

4. Manung levels.
5. The type and scale of technology.

Essential technical factors include output levels and the rate of build-up of capital utilization, and the quantities of costs of related inputs.

The objectives of the proposal have been set out partly to counter problems caused by current economic circumstances, and partly in recognition of the economic and social benefits which their achievement would create.

Although the proposal is essentially for an experimental project, it would firstly by saving foreign exchange, secure an improved supply of essential medicines; and secondly by developing new technical skills and local resources promote economic development.

Products were selected which are in demand in considerable quantities, and which have a common technical base. This allows for either ampicillin or penicillin V to be selected as the basis for the cost-benefit calculations.

Combinations of these products with other products may be desirable, though this could clearly result in higher unit costs.

## 5.2 FINANCIAL ANALYSIS

Product pricing is the crucial issue in determining the financial feasibility of the project. As the products are basic essentials for which there is an inelastic demand, and as the main supply is controlled by government, the manipulation of the prices can be relied upon to produce the desired results. Despite detailed information on a range of current prices, the distribution of products, some free, and other at prices appreciably higher than the manufactured cost, means that it is

difficult to establish an appropriate market price. Sensitivity was applied to prices to determine acceptable limits and at the "landed" price of K860 for Ampicillin the project would have a "marginal" return of 6%, while at a price used by BPI of K1266 adjusted down to K1000 the return would be 11%. For Penicillin V tablets the price was more difficult to establish, because of the intermediate nature of the product. A price of K 35 per 100 x 250 mg tablets was therefore used, as provided by BPI. This results in an IRR of 38% which suggests that production of Penicillin V tablets would be financially feasible. The introduction of indigenous raw materials would slightly improve these returns, but not significantly. In order to anticipate possible changes in capital cost an increase of 10% was applied to ampicillin, reducing the return from 11% to 10% suggesting limited scope for absorbing capital cost increases. An increase in capital costs of 30% applied to Penicillin V reduced the return from 38% to 30%.

In view of the nature of the project it has been assumed that no duties would be applied to the imported components of the capital investment. Whether this would be true in practice is unclear, but in view of the need for external financing there would appear to be little justification for duties to be applied. Duties have however been taken into account in the costing of inputs. In the economic analysis these are ignored. It might be less justifiable to ignore taxes on income. Such taxes have been ignored on the understanding that the project would not show a financial profit, but would attempt to cover all costs and apply any surplus to new research and development; or ultimately to lower the prices of the products.

In view of the absence of information on the possible financing of the project, no assumptions have been made about funding in the cash flows, which have been left with negative values to indicate the finance required. The capital cost estimates which should be financed are as follows:



(K 000's)

Year	1	2	3	Total
Foreign	7458	7665	501	15624
Domestic	7574		1562	9136
	15032	7665	2063	24760

These figures include the foreign costs of expatriate experts and training.

### 5.3 ECONOMIC ANALYSIS

The absence of prepared government economic parameters necessitated a simplified UNIDO approach to the economic appraisal, based on information collected from staff at DCPT and from informal contacts in the township. The project will undoubtedly produce indirect benefits of some value to the country, but it is not possible to quantify their worth. It is not known how far the resources applied to the project would be additional to, or replace, the resources which would otherwise have been employed in the provision of pharmaceuticals to the country. Nor is it clear if the output from the project will affect the supply or price to the consumer. The extent to which benefits may be derived from the saving of life or the curing of sickness from an additional supply of medicines may not be quantifiable, but is worth some consideration. Training in new technology and the development of new products using indigenous raw materials also offers unquantifiable benefits.

Direct benefits are mainly derived from the substitution of indigenous materials and skills for imported products, thereby reducing dependence on scarce foreign exchange. These benefits are measured by applying a premium of 600% to the foreign exchange components of the project. No economic discount rate was adopted, and no adjustment was made to salaries and wages. The

economic cost-benefit of ampicillin production was based on Table J, using the cif price of K600 per kg. This produced a return of just over 11%. The economic cost-benefit of producing penicillin V tablets was derived from Table L, but as no product in this form is imported the cif cost of imported penicillin V was added to the cost of producing tablets. This does not produce any significant return. However, using a quotation from a UK supplier, a cif price of K549 results in an economic IRR of 21%.

## 6. CONCLUSIONS

The economic and political circumstances prevailing at present in Myanmar highlight the fact that in order to succeed a project would require the support of the government. This support may not be forthcoming unless the project can show financial feasibility. This project is concerned with new technology, with experimentation to develop new products from indigenous materials, and the supply of medicines to the population. In an open market it might be considered unlikely that the project could be financially feasible, but under the circumstances and using free market prices as far as they are known, the project does not appear to be financially feasible. The returns are modest but reasonable, and should be considered insofar as they indicate financial viability. The industry is government controlled and prices are currently manipulated. A minor degree of manipulation would ensure the project maintained financial independence.

Although the economic and social benefits should have priority, it is difficult to demonstrate the extent to which the project could benefit the country in view of the unquantifiable nature of the project's objectives. However, taking only the direct benefits there appears to be an acceptable degree of feasibility. When the unquantifiable benefits are considered in addition there would appear to be little doubt that the project would make a valuable contribution to the country.

The main difficulties are two. One is the obstacle in terms of the amount of foreign exchange which must be secured to fund the foreign exchange costs of the investment; and the other is the need to find the

necessary motivation for the staff of such a project. Both would require the unqualified support of the government.

## 7. RECOMMENDATIONS

### 7.1 RECOMMENDATIONS TO BE IMPLEMENTATION ON A SHORT TERM BASIS

#### 7.1.1 Development work, which needs to be undertaken within the capabilities of DCPT

##### Equipment

Since good quality equipment are available in the fermentation department and laboratories of DCPT along with some trained personnel, it is desirable to use these equipment on a continuous basis. This will provide the basis for a meaningful development work in the area of fermentation, import substitution and technology development (Refer IV.10.1.1).

##### Training

As there is a paucity of personnel actually trained in fermentation operations, it is necessary to train other available staff in the existing pilot plant. The trained staff will serve as a nucleus for the proposed pilot plant (Refer IV.10.1.2).

#### - Isolation of microbial cultures and strain improvement

In view of the pivotal role of microbial strains in antibiotic fermentation, it is appropriate to intensify work on Penicillin producing microbial cultures on the lines of work carried out during the tenure of the UNIDO Fermentation technologist. Similarly development work could be carried out on enzyme Amidase for ampicillin production (Refer IV.10.1.3.1).

#### Experimental antibiotic fermentation

It is desirable to carry out fermentation on a continuous basis in both the 30 liter fermentors as well as the 150 liter fermentor for experimental production of Penicillin and Tetracycline. Effort should be made to recover antibiotics of pharmacopoeial quality (Refer IV.10.1.3.2).

#### Import Substitution

As the major raw materials used in fermentation are agro-based and many of these including soybean, sorghum, cotton seed, corn, Peanut, vegetable oils and sucrose are available in large quantities in Myanmar, they could serve as import substitutes. However, a lot of development work needs to be carried out to confirm their suitability on the lines suggested by the UNIDO expert (Refer IV.10.1.3.3.). Further efforts should be made to locate additional raw materials locally as was done by UNIDO expert (Refer VI).

#### 7.1.2 Development work necessary outside the capabilities of DCPT

In order to carry out further development work in the area of antibiotic fermentation, it will be necessary to provide additional equipment and facilities, train abroad few key technologists, microbiologists and engineers and provide a limited international expertise. For this purpose, UNIDO Team leader prepared a detailed project document, which was discussed with BPI, DCPT and local UNDP authorities in March, 1989. It is recommended that BPI may approach concerned Myanmar ministries and UNDP for its approval. This is also essential for creating the necessary base for proposed fermentation pilot plant (Refer IV.10.2)

## 7.2 RECOMMENDATIONS TO BE IMPLEMENTED ON A LONG TERM BASIS

### 7.2.1 Establishment of a fermentation pilot plant

The technical and economic feasibility has been discussed in great depth in the report. There is no doubt, need and justification for a fermentation Pilot plant, as elaborated in detail in the report. Although such a pilot plant is primarily meant for the development and transfer of technology, training, import substitution utilizing locally available agro-based raw materials, experimental production, the pilot plant will have the capacity to meet the projected demand of few essential antibiotics. As is evident from the financial and economic analysis, in such a case and under the given circumstances prevailing in Myanmar and using free market prices, the project does appear to be financially feasible.

Based on above, a design of the fermentation pilot plant has been carried out and this covers a detailed list of equipment, premises, manpower and training needs, identification of location within the territory of DCPT and investment costs in terms of domestic and foreign currency. Since this project has a sizeable foreign exchange component and in view of scarce foreign currency resources, two alternate lines of action are recommended as indicated below.

#### 7.2.1.1 Implementation of the project with external assistance

In the light of the Government's policy to encourage and enlarge the scope for international industrial cooperation, specifically through foreign direct investment, the project could be promoted with a view to attract entrepreneurs from industrialized countries. For this propose, all relevant information is available in the report.

3.2.1.2 Implementation of the project with UN assistance

Here again the paucity of the foreign exchange resources is a limiting factor. Since this project constitutes an experimental pilot plant and not a commercial plant per se, it could qualify for the UN assistance. Of course this would depend on the resources available and the priorities established by the Government and UNDP. In case it is decided to seek UN assistance, a detailed project document needs to be prepared.

INTRODUCTION

## 1.1.

Background and objectives

Historically speaking the 20 Year Long Term Plan of the Government accords great importance to the health of the population. Under the consecutive four year plans Country - wide grass root level public health programmes are being implemented. They are accompanied by efforts to expand the supply of both traditional and modern medicines.

Modern medicines for the most part are produced by the Burma Pharmaceutical Industry (BPI) under the Myanma Pharmaceutical Industries (MPI) of the Ministry of Ho.I Industry, based on imported Pharmaceutical active ingredients. Partly they are imported in the ready to use formulations by some state agencies. Most of the pharmaceutical active ingredients have to be almost entirely imported. In addition many of the machines of BPI are old and obsolete and require replacement and renovation.

In the light of the above, the intention of the Government is to upgrade the national Pharmaceutical industry, advancing, as far as possible, from pure formulation to production of pharmaceutical active ingredients, in order to save foreign exchange and to expand the volume and range of pharmaceuticals.

In September 1988, sweeping economic changes were announced by the Government with a view to promote a rapid transformation from a low - productivity agricultural to a high productivity agro-based industrial economy, favouring a more market oriented and open economic policy frame work.

Before an investment decision is made, it is the intention of the Government, as an interim stage, to propose the establishment of a pilot plant for fermentation based pharmaceuticals for further absorption of technology plus training as well as for the evaluation of locally available agro-based products for their use in fermentation. In this connection, UNDP support has been requested to assess the technical and economic implications of establishing a pilot plant for fermentation based pharmaceuticals.

The complete Terms of Reference are Presented in Annex I.1.

I.2.

Execution of the Study

The United Nations Development Programme (UNDP) is financing this Study and the United Nations Industrial Development Organization (UNIDO) is acting as the Executing Agency. The Study involved the fielding of three Consultants as follows :

<u>Consultant</u>	<u>Duration in the field</u>
- Mr. C. N. Chari (Fermentation Technologist and Team Leader)	November 30th., 1989 to March 29th., 1990
- Mr. C. G. Ludlam (Industrial Economist)	March 5th., 1990 to March 31st., 1990
- Mr. (Chemical Engineer)	1990 to 1990.

The Consultants were based at the Development Centre for Pharmaceutical Technology (DCPT), Yangon. The Team Leader also visited Pagan and Mandalay to examine the agro-based Products, which have potential for their utilization in the fermentation Process.

The Consultants carried out their respective assignments in accordance with the Terms of Reference. Managerial and Technical staff were assigned by DCPT to assist the Consultants.

A preliminary draft report excluding the financial analysis was submitted in March 1990 for review and comments by the parties concerned.

I.3.

Acknowledgment

The Consultants wish to express their appreciation to all the agencies and individuals, who so graciously extended their Cooperation in the Course of the mission. Special thanks are due to Dr. Ko Ko Gyi the National Project Director for his kind advice and assistance throughout and to U Ban Yi, Director, Planning, Myanma Pharmaceutical Industries for his guidance.



II

OVERALL ECONOMIC FRAME WORK

II.1.

GENERAL

Myanmar is situated in South East Asia and shares borders with Bangladesh, India, China, Laos and Thailand. The Country has 2,414 Km. of Coast line bordered on the West by the Bay of Bengal and in the South by the Andaman Sea. As can be seen from Fig. II.1. <sup>1)</sup>, the major Myanma river Irrawaddy, flows South through the Central plain. The Salween, the Sittang and the Chindwin are three other important rivers also flowing in the same direction. The main features of Myanmar are a delta region and a central plain surrounded by mountains.

Myanmar has an area of 676, 577 Sq. Km. The estimated population (1985) was 37.1/million. The Population Growth rate has been 2.0, Population density - Persons/Km<sup>2</sup> in 1984 has been 56 and the GNP per Capita (1985) was US\$ 190. Approximately 80 percent of the population is rural, residing in some 65,300 villages and hamlets. According to the latest Census, 89.4 percent of the people are Buddhists, 6.1 percent are Christians, 3.9 percent are of the Islamic Faith, 0.5 percent are Hindus and 0.1 percent are others.

II.2.

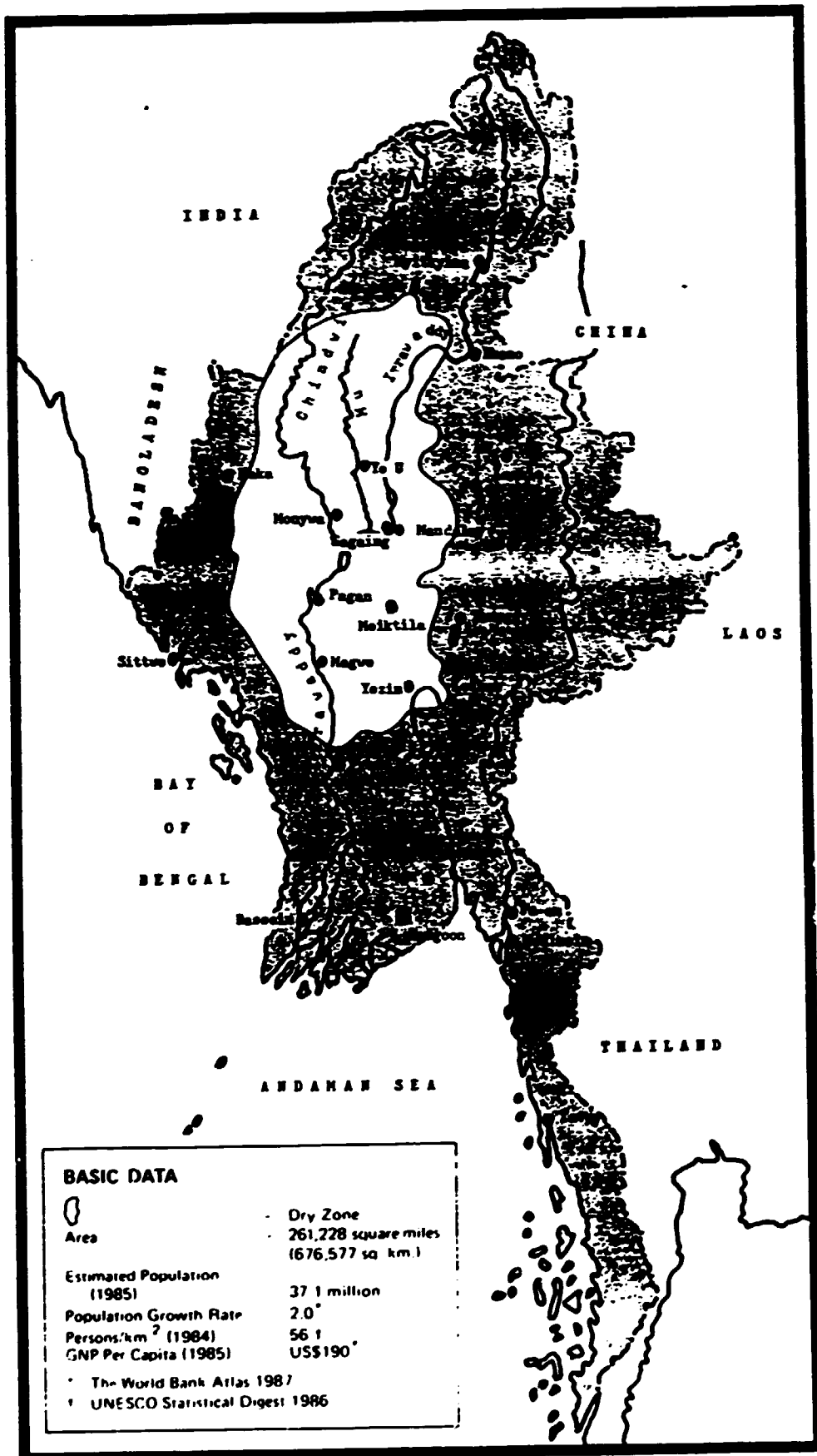
STRUCTURE OF THE ECONOMY

Myanmar is predominantly an agricultural Economy. Agricultural Production constitutes approximately 40 percent of the GDP. Over 62 percent of the active labour force are engaged in agricultural work. The importance of agriculture in the economic development of the Country has gained increasing recognition in recent years. Two major factors have contributed to this, namely population growth, the necessity to expand food production and the success achieved in obtaining dramatic increases in crop yields through the use of new technology. In the past decade, yields have nearly doubled in the case of paddy and increased even more in the case of other grains and pulses.

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1) Source : The United Nations and Burma; UNFIC November, 1987

FIGURE II-1 THE SOCIALIST REPUBLIC OF THE UNION OF BURMA



SOURCE : The United Nations and Burma, UNIC, 1987

Data on sectoral composition of GDP for recent years are given in Table II.1. It can be seen from the provisional figure for 1988/89<sup>1)</sup> that slightly more than 40 percent of GDP originated from agriculture, as pointed out above and another 6.3 percent from live stock and fishery. During the same period, processing and manufacturing activities accounted for 8.9 percent of GDP, services for 16.0 percent and trade activities for 22.5 percent. The export value by type of commodity in recent years is provided in Table II.2, from which it is apparent that the share of agricultural products declined over the recent years partly due to declining prices. The composition of gross manufacturing output during recent years along with long term trends is shown in Table II.3, from which it can be seen that food and beverages account for nearly 77 percent of the gross manufacturing output.

### III

#### THE STRUCTURAL SETTING

#### III.1.

##### THE INDUSTRIAL SECTOR

The manufacturing sector of Myanmar accounts for less than 10 percent of the Country's GDP and employs less than 9 percent of the labour force. The main manufacturing activities are related to the processing of natural, mostly agricultural resources and petroleum refining. As already indicated, the production of food and beverages generates more than three quarters of gross manufacturing output and about 40 percent of manufacturing value added. Private industries have in the past been confined to small scale activities, with a heavy emphasis on agro-processing. Since 1982/83 the real manufacturing value added by and large declined every year, as production was beset by shortages of essential imported inputs due to scarcity of foreign exchange.

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1) Source : UNIDO Industry Sector Review Mission to Myanmar, FPD/R.30; 12 October, 1989.

The fiscal year extends from April 1 - 31 March

Table II-1: GDP by sector (at 1985/86 constant producers' prices)

Economic sector	Value				Structure				Growth Rate		
	1985/86	1986/87	1987/88 <sub>a</sub> /	1988/89 <sub>a</sub> /	1985/86	1986/87	1987/88 <sub>a</sub> /	1988/89 <sub>a</sub> /	1986/87	1987/88 <sub>a</sub> /	1988/89 <sub>a</sub> /
	Kyat in million				P e r c e n t a g e						
<u>Goods</u>	34300.6	33977.0	32245.2	32715.9	61.3	61.3	60.8	61.5	(-) 0.9	(-) 5.1	1.5
Agriculture	22243.5	22343.3	20906.8	21365.7	39.7	40.3	39.4	40.2	0.4	(-) 6.4	2.2
Livestock & Fishery	3981.9	4056.8	4212.5	4388.0	7.1	7.3	7.9	8.3	1.9	3.8	4.2
Forestry	757.7	719.6	688.2	797.2	1.4	1.3	1.3	1.5	(-) 5.0	(-) 4.4	15.8
Mining	533.5	498.4	428.6	346.3	1.0	0.9	0.8	0.6	(-) 6.6	(-) 14.0	(-) 19.2
Processing & Manufacturing	5561.4	5123.3	4810.1	4737.9	9.9	9.3	9.1	8.9	(-) 7.9	(-) 6.1	(-) 1.5
Power	278.0	289.0	300.6	338.6	0.5	0.5	0.6	0.6	4.0	4.0	12.6
Construction	944.6	946.6	898.4	742.2	1.7	1.7	1.7	1.4	0.2	(-) 5.1	(-) 17.4
<u>Services</u>	8300.0	8600.0	8869.3	8494.9	14.8	15.5	16.7	16.0	3.6	3.1	(-) 4.2
Transportation	2010.4	2004.1	2039.0	1781.0	3.6	3.6	3.8	3.4	(-) 0.3	1.7	(-) 12.7
Communications	207.7	254.8	288.5	285.0	0.3	0.4	0.6	0.5	22.7	13.2	(-) 1.2
Financial Institutions	1332.3	1421.1	1498.6	1602.0	2.4	2.6	2.8	3.0	6.7	5.5	6.9
Social & Administrative Services	2567.8	2659.3	2746.9	2616.2	4.6	4.8	5.2	4.9	3.6	3.3	(-) 4.7
Rentals & other Services	2181.8	2260.7	2296.3	2210.0	3.9	4.1	4.3	4.2	3.6	1.6	(-) 3.8
<u>Trade</u>	13388.7	12819.8	11932.9	11944.8	23.9	23.2	22.5	22.5	(-) 4.2	(-) 6.9	0.1
<u>GDP</u>	55989.3	55396.8	53047.4	53155.6	100.0	100.0	100.0	100.0	(-) 1.1	(-) 4.2	0.2

a/ Provisional.

Source : UNIDO Industry Sector Review Mission to Myanmar, FPD/R 30, 1989

**Table II-2. Export value by type of commodity, 1985/86 - 1987/88**  
(in million kyat)

Type of commodity	Export value		
	1985/86	1986/87	1987/88 <sup>a/</sup>
Exports	2566.1	2418.5	1655.2
Agricultural products	1131.0	800.5	453.5
Animal & marine products	99.8	124.5	76.3
Forest products	1051.0	1084.1	754.3
Minerals & gems	205.9	283.9	225.0
Others	78.4	125.5	146.1
Re-exports	87.8	95.4	24.2
<b>TOTAL</b>	<b>2653.9</b>	<b>2513.9</b>	<b>1679.4</b>

**Source:** UNIDO Industry Sector Review Mission to Myanmar, 1989

**a/** Provisional.

**Table II-3. Composition of gross manufacturing output, 1975/76-1988/89**  
(percentage)  
(in current prices)

	1975/76	1976/77	1977/78	1978/79	1979/80	1980/81	1981/82	1982/83	1983/84	1984/85	1985/86	1986/87	1987/88a	1988/89 <sup>a/</sup>
Food and beverages	69.8	66.7	67.4	68.7	67.4	65.8	65.4	64.7	65.6	70.1	72.0	74.0	76.6	76.8
Clothing and wearing apparel	7.8	9.2	9.6	8.3	8.6	8.7	8.2	8.6	7.5	7.1	6.4	5.1	4.3	3.6
Construction materials	3.2	3.3	3.2	3.3	4.4	4.5	4.2	4.1	4.4	3.5	3.5	3.7	3.2	2.6
Personal goods	3.2	3.5	2.8	2.4	2.2	2.7	3.0	2.8	2.2	1.8	1.8	1.5	1.0	0.9
Household goods	0.3	0.4	0.4	0.4	0.4	0.6	0.6	0.7	0.6	0.6	0.5	0.7	0.6	0.6
Printing and publishing	1.1	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.1	1.0	0.8	1.0	0.8	0.8
Industrial raw materials	3.8	4.4	5.2	5.3	5.4	6.1	6.3	6.5	6.7	6.1	5.5	5.3	4.8	4.6
Mineral and petroleum products	6.5	6.8	6.1	5.5	5.4	5.2	5.1	5.7	5.8	4.4	3.9	3.3	3.3	5.2
Agricultural equipment	0.3	0.5	0.5	0.5	0.5	0.6	0.6	0.5	0.5	0.3	0.3	0.4	0.3	0.3
Machinery and equipment	0.1	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.2	0.0	0.1	0.1	0.1	0.2
Transport vehicles	1.1	1.1	1.6	1.9	1.9	1.8	2.0	2.1	2.2	1.8	2.0	1.9	1.5	1.8
Electrical goods	0.6	0.7	0.5	0.5	0.5	0.7	0.8	0.7	1.0	0.7	0.9	0.8	0.6	0.6
Miscellaneous	2.2	2.1	1.7	2.2	2.3	2.2	2.8	2.6	2.2	2.6	2.3	2.1	2.9	2.2
<b>TOTAL</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>

Source: UNIDO Industry Sector Review Mission to Myanmar, 1989

a/ Provisional.

The structure of ownership in the Country's industrial sector is shown in tables III.1. and III.2., from which it is apparent that the private factories and establishments account for nearly 94 percent, the State-owned enterprises account for 4.4 percent and the balance 1.7 percent is shared by the Co-operative Societies. However, the State enterprises account for 60 percent of all units in the case of agricultural equipment and for 70 percent in the case of machinery and equipment. Based on size, 99 percent of all the industrial establishments employing over 100 workers are State-owned. The share of private establishments is particularly high in the small scale light industries producing simple consumer goods. In general, all industrial activity of any significant size is concentrated in State-owned enterprises.

The capacity utilization rates have declined in recent years as can be observed from Table III.3. The main reason attributed to this steep drop is the acute shortage of foreign exchange to finance essential production - related imports. For example, the capacity utilization in the case of pharmaceutical industries dropped from 65.6 percent in 1985/86 to 28.3 percent in 1988/89. Besides, inferior technology and obsolete equipment could also have contributed their share to such a decline as can be seen from some earlier reports which will be discussed subsequently.

In the early sixties, the economic policy adopted in Myanmar was based on comprehensive central planning and State ownership of all important means of production. The main driving force of economic development was to be the public sector investment, while the overall economic strategy was geared towards strictly self-reliant development with priority being assigned to meeting the basic domestic needs. Gradual changes in the economic policy occurred during the formulation of the Twenty years Long Term Plan (1971/72 - 1990/91), in which the need was recognised to depend to a greater degree on Foreign trade and to provide incentives for private economic activities. In 1987, the price controls for rice and other basic commodities were abandoned. In September 1988, Sweeping economic policy changes were announced with a view to promote a rapid transformation from a low-productivity agricultural to a high productivity agro-based industrial economy; the new State Law and Order Restoration Council (SLORC) has officially discarded

Table III-1. Ownership structure of industrial establishments by sector, 1988/89<sup>a/</sup>  
(percentage shares)

Sector	<u>Operating factories and establishments</u>		
	State-owned	co-operative	private
Food & beverages	1.8	2.6	96.0
Clothing & wearing apparel	0.7	1.8	97.7
Construction materials	7.3	5.8	85.7
Personal goods	0.3	0.2	99.5
Household goods	1.1	1.5	97.2
Printing & publishing	20.0	5.0	75.0
Industrial raw materials	37.5	0.3	62.0
Mineral & petroleum products	0.7	0.3	99.0
Agricultural equipment	60.0	-	40.0
Machinery & equipment	70.0	-	30.0
Transport vehicles	1.9	3.1	95.0
Workshops & dockyards	100	-	-
Miscellaneous	0.2	0.6	99.2
<b>TOTAL</b>	<b>4.4</b>	<b>1.7</b>	<b>93.9</b>

Source: UNIDO Industry Sector Review Mission to Myanmar, 1989

a/ Provisional.



Table III-2. Ownership structure of industrial establishments by size, 1988/89

Size	State-owned	co-operatives	private	TOTAL
Below 10 workers	981	409	37,965	39,355
10-50 workers	297	308	1,824	2,429
51-100 workers	150	-	9	159
Over 100 workers	426	-	4	430
<b>TOTAL</b>	<b>1,854</b>	<b>717</b>	<b>39,802</b>	<b>42,373</b>

Source: UNIDO Industry Sector Review Mission to Myanmar, 1989

Table III-3 Capacity utilization rates of state-owned industries by industrial branches, 1985/86 and 1988/89

Industrial branch	1985/86	1988/89
<u>Industries under Ministry of No. 1 Industry</u>		
Myanma Textile Industries	57.1	29.1
Myanma Foodstuff Industries	51.4	48.8 <sup>±</sup>
Myanma Pharmaceutical Industries	65.6	28.3
Myanma Metal Industries	63.0	12.9
Myanma Ceramic Industries	70.2	51.8
Myanma General Industries	65.4	20.5
Myanma Paper & Chemical Industries	57.0	45.6
Myanma Jute Industries	26.5	24.4
<u>Industries under Ministry of No. 2 Industry</u>		
	60.7	48.6 <sup>±</sup>
<u>Average</u>	<u>57.4</u>	<u>34.4</u>

Source: UNIDO Industry Sector Review Mission to Myanmar, 1989

the Centrally planned approach in favour of a more market oriented and open economic policy frame work :

- (i) to encourage and enlarge the Scope for international industrial Co-operation, Specifically in the form of foreign direct investment
- (ii) to infuse modern technology into the Country's industry in order to increase its productivity and competitiveness and to achieve a diversification towards production and export of non-traditional manufactured products
- (iii) to partially deregulate the economy by (a) granting more Autonomy to private, Co-operative and State enterprises in areas Such as trading activities and entering into joint ventures; (b) privatizing and / or commercializing of State economic enterprises; and (c) adjusting and increasing the flexibility of the price structure.

III. 1. 1.

INSTITUTIONAL FRAME WORK FOR INDUSTRIAL DEVELOPMENT

The Ministry of No.1 Industry and the Ministry of No.2 Industry Share between them the overall policy responsibilities to direct and promote industrial investment and production in Myanmar. The Ministry No.1 Supervises industrial enterprises basically producing consumer products and other light products. The State economic enterprises covered by this ministry generate about 75 percent of the total production value under the two ministries of Industry. The Ministry No.2 accounts for the balance 25 percent, which include heavy industries along with machinery and transportation equipment. The State enterprises engaged in industrial production such as rice milling and wood processing are supervised by the ministries of Trade and Agriculture and Forest respectively.

The ministry of No.1 Industry has two service departments and Supervises industries in eight different branches of manufacturing (figure III. 1.):

- Directorate of Regional Industrial Coordination and Industrial inspection
- Industrial Planning Department
- Myanma Textile Industries
- Myanma Food Staff Industries
- Myanma Pharmaceutical Industries
- Myanma Metal Industries
- Myanma Ceramic Industries



- Myanma General Industries
- Myanma Paper and Chemical Industries
- Myanma Jute Industries

Myanma Pharmaceutical Industries includes among others.

Burma Pharmaceutical Industries (BPI) and the Development Centre for Pharmaceutical Technology (DCPT).

The Industrial Planning Department is concerned with all matters pertaining to the planning and implementation of new projects, achievement of production targets, Procurement of industrial raw materials, Capacity utilization, quality improvements and financial management. The aggregate data on the number of factories, employment and Production value under the various Myanma Industries are shown in Table III.4., from which it is evident that textile and feed stuff industries are prominent in that they account between them, for 51 percent of all factories, 51 percent of total employment and 46 percent of total Production value.

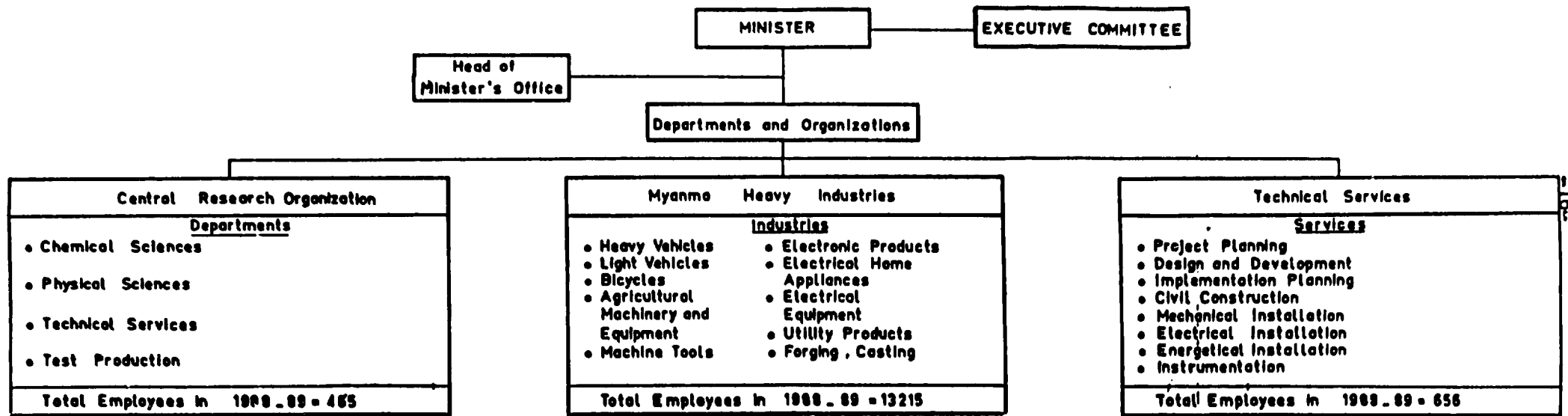
The Ministry of No.2 Industry Supervises the heavy industries including heavy vehicles, agricultural machineries and machine tools as well as the Country's first joint venture with an overseas partner, the Myanma Fritz Werner Corporation, which produces machine tools and metal fabrication equipment. Employment in these industries stood at 13,215 in 1988/89, which amounts to 19 percent of total employment under both the ministries of Industry (figure III.2.). In addition, the Ministry of No.2 Industry has two general service departments, the central Research Organization and the Technical Services. The former is a multi-disciplinary research organization with 10 technical departments including pharmaceuticals and 6 supporting departments employing a total technical staff of about 500 people. Emphasis is being placed on developing appropriate industrial processes responding to the needs of the local industries. Some of the Processes developed are currently under pilot operation at the Central Research Organization.

Table III-4. Myanmar Industries under MI 1: Number of factories, employment and production value, 1988/89

Industries	No. of factories	Employment	Production value (kyat million)
Myanmar Textile Industries	34	19,813	374
Myanmar Foodstuff Industries	37	9,397	675
Myanmar Pharmaceutical Industries	12	4,410	272
Myanmar Metal Industries	5	2,608	303
Myanmar Ceramic Industries	16	5,945	216
Myanmar General Industries	14	2,438	91
Myanmar & Chemical Industries	9	4,544	167
Myanmar Jute Industries	13	3,222	192
<b>TOTAL</b>	<b>140</b>	<b>57,477</b>	<b>2,290</b>

Source: UNIDO Industry Sector Review Mission to Myanmar, 1989

Figure III-2. Organizational chart of Ministry of No. 2 Industry



Source : UNIDO Industry Sector Review Mission to Myanmar, 1989

III.1.2.

MYANMA PHARMACEUTICAL INDUSTRIES (MPI)

Myanma Pharmaceutical Industries (M.P.I) is the successor to the former Pharmaceutical Industries Corporation, which was constituted in 1972. M.P.I was given its new name on August 1, 1989. M.P.I is one of the eight Myanma Industries under the Ministry of No.1 Industry. The organization chart of M.P.I. is presented in Annex III-24. The organization is headed by a Managing Director, who reports to the Minister and a Managing committee is the governing body of MPI. The latter comprises four departments viz. Planning, Production, Finance and Administration each under the charge of a Director. There are 12 factories and the Development Centre for Pharmaceutical Technology under M.P.I. as mentioned below.

<u>Factory</u>	<u>Location</u>
(1) Burma Pharmaceutical Industry	Gyogon, Yangon
(2) Pharmaceutical Raw Materials Factory	Hmawbi
(3) Toilet Industry	Thu Huma, Yangon
(4) Plastic Factory No.1	North Okkapa, Yangon
(5) Plastic Factory No.2	Thamaing, Yangon
(6) Plastic Factory No.3	Hmawbi
(7) Soap Factory No.1	Okkyin, Yangon
(8) Soap Factory No.2	Hlaing, Yangon
(9) Soap Factory No.3	Mandalay
(10) Industrial oil Factory	Hlaing, Yangon
(11) Refined oil Factory	Nayangon, Yangon
(12) Coconut Industry	Yangon
(13) DCPT	Gyogon, Yangon

The constitution of M.P.I. also provides for performing such other functions as are related to the above activities, inter-alia, the implementation of new projects by itself or by Joint Venture with foreign industrialists or entrepreneurs.

M.P.I. is currently implementing a Pesticide Formulation plant at Hmawbi, 56 Kilometers to the north of Yangon with financial

assistance from UNIP. The number of Personnel employed by M.P.I. and different factories are shown below :

<u>Unit</u>	<u>No. of Personnel</u>
(1) M.P.I. (Head office)	205
(2) Burma Pharmaceutical Industry (BPI)	2125
(3) Pharmaceutical Raw Material Factory	52
(4) Toilet Industry	443
(5) Plastic factories No.1,2 and 3	311
(6) Soap factories No.1,2 and 3	856
(7) Industrial oil factory	153
(8) Refined oil Factory	89
(9) Coconut Industry	157
(10) Development Centre for Pharmaceutical Technology (DCPT)	176
TOTAL	4567

The annual working capital, total sales turn over and annual profits of M.P.I. are 606.0; 286.4 and 26.7 million kyats respectively for the fiscal year 1988-89.

The major production unit amongst the above factories is Burma Pharmaceutical Industry (BPI) in Yangon, which is dealt with subsequently under section III.3.3.2.1. The Development Centre for Pharmaceutical Technology (DCPT) also located in Yangon is described in detail in Chapter IV below :

The factory wise Production value for the years 1984/85 to 1988/89 is presented in Annex III - 25. The basic data for BPI and Pharmaceutical Raw Material Factory are indicated in Annex III - 26.



III.2.

THE HEALTH CARE SECTOR

As the production of pharmaceuticals forms Part of a drug supply system, which in turn is part of the health care system, some basic data about this field are presented below.

III.2.1.

Morbidity and Mortality Patterns (Priority health problems)

Data relating to morbidity and mortality patterns are indicated in Tables III.5. and III.6., Annexes III.1,2,3,4 and 5. From these data, it can be concluded that the leading diseases resulting in morbidity in Myanmar are malaria, upper respiratory tract infections, gastro-intestinal infections and parasitic diseases.

III.2.2.

The Health Care System

The expenditure on public health during 1984/85 to 1986/87 is presented in Annex III.6. In 1986/87 this expenditure amounted to Kyats 616.0 million, out of which Kyats 233.4 million refer to Capital expenditure and Kyats 382.6 million to Current expenditure. The total expenditure on Public health amounts to 1.05 percent of GDP.

Other Key indicators relating to the Health Care System are shown in Annexes III.7,8,9 and 10. It can be observed from these annexes that the number of medical doctors and dental surgeons in 1987-88 amounted to 11,826, roughly equally distributed between public service and private practice. Population per medical doctor/dental surgeon amounted to 3137 in 1987/88. The number of health facilities in Myanmar is presented in Annex III-11. The above indices compare favourably with those of other low-income Countries :

Table III.5. 15 Leading Causes of Morbidity Treated in Hospitals 1982-1984

Basic List	Cause Group	1982		1983		1984	
		Cases	%	Cases	%	Cases	%
052	Malaria	125966	14.5	104052	11.0	161749	17.4
016	Ill-defined intestinal infections	59020	6.6	61111	6.5	54735	5.9
410	Normal Delivery	62464	7.2	54508	5.8	45100	4.8
383	Unspecified abortion	33295	3.8	37002	3.9	31559	3.4
328	Other diseases of Respiratory System	22728	2.6	23290	2.5	25044	2.7
395	Other complications mainly related to pregnancy	6177*	0.8	22753	2.4	23500	2.5
321	Pneumonia	20443	2.4	27990	3.0	22743	2.4
551	Certain traumatic complication and unspecified injuries	20387	2.4	21187	2.2	21709	2.3
349	Other diseases of the digestive System	18033	2.1	21156	2.2	19099	2.1
020	Pulmonary tuberculosis	16842	1.9	18262	1.9	17525	1.9
046	Viral hepatitis	14543	1.7	28721	3.0	16305	1.8
341	Ulcer of stomach & duodenum	16869	1.9	18591	2.0	16135	1.7
420	Infectious of skin and Subcutaneous tissue	15332	1.7	12771*	1.4	15964	1.7
323	Bronchitis chronic, and unspecified emphysema & Asthma	17479	2.0	17023	1.8	15950	1.7
531	Toxic effects of substances chiefly non medicinal as to source	12382*	1.5	19411	2.1	14065	1.5
	All other causes	406047	46.9	456225	48.3	429618	46.2
Grand Total		868007	100.0	944048	100.0	930800	100.0

\* Not included in the 15-Leading Causes of Morbidity in Respective Years.

SOURCE : MINISTRY OF HEALTH

Table III-6: 15 LEADING CAUSES OF MORTALITY TREATED IN HOSPITALS 1982-1984

BASIC LIST	CAUSE GROUP	1982		1983		1984	
		Deaths	%	Deaths	%	Deaths	%
052	Malaria	3346	11.6	3204	9.9	5365	17.7
321	Pneumonia	2578	9.0	3079	9.5	2574	8.5
016	Ill-defined intestinal infections	2050	7.1	1880	5.8	1492	4.9
020	Pulmonary tuberculosis	1361	4.7	1611	5.0	1492	4.9
328	Other diseases of Pulmonary circulation and other forms of heart diseases	1249	4.3	1504	4.7	1147	3.8
283	Other diseases of Respiratory system	848	3.0	842	2.6	1406	4.7
331	Toxic effects of substances chiefly non-medicinal as to source	801	2.8	1521	4.7	1038	3.5
349	Other disease of the digestive system	977	3.4	841	2.6	692	2.3
037	Tetanus	928	3.2	699	2.2	605	2.0
452	Slow fetal growth fetal mal-nutrition & immaturity	496	1.7	622	2.1	584	1.9
456	Other disorders originating in the perinatal period	464	1.6	662	2.1	562	1.9
293	Acute but ill-defined cerebro-vascular diseases	496	1.7	537	1.6	541	1.8
046	viral hepatitis	288*	1.0	805	2.5	476	1.6
491	Other intracranial injuries	432*	1.5	573	1.8	433	1.4
038	Septicaemia	240*	0.8	1199*	3.7	433	1.4
	All other Deaths	12248	42.6	12637	39.2	11420	37.7
GRAND TOTAL		28802	100.0	32256	100.0	30260	100.0

\* Not included in the 15 Leading Causes of Mortality in respective years.

SOURCE: MINISTRY OF HEALTH

III.3.

THE PHARMACEUTICAL SUBSECTOR

III.3.1.

Pharmaceutical requirements

III.3.1.1.

Basis for the assessment of Pharmaceutical requirements

In recent years and since 1982/83 in particular, on account of scarcity of foreign exchange, the domestic production of pharmaceutical formulations as well as the official imports of the same have gone down steeply (in the case of certain agencies, there have been no imports at all in recent years). Apparently, the gap has been filled by illegal receipts from abroad, which are unrecorded. In addition, sweeping changes in economic policy have been announced in 1980 favouring more market oriented and open economic policy frame work. Under these circumstances, it is felt that any projection to arrive at future demand based on the present official supply of pharmaceuticals would be an exercise in futility. This aspect has been discussed recently with the concerned authorities of the Directorate of the planning/<sup>Myanmar</sup>Pharmaceutical Industries Corporation of the Ministry of No.1 Industry as well as the Directorate of the Ministry of Health of Myanmar; during the course of which, the concerned authorities advised that the pharmaceutical requirements be calculated based on the conventional morbidity / mortality statistics and these figures should be taken as the upper limit and the present official supplies of pharmaceuticals through domestic production and official imports as the lower limit. This advice has been taken into account during the present study. At this juncture, an important development in this area needs to be mentioned. The World Health Organization is funding the " Myanmar Essential Drugs Project " in collaboration with the Ministry of Health, Myanmar. The project input is US \$ 2.5 million and is of 3½ year duration. One of the objectives of this project is to assess the actual requirement of different pharmaceuticals to treat the leading diseases. The project aims to carry out this assessment in 9 townships. Out of these, in the initial phase 4 townships are being surveyed since 1989 in PAGO Division at different levels; i.e. Township Hospital, Station Hospital, Rural health centre and

subrural health centre levels. The population of the selected township is around 100 - 150,000 people. A standard treatment is fixed for each disease involving the usage of a limited number of cost effective drugs from the essential drug list for all the affected people within the township area. The recent trends in the usage of pharmaceuticals are taken into account, while formulating the standard treatment regime. For example, for TB treatment the regime stipulates the usage of Rifampicin, Isoniazid and Pyrazinamide for period of 2 months followed by the usage of Rifampicin and Isoniazid for 6 months thus eliminating completely the usage of Streptomycin during the first phase of the Project. This Project is stated to be the first of its kind in Myanmar.

It is expected that the actual requirements of an average township included in the first phase will be available at the end of 1990. The above Project encourages the use of pharmaceuticals produced in Myanmar where available. After the implementation of the above Project, it should be possible to quantify the actual requirements of pharmaceuticals out of the essential drug list, in the selected 9 townships based on morbidity/ mortality patterns prevailing in these townships. Based on this, somekind of projection could be attempted for the entire Country for the assessment of pharmaceutical requirements.

### III.3.1.2

#### Calculation of pharmaceutical requirements

Two Separate studies have been carried out during the past decade concerning the requirements of pharmaceuticals in Myanmar. The first study was carried out during 1979-1981 under the auspices of the German Agency for Technical Co-operation Ltd; (GTZ)\*. This study considered the Case frequency rate, CF-rate of the Common diseases as one of the

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\* Technical Co-operation between the Socialist Republic of the Union of Burma and the Federal Republic of Germany

- Feasibility study in Investment Programme for the Pharmaceutical Sector in Burma, December, 1982.

basic elements for calculating the Myanmar populations need for drugs. Taking into account the available Myanmar morbidity Statistics, the GTZ Study complemented official CR-rates of the Myanmar Health department by its own random sampling of Primary Surveys and compared the results with reliable health statistics from Thailand to arrive at priority health problems and the number of morbidity cases. The GTZ-study took the essential and complementary drugs for Burma (1979) as the basis for the choice of drugs to treat the Myanmar priority health problems and considered the total population of Myanmar as the target consumption group for drugs, since the National health system of the time took on responsibility for providing the entire population with sufficient quantities of the drugs required, aiming to curb self-medication and illegal imports. The Study also assumed no major changes in the trends of morbidity and mortality rates up to 1990, chose the most simple administering forms (oral/peroral) whenever possible and took trends in drug usage apparent at that time into account as well as the need to implement various flanking measures such as improvement of Public health Service system to achieve comprehensive and requirement oriented drug supply. The requirements of pharmaceuticals for 1981 as calculated in the GTZ study for 1981 are shown in Table III.9. This Study also provided details on the basis of which these figures were arrived at. The GTZ Study is comprehensive and probably represents the best realistic approach so far to calculate the requirements, given the limitation to obtain reliable data especially from the rural areas of Myanmar where the required information is lacking and based on recent discussions with the concerned Myanmar authorities of Ministry of Health and Industry.

However, in the Present context, there are some deviations from the assumptions made by the GTZ study. First, as indicated in III.1. above, the Government in 1988 discarded the centrally planned approach in favour of a market oriented and open Economic Policy frame work. Second the list of essential and complementary drugs and Vaccines for Myanmar was revised in 1987, where in the number of essential drugs has been reduced to 88, complementary drugs/vaccines increased to 122 and the total number goes up by 10. Due to various other factors the anticipated trend in drug usage has not materialized as envisaged by the team. For example, for Tuberculosis treatment, the team gave weightage probability of 60 percent for Rifampicin and 20 percent for Streptomycin. On this

Substance (compound)	Disease No. 1)	Doses (million)	Substances (kg)	Tablets (t) dragees (d) capsules (c) (million)	Ointments (o) jellies (j) pastes (pa) (million doses)	Powders (p) granulates (g) (kg)	Transfusions (tr) injections (i) (million ampoules/vials)	Syrups (s) tinctures (ti) liquids (l) (million doses)	Biologicals (b) supp. (su) others (o) (million ampoules/vials or doses)	Production technique (2) (mpbrt, IT, IP)
ASA Acetylsalicylic acid	Diarrhea etc.	8	130.00	54,040	t 130.00					F/S
	Haemorrhagic fever	9	0.40	50	t 0.40					F/S
	Acute endocarditis/Rh.	21	0.72	350	t/c 0.72					F/S
	Bronchitis	22	2.22	1,100	t 2.22					F/S
	Influenza	25	6.70	3,600	t 6.60					F/S
	Dental diseases	27	1.30	700	t 1.30			1/s 0.10		F/S
	Prostatic hypertrophy	30	0.13	70	t 0.13			1/s 0.10		F/S
	Abscess	31	0.25	120	t 0.25			1/s 0.10		F/S
	Measles	33	0.20	70	t 0.10			1/s 0.10		F/S
	Low backpain	48	86.50	43,200	t 86.38			1/s 0.12		F/S
	Joint dis.	49	320.00	160,000	t 319.20			1/s 0.18		F/S
Symphomatic	51	39.30	16,800	t 39.15			1/s 0.15		F/S	
Others non spec.		85.00	32,730	t 79.80	o/j 0.01	g 2.80	l/tr 0.29	1/s 2.10	su 0.10	F/S
Total		672.72	312,810	t/c 666.17	o/j 0.01	g 2.80	l/tr 0.29	1/s 3.35	su 0.10	F/S
Paracetamol	Poliomyelitis	7	0.18	33	t 0.10			s/l 0.80		F/S
	Haemorrhagic fever	9	0.07	41	t 0.06			s/l 0.01		F/S
	Leptospirose	17	0.05	30	t 0.05					F/S
	Pneumonia	19	0.85	280	t 0.80			s/l 0.05		F/S
	Influenza	25	5.90	2,200	t 5.72			s/l 0.18		F/S
	Dental diseases	27	0.56	258	t 0.56					F/S
	Prostatic hypertrophy	30	0.13	67	t 0.13					F/S
	Abscess	31	0.16	70	t 0.16					F/S
	Measles	33	0.25	70	t 0.18			s/l 0.07		F/S
	Pregnancy compl.	39	4.80	1,200	t 4.80					F/S
	Symphomatic	51	15.70	6,000	t 14.80			s/l 0.90		F/S
Others non spec.		18.55	14,480	t 15.57		g 0.28	l/tr 0.18	s/l 1.32	su 1.20	F/S
Total		47.20	20,729	t 42.95		g 0.28	l/tr 0.18	s/l 1.86	su 1.20	F/S
Trimethoprim	Cholera	4	0.022	3	t 0.20			t/s/l 0.002		F
	Diarrhea	8	8.50	2,400	t 8.00			t/s/l 0.50		F
	Thyphoid fever	10	0.26	32	t 0.20			s 0.06		F
	Abscess	31	0.05	10	t 0.03					F
	Pyelonephritis	41	0.33	51	t 0.33					F
	Others non spec.		0.48	76	t 0.34		g 0.04		t/s/l 0.10	
Total		9.622	2,572	t 8.92		g 0.04		t/s/l 0.0662		F
Sulfamethoxazole	Cholera	4	0.022	11	t 0.02			s 0.002		F
	Diarrhea	8	8.50	11,700	t 8.00			s 0.50		F
	Thyphoid fever	10	0.26	160	t 0.20			s 0.06		F
	Abscess	31	0.03	50	t 0.03					F
	Pyelonephritis	41	0.33	255	t 0.33					F
	Others non spec.		0.48	650	t 0.34		g 0.04		s/d 0.10	
Total		9.622	12,862	t 8.92		g 0.04		s/d 0.662		F
Sulfadiazine or other sulfonamid	Malaria	1	0.45	230	t 0.45					F/S
	Diarrhea	8	162.00	56,000	t 156.60			s/t 2.40		F/S
	Thyphoid fever	10	0.47	120	t 0.42			s/d 0.05		F/S
	Pyelonephritis	41	0.22	105	t 0.21			s/d 0.01		F/S
	Sexual transm. dis.	36	0.56	385	t 0.56					F/S
	Others non spec.		18.00	7,500	t 16.62		g 0.18	tr 0.05	s/l 1.00	su 0.15
Total		181.70	64,340	t 177.86		g 0.18	tr 0.05	s/l 3.46	su 0.15	F/S

Table III-7 Burma - Demand of essential pharmaceutical substances for treatment of Priority Health Problems, production technique and recommendations of import procedure, 1981

Table III-7, cont. (1)

Substance (compound)	Disease No. <sup>1)</sup>	Doses (million)	Substances (kg)	Tablets (t) dragees (d) capsules (c) (million)	Ointments (o) jellies (j) pastes (pa) (million doses)	Powders (p) granulates (g) (kg)	Transfusions (tr) injections (i) (million ampoules/vials)	Syrups (s) tinctures (ti) liquids (l) (million doses)	Biologicals (b) supp. (su) others (o) (million ampoules/vials or doses)	Production technique (7, 5 <sup>2</sup> ) IT, IP
Ampicillin	Diarrhea	8	23	4,600	c 21.80			s/ti 1.20		F
	Thyphoid fever	10	0.41	80	c 0.40			s/ci 0.01		F
	Pertussis	16	0.03	9	c 0.02			s/ci 0.04		F
	Inf. bronchitis	22	1.65	620	c 1.48			s/ci 0.17		F
	Pregnancy compl.	39	1.60	800	c 1.50		i 0.10			F
	Others non spec.		1.20	765	c 1.00			s/ci 0.20		F
<b>Total</b>		<b>27.91</b>	<b>6,874</b>	<b>c 26.20</b>			<b>i 0.10</b>	<b>s/ci 1.62</b>		
Penicillin V +/or G	Tetanus	4	0.23	60			i 0.23			F
	Diarrhea	8	65.00	12,830	c/t 40.00		i 24.00	l/s/ti 1.0		F
	Diphtheria	13	0.01	14				l/ti 0.01		F
	Leptospirose	17	0.001	1			i 0.001			F
	Pneumonia	19	0.85	160	c/t 0.70		i 0.150			F
	Endocarditis	21	0.24	65	c/t 0.12		i 0.120			F
	Dental diseases	27	0.38	50	c/t 0.30		i 0.080			F
	Prostatic hyp.	30	0.04	11	c/t 0.04					F
	Abscess	31	0.10	26	c/t 0.08			i 0.020		F
	Skin disorders	35	0.10	25	c/t 0.09			i 0.010		F
	Sexual trans. dis.	36	0.02	45	c/t 0.01	j 0.005	p 0.03	i 0.010		F
	Others non spec.		3.25	725	c/t 1.745			i 1.020	l/s/ti 0.45	F
	<b>Total</b>		<b>70.22</b>	<b>14,012</b>	<b>c/t 43.085</b>	<b>j 0.005</b>	<b>p 0.03</b>	<b>i 25.640</b>	<b>l/s/ti 1.47</b>	
Tetracyclin	Tetanus	4	0.17	52	c/t 0.15			s/ti 0.02		F
	Cholera	5	0.01	3	c/t 0.02					F
	Diarrhea	8	20.30	3,110	c/t 19.80			s/ti 0.70		F
	Amoebiasis	12	0.01	3	c/t 0.01					F
	Leptospirose	17	0.10	17	c/t 0.10					F
	Brucellosis	18	0.10	30	c/t 0.10					F
	Inf. bronchitis	22	0.14	27	c/t 0.14					F
	Prostatic hyp.	30	0.04	11	c/t 0.04					F
	Abscess	31	0.15	40	c/t 0.15					F
	Plague	34	0.01	6	c/t 0.01					F
	Skin disorders	35	0.055	6	c 0.04	o/j/pa 0.01	p/g 0.005			F
	Sexual trans. dis.	36	0.45	200	c 0.30	o/j/pa 0.10	p/g 0.05			F
	Pregnancy compl.	39	1.60	400	c 1.60					F
	Pyelonephritis	41	0.44	200	c/t 0.44					F
Others non spec.		4.75	1,295	c 3.15	o/j/pa 0.29	p/g 0.65	i 0.24	s/ti 0.42	F	
<b>Total</b>		<b>28.52</b>	<b>7,400</b>	<b>c/t 26.04</b>	<b>o/j/pa 0.40</b>	<b>p/g 0.705</b>	<b>i 0.24</b>	<b>s/ti 1.14</b>		F
Streptomycin	Tuberculosis	2	58.00	34,560	c 58.00					F
	Brucellosis	18	0.03	25	c 0.03					F
	Endocarditis	21	0.07	17	c 0.07					F
	Plague	34	0.002	1	c 0.002					F
	Others non spec.		6.81	3,670	c 5.68	o/j 0.13	p/g 0.52	i 0.07	s/ti 0.41	F
<b>Total</b>		<b>64.912</b>	<b>38,273</b>	<b>c 63.782</b>	<b>o/j 0.13</b>	<b>p/g 0.52</b>	<b>i 0.07</b>	<b>s/ti 0.41</b>		F
Rifampicin	Tuberculosis	2	96.80	29,400	c 96.80					F/IT
	Lepra	3	15.30	8,017	c 15.30					F/IT
	Others non spec.		18.65	6,128	c 18.65					F/IT
	<b>Total</b>		<b>130.75</b>	<b>43,545</b>	<b>c 130.75</b>					

Footnotes: cf. end of table



Substance (compound)	Disease No. <sup>1)</sup>	Doses (million)	Substances (kg)	Tablets (t) dragees (d) capsules (c) (million)	Ointments (o) jellies (j) pastes (pa) (million doses)	Powders (p) granulates (g) (kg)	Transfusions (tr) injections (i) (million ampoules/vials)	Syrups (s) tinctures (ti) liquids (l) (million doses)	Biologicals (b) supp. (su) others (o) (million ampoules/vials or doses)	Production technique F, S <sup>2)</sup> import; (million ampoules/vials or doses)
Chloramphenicol	Diarrhea	8	24.12	4,600	c/d 24.12					F
	Typhoid fever	10	0.54	140	c/d 0.54					F
	Plague	34	0.01	4	c/d 0.01					F
	Skin disorders	35	0.02	10	c/d 0.01	0.01				F
	Others non spec.		2.52	458	c/d 2.00	o/j 0.09	p 0.22		1/s/ti 0.21	F
<b>Total</b>		<b>27.21</b>	<b>5,212</b>	<b>c/d 26.68</b>	<b>o/j 0.10</b>	<b>p 0.22</b>		<b>1/s/ti 0.21</b>		
Erythromycin	Diphtheria	15	0.01	20	d/c 0.003			s 0.007		F
	Pertussis	16	0.13	30	d/c 0.030			s 0.05		F
	Skin disorders	35	0.02	5	d/c 0.020					F
	Sexual transm. dis.	36	0.72	405	d/c 0.720		p 0.02		s 0.12	F
	Others non spec.		0.25	138	d/c 0.110		p 0.02		s 0.177	F
<b>Total</b>		<b>1.13</b>	<b>598</b>	<b>c/d 0.933</b>		<b>p 0.02</b>		<b>s 0.177</b>		
Chloroquin	Malaria	1	7.76	3,100	t 7.760					F
	Amoebiasis	12	0.01	2.5	t 0.010					F
	Others non spec.		0.018	2.5	t 0.018					F
	<b>Total</b>		<b>7.788</b>	<b>3,105</b>	<b>t 7.788</b>					
Quinine-phosphat	Malaria	1	1.15	543	t 1.150					F
Nepiridine	Poliomyelitis	7	0.25	0.5	t/d 0.25					F
	Low back pain	48	32.40	3,240	t/d 32.40					F
	Others non spec.		2.90	330	t/d 2.90					F
	<b>Total</b>		<b>35.50</b>	<b>3,580.5</b>	<b>t/d 35.50</b>					
Metronidazol	Amoebiasis	12	0.31	135	t 0.31					F
	Skin disorders	35	0.20	385		o/j 0.20				F
	Sexual transm. dis.	36	0.24	60	t 0.08	o/j 0.20				F
	Others non spec.		0.10	87	t 0.03	o/j 0.03	p 0.04			F
	<b>Total</b>		<b>0.85</b>	<b>667</b>	<b>t 0.42</b>	<b>o/j 0.39</b>	<b>p 0.04</b>			
Phenobarbital	Pertussis	16	0.055	3.0	t 0.04		i 0.01	1/s 0.015		F
	Schizophrenia	43	0.06	3.0	t 0.04		i 0.02			F
	Epilepsia	47	0.288	24.2	t 0.20		i 0.08	1/s 0.008		F
	Symptomatic	51	34.00	240.0	t 30.80		i 3.00	1/s 0.200		F
	Others non spec.		0.208	25.0	t 0.16		i 0.029	1/s 0.019		F
	<b>Total</b>		<b>34.611</b>	<b>295.2</b>	<b>t 31.24</b>		<b>i 3.139</b>	<b>1/s 0.223</b>		
Diazepam	Pre-eclampsia	37/38	1.40	14.1	t 0.95		i 0.40	s 0.05		F
	Pregnancy compl.	39	1.60	16.0	t 1.00		i 0.50	s 0.10		F
	Dependence symph.	42	0.72	7.2	t 0.58		i 0.18	s 0.01		F
	Epilepsia	47	0.75	8.0	t 0.60		i 0.13	s 0.02		F
	Symptomatic	51	8.00	70.0	t 6.70		i 1.90	s 0.10		F
	Others non spec.		1.80	18.0	t 1.40		i 0.40			F
	<b>Total</b>		<b>14.27</b>	<b>133.30</b>	<b>t 11.23</b>		<b>i 3.34</b>	<b>s 0.28</b>		
Hydrochlorothiazid	Hypertension	28	17.00	420.0	t/d 17.0					F

Footnotes: cf. end of table

Table III-7, cont. (2)

Table III-7, cont. (3)

Substance (compound)	Disease No. 1)	Doses (million)	Substances (kg)	Tablets (c) droplets (d) capsules (e) (million)	Sintments (o) Jellies (j) Pastes (pa) (million doses)	Powders (p) granulates (g) (kg)	Transfusions (t) (million ampoules/vials)	Syrups (s) emulsions (r) liquids (l) (million doses)	Single-dose (b) ampoules (su) others (a) (million ampoules, vials or doses) or 0.42	Production (tech) (p, 3) (import) (i)	
Hydrocortisone	39	0.84	12.6	c 0.08	o 0.42				su 0.42	f	
	35	0.28	2.6	c 0.20	o 0.20					f	
	39	0.32	8.0	c 0.32						f	
	Total	1.44	35.6	c 0.60	o 0.62				su 0.42	f	
Chlorpromazine	Sexual-transm. dis.	1.08	3.1	c/d 0.06						f	
	Dependence	0.34	108.0	c/d 1.08						f	
	Schizophrenia	0.34	54.0	c/d 0.34						f	
	Others non spec.	0.306	31.0	c 0.30					su 0.006	f	
Total	1.986	196.1	c 1.98					su 0.006	f		
Chlorpheniramine	6	12.84	48.3	c 12.84						f	
	33	0.20	2.4	c 0.20						f	
	34	0.02	0.3	c 0.02						f	
	Others	0.33	0.38	c 0.33						f	
Total	13.39	53.00	c 13.39							f	
Mebendazole	14	3.00	315.0	c/e 3.0						f	
Dapsone	3	34.10	8,600	c 34.1						f	
Oxyphenbutanone	Low back pain	43.20	3,160	c 43.2						f	
	Dependence, joints	3.60	360	c 3.6				1/a 0.35	su 0.50	f	
	Others non spec.	8.85	1,010	c 8.8				1/a 0.35	su 0.5	f	
	Total	57.65	4,730	c 55.6				1/a 0.35	su 0.5	f	
Other chem. therapeutic agents - antibiotics	Tetracycline	1	0.27	c 0.27						1p	
		2	44.40	e/d 44.40						1t	
	Tetracycline	2	534.22	476,440	c 534.22					f/s	
		6	162.00	56,000	c 162.00					f/s	
	Sulfamonomethoxime	11	0.01	3.0	c 0.01					1t	
		24	1.70	710.0	c 1.70					f	
	Cephacortin	21	0.02	3.5	c 0.02					1t	
		41	0.93	86.5	c 0.93					f	
	Soniclone	148.70	51,400	c 100.00	o/j 14.25	p 12.25			o/LA 12.6		f/1t
		892.25	629,110	c/e 843.55	o/j 14.25	p 12.25			o/LA 12.6		f/1t
Total											

Footnotes at end of table

Table III-7, cont. (4)

Substance (compound)	Disease No. 1)	Doses (million)	Substances (kg)	Tablets (c) dragees (d) capsules (e) (million)	Ointments (f) jellies (g) pastes (pa) (million doses)	Powders (p) granules (q) (kg)	Transfusions (tr) injections (l) (million ampoules/vials)	Syrups (s) tinctures (t) liquids (l) (million doses)	Biologicals (b) supp. (su) others (o) (million ampoules/vials or doses)	Production technique (p, g, l) (import, j)
<b>Other materials.</b>										
<b>Chemicals.</b>										
Griseofulvine	35	0.45	45.0	c 0.08	a/j/ps 0.37					7
Nystatin	35	0.21	108.0	e 0.06	a/j/ps 0.15					7
	36	0.032	10.0	e 0.02	a/j/ps 0.032					7
Others non spec.		0.380	38.0	c 0.14	a/j/ps 0.06			a/l 0.08		7
<b>Total</b>		<b>1.052</b>	<b>201.0</b>	<b>c 0.30</b>	<b>a/j/ps 0.612</b>	<b>p 0.10</b>		<b>a/l 0.08</b>		<b>7</b>
<b>Biological products</b>										
Human rabies vaccines	6	0.002	2,700,000 IU				l 0.002			17
Tetanus anti-toxine	4	0.003	142,000MTU				l 0.003			7/8
Diphtheria antitoxine	24	0.002	176 MTU				l 0.002			7/3
Polyval. snake venom	40	0.020	20,250 doses			p 0.020	l 0.020			7/3
Insulin	46	1.040	2,813 MTU				l 1.40			17
Insulin prec.	46	6.100	23,380 MTU				126.06			17
Other incl. prophylaxis							l 3.18			
<b>Total</b>							<b>l 10.707</b>			
<b>Mineral and vitamin deficiency</b>										
Ferrous-sulfate	23	30.0	5,200	d/e 268				a/l 1.00		7
Ferrous-dextran	23	1.82	260					a/l 1.82		7
Ferrous-gluconate	23	30.0	3,000	d/e 6.75			l 8.60	a/l 14.65		7
Vit. B12	32	11.2	0.48	e 9.10			l 1.90	a/l 0.13		7
Folic acid	32	14.4	72.00	e 12.20			l 2.00	a/l 0.20		7
Vit. A		6.6	3.25	a/d 4.20	o 3.20		l 0.20			7
Vit. C		5.85	10.50	e/c 5.02			l 0.20	a/l 0.35		7
Pantothenylic alcohol		0.28	0.40	e/c 1.12	o 0.16					7
Nicotin acid		6.30	4.80	e/c 5.80	o 0.01			a/l 0.40		7
Biotin		42.80	280,000							7
Cr.-D-Pantothenate		7.65	1,800	e/c 2.88	o 1.64		l/cr 14.30			7
Aminoacids		28.41	22,480	e/c 18.20			l/cr 0.48			7
Others non spec. incl. prophylaxis		36.85	48,999	e/c 30.10	a/j 0.84		l 1.01	a/l 6.80		7
<b>Total</b>		<b>222.82</b>		<b>121.17</b>	<b>4.85</b>	<b>p 39.81</b>	<b>l 28.79</b>	<b>a/l 2.85</b>		<b>7</b>

Substance (compound)	Disease No. 1)	Doses (million)	Substances (kg)	Tablets (t) dragees (d) capsules (c) (million)	Ointments (o) jellies (j) pastes (pa) (million doses)	Powders (p) granulates (g) (kg)	Transfusions (tr) injections (i) (million ampoules/vials)	Syrups (s) tinctures (tl) liquids (l) (million)	Biologicals (b) supp. (su) others (o) (million amp./vials or doses)	Production technique F, S, 2) import: IT, IP 3)
<b>Sonstige</b>										
Iodine	Goitre 13	2.90	0.475					e/d/i 2.90		F
Diethylcarbamidine	Amoebiasis 12	0.69	10.700	t 0.69						F
Aminophylline	Endocarditis 21	0.02	8.600	t 0.01			l 0.01			F
Epinephrine	Endocarditis 21	0.04	0.1				l 0.04			F
Predisone	diff. diseases	0.38	5.8	t 0.09			l 0.29			F
Marcotine	Influenza 25	1.70	60.0	t 0.82				e 0.88		F
Dexamethasone	Cirrhosis of liv. 26	2.40	1,600.0	t 2.40						F
Salt tablets	Dental diseases 27	1.55	720.0	t 1.55						F
Chlorhexidin	Dental diseases 27	2.76	430.0					e 2.76		F
Lorfan	Antidot	0.002	0.1				l 0.002			IT
Probenecid	Sex.trans.dis. 36	0.072	305.0	t 0.072						F
Primidone	Epilepsy 47	1.40	680.0	t 1.40						F
<b>Total</b>		<b>13.914</b>		<b>7.032</b>			<b>l 0.342</b>	<b>e 6.54</b>		
<b>Others incl. prophylaxis (estimation)</b>		<b>550</b>		<b>t/d/c 228</b>	<b>o/j 3.60</b>	<b>p/g 7.15</b>	<b>l/tr 21.6</b>	<b>e/tl/l 16.85</b>	<b>su 6.42</b>	<b>F/S/IT/IP</b>
<b>Total</b>				<b>t/d/c 2,496.792</b>	<b>o/j/pa 24,347</b>	<b>p/g 63,785</b>	<b>l/tr 93,581</b>	<b>e/tl/l 130,724</b>	<b>b 10,707+ so/o 2,786</b>	

Footnotes: 1) for no. compare annex 2/6

2) F = formulation; S = synthesis

3) IT = import on tender basis; IP = import from special producer

Source: GTZ Study, 1982.

basis, the annual requirements of Rifampicin worked out to 43,545 Kgs for TB, leprosy and other diseases, as against the official imports of Rifampicin at 1,160 Kg during 1988/89. By the way, there are apparently several typographical errors in the requirement figures for Rifampicin indicated in GTZ study. One comes across in the study three widely varying figures for the latter depending on which Table/annex one refers to, although all the latter are supposed to be interlinked. For example, the requirements of Rifampicin for TB and leprosy treatment for the adults and children put together is shown as 59,681 Kg according to annexes 2/4 on page 179 and 2/5 on page 184 of the report; 108,217 Kgs according to annex 2/6 on page 189 and finally 37,417 Kg according to Table 2/4 on page 70 for both the above mentioned diseases and 43,545 Kgs for the latter diseases plus other diseases. Further as regards the requirements of Rifampicin for TB treatment, the total number of doses for adults and children as shown in Table 2.4 on page 70 at 96.8 million doses was multiplied by a uniform figure of 300 mg. per dose although the doses for adults at 86.8 million were 600 mg. per dose (P179) and those for children at 10.8 million were 300 mg. per dose (P184). Again in Annex 2/4 on page 179, the number of days of treatment for leprosy in the case of adults was stated as 730 days (column 6), whereas in the calculation of quantity (column 8) the number of days was actually taken as 365.

In any case, even the lowest figure of 43,545 Kgs representing the annual requirement of Rifampicin is far fetched in the conceivable future. Yet, as discussed above, the quantities arrived at by the GTZ study represent a comprehensive effort in this area so far and these figures could be taken as the upper limit in the absence of more realistic figures.

The other study for assessing the requirements of pharmaceuticals utilizing morbidity patterns pertains to the study carried out under the auspices of UNDP and the International Bank for Reconstruction and Development (IBRD)\*. The estimate of the annual need of selected major Pharmaceuticals in Myanmar 1985/86 as worked out

\* Study of the Pharmaceutical Industry in Burma :  
BUR/82/004-21.06 -financed by the United Nations  
Development Programme (UNDP) with the International Bank for  
Reconstruction and Development (IBRD) as Executing Agency-  
February, 1987.

in this Study is presented in Table III.8. In the Study, the sample statistics obtained from the Ministry of Health were modified under the assumption that the propensity to contact health centres varies depending on the disease in question. Further more, Pharmaceuticals which should be consumed, rather than those which actually were being consumed guided the estimate provided by this Study. This report admits that although the compilation contained great arbitrariness, it states that it presented certain indications regarding desired directions of future changes in the consumption pattern.

The GTZ Study and the IHRD Study are not strictly comparable, since they are based on different premises altogether. For example, the GTZ Study assumes the entire Population as the target consumption group, whereas the IHRD Study arbitrarily assumed certain morbidity figures and the pharmaceuticals which should be taken in their opinion, and not what they were being taken at that time. Unfortunately due to various historical reasons, vast promotional work carried out by vested interests, influence of medical practitioners, unavailability of medicines, the absence of the required medical infrastructure, poverty and ignorance; Certain patterns of pharmaceutical usage have been prevalent in many of the developing Countries and it is not easy to introduce radical changes in such usage. For example, the consumption of Vitamins in many of these Countries is far in excess of the actual needs and this results in diverting scarce foreign exchange to import much larger quantities of vitamins in place of other more essential drugs. Reverting to the comparison between the two studies and taking the example of TB treatment, the GTZ Study assumed 900,000 Cases (Adults 800,000 and children 100,000) and the usage of Isoniazid, ~~Paraaminosalicylic acid~~ (deleted from 1987 essential drug list), Streptomycin, Rifampicin and Ethambutol apportioning certain percentage of weightage probability to each of these drugs. Based on this, they arrived at figures for annual requirement of 34,560 Kgs for Streptomycin; 44,400 Kgs of Ethambutol. 65,785 Kgs of Isoniazid and 29,400 Kgs of Rifampicin. As against this the IHRD Study assumed 40,000 Cases and arrived at annual requirement of 10,000 Kgs of Streptomycin and 4,880 Kgs of Isoniazid. They did not select

**Table III-8** ESTIMATE OF THE ANNUAL NEED OF SELECTED MAJOR PHARMACEUTICALS IN BURMA 1985/86 BY THE POPULATION SECTOR HAVING POTENTIAL ACCESS TO MODERN PHARMACEUTICALS <sup>a/</sup>

<u>Products and diseases</u> <sup>b/</sup>	<u>Dose per case</u>	<u>Cases in thousands</u>	<u>Total need in thousands</u>
<b>Acetylsalicylic acid 300 mg (Buspro)</b>			
- Otitis	25	300	7,500
- Acute upp. resp. tract. inf	25	1,500	37,500
- Influenza	25	1,000	25,000
- Fever	25	7,500	187,500
			<u>257,500</u>
<b>Paracetamol 500 mg</b>			
- Otitis	20	100	2,000
- Acute upp. rep. tract. ing	20	500	10,000
- Influenza	20	500	10,000
- Fever	20	2,500	50,000
			<u>72,000</u>
<b>Atropine Inj. 0.6 mg, 1 ml</b>			
- Colic pain	3	250	750
<b>Ampicillin 250 mg tabs</b>			
- Shigellosis	50	25	1,250
- Gonococcal inf.	100	30	3,000
- Syphilis	14	30	420
- Otitis	28	100	2,800
- Acute bronchitis	28	100	2,800
- Pneumonia	48	100	4,000
- Cronic bronchitis	50	500	25,000
			<u>40,070</u>
<b>Ampicillin syr. 125 mg/5 ml</b>			
- Shigellosis	100 ml	1,000	100
- Otitis	300 ml	1,000	300
- Acute bronchitis	160 ml	2,000	320
- Pneumonia	160 ml	3,000	480
			<u>1,200 (litres)</u>
<b>Fort. Penicillin Proc. inj. 400.000 I.U.</b>			
- Gram positive infections	20	750	15,000 (vials)
<b>Phenoxymethyl penicillin tab. 250 mg</b>			
- Otitis media, adults	100	50	5,000
- Otitis media, children	50	200	10,000
- Upper resp. tract inf.	45	200	9,000
- Other penicillin sens. inf.	40	100	4,000
- Acute bronchitis	45	125	5,625
- Pneumonia	45	125	5,625
- Cronic bronchitis	30	80	2,400
			<u>41,650</u>

Table III-8 Cont'd

<u>Products and diseases</u>	<u>Dose per case</u>	<u>Cases in thousand</u>	<u>Total need. in thousands</u>	
Chloramphenicol cap. 250 mg				
- Typhoid fever, paratyphoid fever	105	145	15,225	
Chloramphenicol syr. 150 mg/5 ml				
- Enteric fevers	400 ml	32	12,8	
- Bronchitis	200 ml	32	6,4	
			<u>19,2</u>	(litres)
Metronidazole tab. 200 mg				
- Amoebiasis, adults	40	125	5,000	
- Amoebiasis, children	20	125	2,500	
- Giardiasis	36-40	150	5,000	
- Preoperative prophylaxis	10	150	1,500	
- Trichomonas inf.	20-40	150	5,000	
			<u>21,000</u>	
Sulfadimidine tab. 200 mg				
- CHW medicine chest	2x1.000	1	2 000	
- S'mide sensitive inf.	50	1,000	50 000	
- Bronchitis	60	500	30 000	
- Urogenital diseases	84	150	12 500	
Co-trimoxazole tab.			<u>94 600</u>	
Sulfamethoxazole = 400 mg			94 600	
Trimethoprim = 80 mg				
- Urogenital inf.	28	200	6,000	
- Chronic bronchitis	28	500	14,000	
- Other sulpha sensitive infections	30	1,000	30,000	
			<u>50,000</u>	
Tetracycline tab. 250 mg				
- Cholera	84	3	252	
- Upper rep. tract inf.	48	300	14,400	
- Bronchitis	28	100	2,800	
- Urogenital diseases	40	50	2 000	
			<u>19,452</u>	
Isoniazid tab. 100 mg				
- Tuberculosis	1,220	40	48,800	
Streptomycin inj. 1 g				
- Tuberculosis	250	40	10,000	
Chloroquine phosph. tab. 250 mg (150 mg base)				
- Malaria	10	300	9,000	
Chloroquine phosph. syr. 60 mg/5 ml, 60 ml				
- Malaria, prophylaxis, children	420 ml	2,000	840 (litres)	



Table III-8 Cont'd

<u>Products and diseases</u>	<u>Dose per case</u>	<u>Cases in thousands</u>	<u>Total need in thousands</u>
Quinine tab, 300 mg			
- Malaria	30	300	9,000
Quinine inj. 300 mg/ml, 2 ml			
- Malaria	3	800	2,400
Sulfadoxine + pyrimethamine tab. 500 + 25 mg			
- Malaria, adults	3	10,000	30,000
- Malaria, children	1,5	10,000	15,000
			<u>45,000</u>
Prednisolone tab. 5 mg			
- Rheumatoid arthritis	20	300	6,000
- Bronchial asthma	20	300	6,000
- Status asthmaticus	20	300	6,000
			<u>18 000</u>
Ferrous sulphate tab. 60 mg Fe <sup>++</sup>			
- Pregnancy and iron deficiency anemia	200	1,000	200,000
- Helminthiasis	100	10,000	1 000,000
			<u>1 200,000</u>
Propranolol tab. 40 mg			
- Hypertension	400	100	40,000
- Angina pectoris	400	10	4,000
- Arrhythmia	400	7,5	3,000
			<u>47 000</u>
Reserpine tab' 0.25 mg			
- Hypertension	400	40	16,000
Digoxin tab. 0.25 mg			
- Cardiac insufficiency	100	200	20,000
Furosemide tab. 40 mg			
- Oedema	20	100	2,000
- Hypertension	40	200	8,000
			<u>10,000</u>
Gelmag tab.			
- Hyperacidity, gastric ulcer	100	600	60,000
Sodium bicarbonate (Sodamint)			
- Hyperacidity, gastric ulcer	100	600	60,000
Cream of magnesia tab' 300 mg			
- Hyperacidity, gastric ulcer	100	90	9,000
Bellaneutron tab. 100 tab.			
- Gastric & duodenal ulcer	200	170	34 000

Table III-8 Cont'd

<u>Products and diseases</u>	<u>Dose per case</u>	<u>Cases in thousands</u>	<u>Total need in thousands</u>
Atropine sulphate tab. 1 mg			
- Antispasmodic	30	200	6,000
Oral rehydration salts, 27.5 g			
- Diarrhoea	2-3	10	25,000
Aminophylline tab. 100 mg			
- Asthma	300	400	120,000
Aminopylline inj. 250 mg/10 ml			
- Asthma	3	450	1,350
Ephedrine tab. 30 mg			
- Bronchial asthma	300	150	45,000
Adevit tab. (vit. A & D)			
- Vit. A & D deficiency	30	1,000	30,000
Thiamine tab. 50 mg (Bevit)			
- Beri-beri	100	300	30,000
Vitamin B complex tab. (Burplex)			
- Hypo - or avitaminosis, B - complex	100	1,000	100,000

Footnotes to Annex IV-1:

a/ The figures in this table are based on sample statistics by the Ministry of Health regarding morbidity pattern as reported to health centres. However, it has been modified under the assumption that the propensity to contact health centers differs between diseases. It has been assumed that the propensity to contact some health institution increases by the degree of severity of the disease. Furthermore, normative aspects have been included in the figures in the sense that pharmaceuticals that should be consumed, rather than those which actually are consumed, have guided the calculations. The figures have been worked out in cooperation with BPI and other representatives for health institutions. Although the compilation contains great arbitrariness it presents certain indications regarding desired directions of future changes in the consumption pattern.

b/ In order according to WHO classification system.

Source : IBRD Study, 1987

Rifampicin for TB treatment although it is an essential drug according to 1987 " Essential drug list " of Myanmar. Further, according to the local Health authorities the present trend in this Country is to use Rifampicin in place of Streptomycin for TB treatment, as pointed out in III.3.1.1. above concerning the on going WHO Project on " Essential drugs " in 9 selected townships in Myanmar.

As discussed subsequently in III.3.2., the GTZ Study states that the actual demand raised by MSSTC, CMSD, SSB and others in 1981/82 in the product groups " essential drugs " (for instance antibiotics) is very similar to the drug requirements as calculated in the GTZ Study for that year, which lends further support to their approach for calculating the pharmaceutical requirements.

In the light of above discussion, the requirements of pharmaceuticals as calculated in the GTZ Study are taken as representing the upper limit for that period in the present Study.

### III.3.2.

#### Pharmaceutical demand

The Health Department of Myanmar records the drug demand of the public health service and Private institutions. The Medicine and Medical Stores Trade Corporation (MMSTC) Supplies drugs to the state - owned pharmacies, which attend to the demand of the Public Sector. The Central Medical Stores Depot (CMSD) supplies drugs to the hospitals and basic health stations. Similarly, the Army Medical Stores Depot (AMSD) supplies to the Army Sector and the Social Security Board (SSB) to the Social facilities in industrial firms. Besides drugs are also required by Co-operatives, Private pharmacies, Clinics and doctors' private practices.

MMSTC absorbed in 1981/82 54 percent of the planned production value of MPI. CMSD holds the second place among the consumer groups. CMSD fully depends on the fund allocations of the Health Ministry, since it distributes drugs to hospitals and health stations, which in their turn distribute them free of charge. MMSTC and CMSD aggregate the individual enquiries by pharmacies, hospitals and basic health services; based on which they submit their demands in the form of " standard lists of essential and complementary drugs " several times a year. Quantities ordered

often exceed actual requirements, since only a fraction of what is requested is supplied. A commission chaired by the Director General, Ministry of Health and including representatives of different consuming departments and others examines the total demand of MASTC, CMSD, AMSD, SSB and the Private Sector and tailors the same to the given financial scope for imports and to the production capacity of MPI. Based on this, the final demand for domestic products is then submitted to MPI.

The 1981/82 demand for pharmaceuticals by the above mentioned institutions in terms of administering forms is given below :

-	Biological products	13.8 million ampoules/vials
-	Tablets, dragees, Capsules	2,585 million
-	Ointment's and similar Preparations	313 tons
-	Liquids	991 tons
-	Solids	992 tons
-	Sterile products	86.2 million ampoules/vials

According to GTZ Study, it is interesting to note that the 1981/82 demand in the Product groups of " essential drugs " (for instance antibiotics) raised by the above committee is very similar to the drug requirements calculated as discussed in III.3.1.2. above and these are shown below in terms of administering forms ( cf. Table III.7. )

-	Biological products	10.7 million ampoules/vials
-	Tablets/dragees/capsules	2,497 million
-	Ointments, Jellies, Pastes	24.3 million doses = 243 t (1 dose = 10g)
-	Solids (Powders, granules)	63.8 million doses = 638 t
-	Sterile Products (transfusions, injection)	93.6 million ampoules/vials
-	Suppositories	2.8 million doses

III.3.2.1.

Projection of Pharmaceuticals demand

As regards the projection of Pharmaceuticals demand, the GTZ and IERD studies made different approaches. The GTZ Study assumes that as demographic data (i.e. population growth, morbidity rates etc.) only change over very long periods, with a steady population growth of approximately 2.3 percent, the demand for more pharmaceuticals would develop accordingly. The demand and production of pharmaceuticals in 1981 as compiled by GTZ Study are presented in Table III.9. From this table, it is evident that neither the production figures achieved so far nor the installed production capacity of EPI is sufficient to meet the present (1981) requirements and demand for drugs. The demand projection made by GTZ Study from 1981 to 2000 is shown in figure III.3. The projection figures as in the case of requirements calculated for 1981, represent the upper limit of pharmaceutical requirements by the year 2,000, as discussed earlier. Based on this projection, the demand in the product groups of "essential drugs" (for instance antibiotics) in the year 2000 is projected to be about 55 percent over that calculated for 1981. For example, 145.1 million ampoules/vials of sterile products are expected to be required in the year 2,000 as against 93.6 million in 1981, which works out to 55.02 percent increase. Similarly, 3,860 million of Tablets, dragees, capsules are projected to be the demand in the year 2,000 as against 2,497 million calculated for 1981, i.e. 54.59 percent increase. The Study assumes that antibiotics are mostly used in the above forms. Based on the GTZ Study, therefore, the projected requirement of antibiotics in the year 2000 work out to about 55 percent <sup>over</sup> those calculated for 1981.

IERD Study presented three alternative demand/supply projections up to the year 2,000 as follows : Alternative A is based on an average real growth of consumption of pharmaceuticals from recorded sources of 5.0 percent annually. According to this Study, this growth rate was basically a continuation of the previous Government Policies and priorities as revealed by

**Table III-9: Burma - Demand and production of pharmaceuticals, 1981**

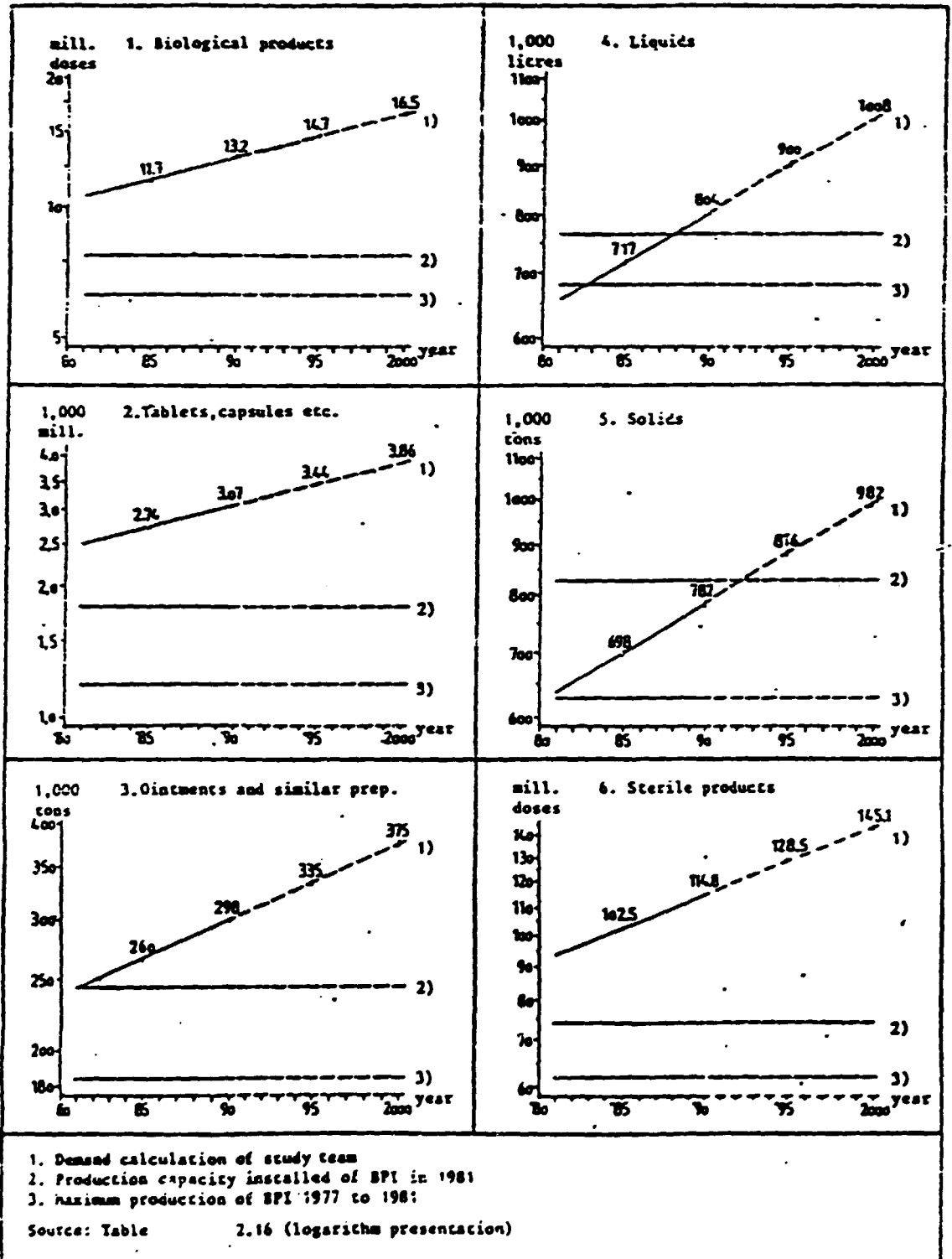
Sr. No.	Type of products	Unit of quantity	Demand <sup>1)</sup> calculation of study	Demand of Burmese health system presented to BPI	Production capacity of BPI (installed)	Production programme of BPI for 1981/82	Max. production of BPI 1977 to 1981
1	Biological products	million doses	10.7	13.8	6.3	6.1	7.7 (1979/80)
2	Tablets, capsules, etc.	million	2,497	2,598	1,800	1,834	1,200 (1980/81)
3	Ointments and similar preparations	t	243	313	242	242	184 (1977/78)
4	Liquids	1,000 l	654	991	765	619	680 (1980/81)
5	Solids	t	638	922	825	648	631 (1977/78)
6	Sterile products	million doses	93.6	86.2	74.0	74.5	62.6 (1978/79)

1) plus 2.8 million doses of suppositories

Source: Tables 2.4, 2.6, 2.12, 2.13, 2.14

Source: GTZ Study, 1982

**Figure III-3:** Burma - Demand of pharmaceuticals (main product groups), 1981 to 2000, production capacity and production of Burma Pharmaceutical Industry (BPI) in 1981



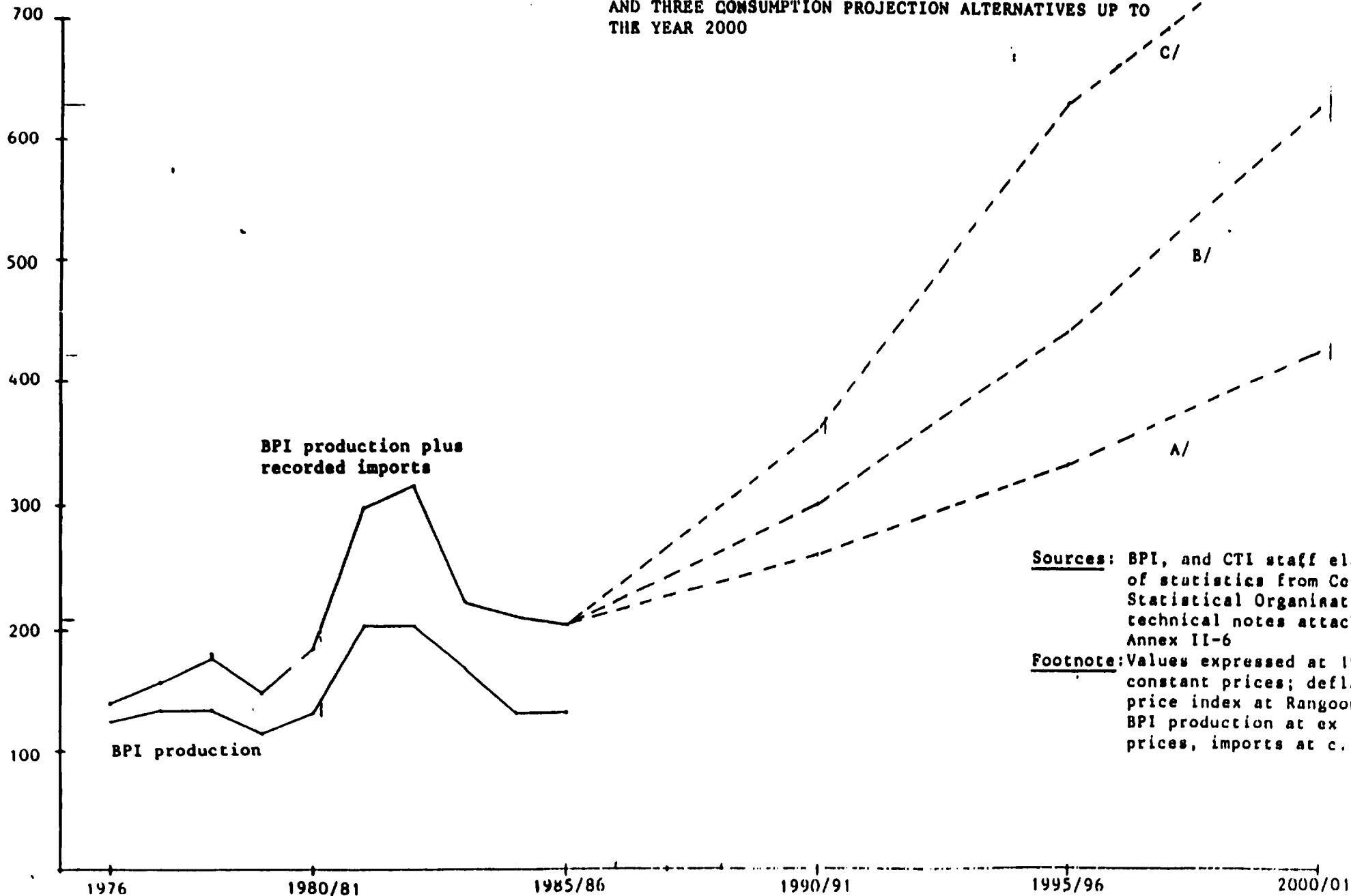
actual decisions on foreign exchange allocation at that time. Alternative B of the Study is based on an average real growth of consumption of pharmaceuticals from recorded sources by 9.0 percent annually. The Study states that alternative B would constitute an effort by the Government to bring the Myanma consumption of pharmaceuticals closer to internationally common levels considering Myanma GNP level. This alternative relies also on supplies from illegal unrecorded sources. These two alternatives assume the rehabilitation of MPI as proposed by the IERD Study, which has not materialized so far (1990). The alternative C is based on the assumption that consumption of pharmaceuticals should reach a level corresponding to 0.7 percent of the GDP in 10 years and should after that increase a real 5 percent annually. Further according to the IERD assumption, the average real growth rate during the first 10 years, viz 12 percent is based on a hypothetical average real GDP growth of 4.4 percent annually and assumes that by 1995 about 4 percent of total imports would be allocated for pharmaceuticals and inputs for the same and that 50 percent of the total demand is produced in Myanmar and the rest are imported. The materialization also implies explicit policy decisions. In view of the many preconditions attached to alternative C, IERD Study concentrated on elaboration of rehabilitation packages of MPI assuming a development of demand according to alternatives A and B above. The Projections relating to the three alternatives are shown in figure III.4. The consumption levels of pharmaceuticals as projected by this study in terms of 1985/86 constant prices and actual total sales of MPI for the years 1986/87 ; 1987/88, 1988/89 and 2,000 are given in Table III.10. below :



Kyats Million

**Figure III-4**

**HISTORICAL CONSUMPTION OF PHARMACEUTICALS IN BURMA 1976-1985 AND THREE CONSUMPTION PROJECTION ALTERNATIVES UP TO THE YEAR 2000**



**Sources:** BPI, and CTI staff elaborations of statistics from Central Statistical Organisation. See technical notes attached to Annex II-6

**Footnote:** Values expressed at 1985/86 constant prices; deflator of price index at Rangoon. BPI production at ex factory prices, imports at c.i.f prices

Table III.10 Comparison of Pharmaceutical Consumption  
Projection according to IHRD Study and actual total  
Sales of RPI

YEAR	RPI Sales At Current Prices (Kyats million)	Pharmaceutical Consumption Projection according to IHRD Study (Kyats million, 1985/86 Constant Prices)*	
		<u>Alternative A</u>	<u>Alternatives E</u>
1980/81	105 <sup>+</sup>		
1981/82	164 <sup>+</sup>		
1982/83	171 <sup>+</sup>		
1983/84	149 <sup>+</sup>		
1984/85	124 <sup>+</sup>		
1985/86	134 <sup>+</sup>		
1986/87	113.803 <sup>++</sup>	225	230
1987/88	76.789 <sup>++</sup>	230	245
1988/89	126.468 <sup>++</sup>	240	260
2,000		420	630

\* Includes Production of RPI and official imports.

+ Source : IHRD Study.

++ Source : RPI

It can be seen from Table III.9 that the Sales of BPI have started a down ward trend from 1982/83 onwards and declined very steeply in 1987/88. Such a sharp drop, according to BPI, was due to nonavailability of foreign exchange. A look at the above table also reveals that the projected quantities based on IBERD Study and the actual Sales of BPI are not at all comparable and the Sales in recent years are a small fraction of the Projected quantities. Further, it is learnt from BPI that based on the quantum of foreign exchange becoming available in any Particular year, the import of active ingredients and the spectrum of pharmaceutical production are readjusted to maximise units of Production i.e. larger quantity of less expensive active ingredients is imported than the more expensive ones in order to obtain a larger number of units of Production and to maintain their presence in the market.

In view of several preconditions attached to IBERD Study demand Projection, which have not materialized so far and many new factors arising since 1985/86, it seems that IBERD Study Projection is more of an academic exercise. In contrast, the GTZ Study demand Projection is based on morbidity/mortality statistics assuming total population as target consumption group and can be considered as the upper consumption limit and is also in line with advice given by Myama Health and Industry authorities recently. The pharmaceutical demand Projection made by GTZ Study, therefore, is taken as the basis in the Present Project and relevant figures are presented in Table III.11., alongside the estimate made by IBERD Study.

### III.3.3.

#### Supply of Pharmaceuticals

The supply of pharmaceuticals in finished dosage form originates from two sources, viz. from BPI and from imports. During the early eighties, BPI accounted for nearly two thirds of the supply with annual sales in the range of Kya 124-171 million. The balance consisted of imports, which were mainly carried out by MESTC, accounting for about two thirds of total imports and selling to Government pharmacies. CMSD accounted for the rest of the imports distributing to Hospitals and health centres, excluding a minor volume directly imported by AMSD. Besides, donor agencies such as UNICEF supply pharmaceuticals and active ingredients. For example, UNICEF recently supplied active ingredients and

TABLE III-11 ESTIMATE OF ANNUAL DEMAND OF  
PHARMACEUTICALS BASED ON MORBIDITY/MORTALITY  
STATISTICS

Sr.No.	PRODUCT (IN BULK)	IBRD STUDY*		GTZ STUDY <sup>+</sup>	
		1985/86 ACTUAL IMPORT TONS	1985/86** ESTIMATE TONS	1981 <sup>++</sup> ESTIMATE TONS	2000 <sup>+++</sup> ESTIMATED PROJECTION TONS
1.	Penicillin G	6.74	5.40	14.012 G + OR V	21.72 G + OR V
2.	Penicillin V	3.434	10.413		
3.	Ampicillin	1.60	10.048	6.874	10.66
4.	Streptomycin Sulphate	5.40	10.0	38.273 <sup>+++</sup>	59.32
5.	Tetracycline	2.506	4.863	7.40	11.47
6.	Chloramphenicol	3.566	3.806	5.212	8.08
7.	Rifampicin	-	-	43.545 <sup>+++</sup>	67.50
8.	Erythromycin	-	-	0.598	0.93
9.	Griseofulvin, Nystatin	-	-	0.201	0.31
10.	Vitamin C	7.915		10.5 (Kilos)	16.28 (Kilos)
11.	Folic acid	121 (Kilos)		72 (Kilos)	111.6 (Kilos)
12.	Prednisolone (HydroCortisone)	90 (Kilos)	90 (Kilos)	77 (Kilos)	119.35 (Kilos)

\* SOURCE : IBRD STUDY

\*\* cf. TABLE III-8

+ SOURCE : GTZ STUDY, UPPER LIMITS

++ cf. Table III-7

+++ cf. Figure III-3

++++ cf. III.3.1.2

aluminium tubes to MPI to produce one million tubes of Tetracycline hydrochloride eye ointment and also all the raw materials and packaging materials for the production of oral rehydration salts in both cases to meet total demand. UNICEF also provided some equipment 5 or 6 years ago to MPI.

III.3.3.1.

Imports of Pharmaceuticals

The main imports are in the form of pharmaceutical formulations in finished dosage form. There are imports of active ingredients by MPI for the purpose of formulation. The quantities of pharmaceuticals (finished dosage form) imported by different agencies in recent years are presented in Annexes III.12,13,14 and 15.

In the case of MESTC and AMSD, the import figures shown pertain to the years 1986/87 to 1988/89. In the case of CUSD, the import figures relate to 1981/82 and there have been no imports at all during 1986/87 to 1988/89 due to nonavailability of foreign exchange. As regards SSB, the demand figures for 1990-1991 are given, since there were no imports during recent years, again due to nonavailability of foreign exchange. In addition to above, as already discussed, there have been substantial illegal imports of pharmaceuticals apparently across the borders from neighbouring countries and these are obviously unrecorded. It seems that some of the domestic supplies also find their way into the parallel market. Due to paucity of foreign exchange in recent years in Myanmar, it is understood that such illegal imports have been on the increase.

The quantities of active ingredients imported by MPI during the years 1986/87 to 1988/89 are indicated in Annex III.16.

In this case also the quantities fluctuate widely based on the quantum of foreign exchange available.

III.3.3.2.

Domestic Production of Pharmaceuticals and Active ingredients

III.3.3.2.1.

Production of Pharmaceuticals

MPI is the only unit in Myanmar engaged in the Production of Pharmaceuticals (in finished dosage form). MPI is under the

Myanmar  
administrative Control of/Pharmaceutical Industries Corporation MPI, which is subordinated to the Ministry of No. 1 Industry ( cf. Figure III.1.). MPI was set up in the years 1954-1957 on a 17 hectare site in Gyegone, one of the suburbs of Yangon. This plant was constructed by Evans Medical Supplies Ltd., Liverpool, U.K.

The production of 200 products covers a wide range of essential drugs including Vaccines and Sera in finished dosage forms based essentially on imported active ingredients, in addition to yeast and alcohol. The lay out plan of MPI is shown in Fig.III.5. The site covers an area of 17 hectares and the buildings have a total floor space of 45,000 m<sup>2</sup>.

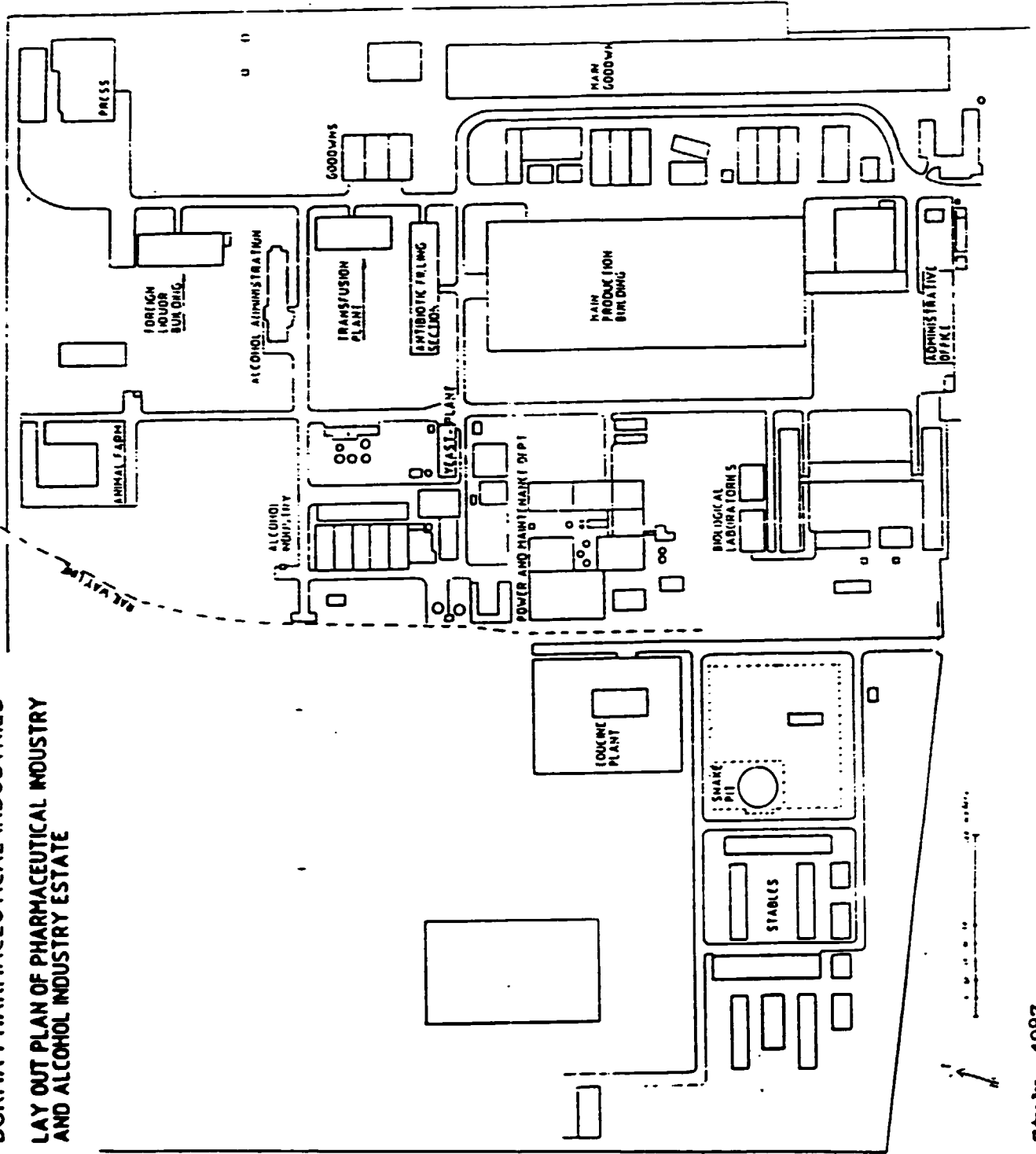
MPI has three Production divisions, e.g. for (i) formulation of drugs; (ii) Production of Vaccine and Sera; and (iii) Production of alcohol and yeast. These divisions are backed by a Planning division, quality control division and finance and administrative divisions. The number of employees amount to about 2,300.

Various facets of MPI have been dealt in great depth by IBRD Study as well as GTZ Study. IBRD Study made a detailed assessment of the status of MPI, Proposed a modified Project Proposal for rehabilitation of MPI and a Project for Production of Vaccines and Sera. GTZ Study Similarly recommended measures for the extension of capacity of MPI, improvement of quality and prepared a project for modernization and extension of MPI in Yangon.

During the Course of recent discussions with the Directorate of Planning, MPI it transpired that none of the above Project Proposals has been taken up for implementation so far; In the light of the recent sweeping changes in Government Policy discarding Socialistic economy ( distributing medicines free of cost and subsidizing domestic production) and favouring market oriented economy, abolishing subsidies and encouraging private enterprises. Further, the Government is also handicapped by Scarcity of resources particularly foreign exchange.

**BURMA PHARMACEUTICAL INDUSTRIES  
LAY OUT PLAN OF PHARMACEUTICAL INDUSTRY  
AND ALCOHOL INDUSTRY ESTATE**

Figure III-5



In view of above, there appears to be partially no possibility for the implementation of any Project in the Pharmaceutical Sector in the Public Sector in the for seeable future unless, as became apparent during recent discussions, the Project is economically viable. Following is additional information relating to MPI taken from GTZ and IBERD Studies respectively, which illustrates the magnitude and diversity of production operations as well as historical trends in pharmaceutical supply. The main areas in the layout plan of MPI Presented in Figure III-5 are detailed in Annex III-17. Historical data on the production capacity and production in 1980/81 are shown in Annex III-18. Similarly the Production of MPI by quantity as well as value of main items during 1977/78 to 1980/81 is presented in Annexes III-19 and III-20 respectively. The Sales of major product groups according to dosage form in 1985/86 are indicated in Annex III-21. Sales in 1985/86 in terms of major therapeutic classes and comparative figures from selected other Countries are shown in Annex III-22. Detailed comments on above data are contained in the respective reports. More recent data concerning production of antibiotics (quantity) are presented in Annex III-23. A perusal of the above data high lights two important features. First, as already discussed in III.3.2.1 above (cf. Table III-10), there has been a steep drop in sales in 1987/88 due to paucity of foreign exchange. Recent Sales are a fraction of those of a decade ago, Second, such a reduction in supply should in normal course have created a tremendous shortage of pharmaceuticals within the Country. Since no such shortage has been reported, the shortfall should have been met by receipts of Pharmaceuticals through illegal channels. This in its turn illustrates the enormity of the problem.



III.3.3.2.2. Production of active ingredients (raw materials)

The factory visited by the UNIDO expert and which is engaged in the production of raw materials (active ingredients) for MPI is located at Hmawbi about 70 Kilometres away from Yangon. The factory established in 1973 carries out small scale production of raw materials derived from mineral as well as plant sources. It also has farms to grow some of the plant raw materials utilized in the production. It consists of several small buildings spread over a wide territory located in the Industrial Estate of Hmawbi and employs 69 workers. DCPT collaborated in some of their production projects. The production of this factory is primarily geared to the requirements of MPI and fluctuates based on the latter's demand.

As regards inorganic raw materials, the factory has pilot scale production facilities for Ferrous Sulphate and Magnesium Carbonate located in separate buildings. The raw material for Ferrous Sulphate is iron scrap and that for Magnesium Carbonate are Salt bitterns. The design in both cases is rather primitive, equipment outdated and corrosion problems are apparent. Ferrous Sulphate at the rate of 6 tons per year is supplied to MPI and is stated to meet B.P. specifications. The annual production of Magnesium Carbonate is 2 tons meant primarily for the Cosmetic industry.

In another building, Tapioca starch/sago is converted to gum or liquid glucose. This unit has a capacity of 2.5 tons per year, out of which one ton is supplied to MPI and balance to Food Stuff Industries. DCPT is collaborating on enzyme conversion. Here again the operations are rather primitive and more in the nature of Cottage Scale. For example, liquid gum was placed in open bowls and stirred manually with wooden paddles to cool in the absence of proper cooling facilities.

As regards plant extraction, Lemongrass is grown in a 16 Hectare farm in the factory territory and is also procured from Army Cooperatives. The lemongrass oil produced through steam distillation is supplied to the State Soap factories. In another building

is located a small vegetable oil refining plant and Coconut oil was being refined. In another, building, Pyrethrum is extracted from chrysanthemum flowers obtained from upper state using Kerosene as a Solvent. Since Kerosene is highly hazardous, the factory management was advised to adopt forthwith all precautionary measures such as provision of explosion proof motors, fixtures etc. necessary in such cases. Other experimental ventures either completed or are under experimentation include menthol and Turpinolei extraction, Avocado oil, Cinnamon, cinchona, Acacia, coconut shell charcoal, copra oil, stearic acid BP. DCPT is also collaborating in the extraction of Artemesia, as antimalaria drug particularly in chloroquine resistant cases.

The above factory has a potential for producing the following raw materials required for the proposed fermentation pilot plant :

- Precipitated Calcium Carbonate
- Starch products including liquid glucose
- Solvent extraction of oil cakes (cotton seed, Soy bean)
- Refined vegetable oils

III.4.

Traditional Medicine in Health Care in Myanmar

Having examined the situation with regard to the supply of Pharmaceuticals in the foregoing sections and in light of the limited accessibility of Pharmaceuticals to the rural population on account of paucity in Health Service infrastructure, communications and inadequate purchasing power, the question naturally arises as to the role of traditional medicine in the rural segment of Myanmar. In this connection, discussions were held with the officials of the Ministry of Health as well as the teaching institution for Traditional medicine.

The Government recognized the importance of traditional medicine in Health Care towards attainment of the goal 'Health for all by 2,000' and recently upgraded the concerned department within the Ministry of Health and established a Separate Department of Indigenous Medicine in August 1989 headed by a Director General to develop Traditional medicine. According to the Health authorities, the cost of organization of traditional medicine is less and offers a wide choice within a limited budget. As regards cost benefit analysis, the concerned officials stated that in 1983/82, 2.2 million patients were treated on the basis of Traditional medicine and the average cost worked out to 0.22 Kyat per person. This cost was 0.9 Kyat in 1987/88. In 1973, the cost of visit worked out to 1.30 Kyats per person. The concerned authorities are convinced the Traditional Medicine could take care of total medical care as a complement to western medicine. In view of this, concerted measures are being taken in different areas to promote Traditional medicine.

Concerning health facilities, 100 clinics have been established at township level. With respect to production, two small scale production units to produce powders have been set up, one each at Yangon and Mandalay. As far as education is concerned, the Government prescribed books as far back as 1962 to enable the traditional medicine practitioners in rural area to study and pass an examination to obtain a diploma. 7000 persons registered for this examination, out of which 3,700 passed. If a person is aged 50 years or more, he need not pass the examination and is allowed

to Practice. There are several more traditional medicine practitioners in rural areas and their number is not known. The Government established the Institute of Traditional Medicine in Mandalay in 1976 to offer a 3 year course in Traditional medicine followed by one year internship. The successful candidates are awarded a Diploma in Traditional medicine. The institute has a 25-Bedded Hospital and a pharmacy with small scale production facilities for tablets and powders. The institute <sup>turns out</sup> 30 Diploma holders per year as against 500 graduates in Western Medicine from 2 colleges in Yangon and one in Mandalay. The diploma holder in Traditional Medicine is appointed as chief clinician in the Government Clinic. So far 13 batches have been trained. Facilities are being expanded to increase intake to 50 students per year and also 50-60 inpatients in the Hospital on the assumption that traditional medicine will become more popular.. There is a small medicinal plants farm around the Institute.

As regards medicinal plants, the Department of Agriculture Coordinates preservation of species, certification of species and distribution. There are plans to develop 4 Centres for the preservation of species in low wet area, Mandalay, Shan and mountain region. During the period, 1981-88, 6,967 medicinal plants have been identified and some of these have export possibilities.

With respect to standardization, a Traditional Pharmacopoea containing 58 monographs has been published. Out of the latter, 27 formulae for essential drugs have been prepared.

It can be seen from above that the Government has taken various measures to develop indigenous medicine so that it can play an important role particularly in the rural areas in the promotion of health care.

IV.

## DEVELOPMENT CENTRE FOR PHARMACEUTICAL TECHNOLOGY (DCPT)

Within the frame work of Myanna/Japanese Technical Co-operation, the Development Centre for Pharmaceutical Technology was Set up. On June 18, 1980 Myanmar and Japan exchanged notes for a grant aid of 2 billions Yen for the establishment of the above Centre. The record of discussion was signed between Myanmar and Japan on July 6, 1981 to establish the Centre with a provision of additional 200 million Yen for 4 years. DCPT is situated on Insein road, Gyogon in the vicinity of Burma Pharmaceutical Industries (BPI). The Construction of the Centre commenced on December 1, 1980, was completed on March 26, 1982 and the Centre became operational from April 1, 1982. DCPT is under the management of the ~~Myanna~~ Pharmaceutical Industries (MPIC) which in its turn, is under the Control of the Ministry of No.1 Industry.

IV .1.

### The layout of the Centre

The layout of the Centre is shown in Figure IV.1..

DCPT consists of the main building, utilities building, fermentation and medicinal plants building, animal testing building, canteen, administration building, engineering store, chemical store and gate house. The Centre covers a total floor area of 4,382 Sq. meters (0.44 hectares) in a total area of 37,800 Sq. meters (3.78 hectares). The layout of the main building is shown in Figure IV.2. The layouts of the Fermentation and medicinal plants building and that showing the equipment in the main building are indicated in Figures <sup>IV.3</sup> and 4 respectively.

IV.2.

### Budget allocation for the Centre

The expenditure incurred during the construction period and the additional expenditure for the provision of machinery, equipment, spare parts, chemicals and Books relating to the Japanese aid are shown in Tables IV.1. and 2 respectively.

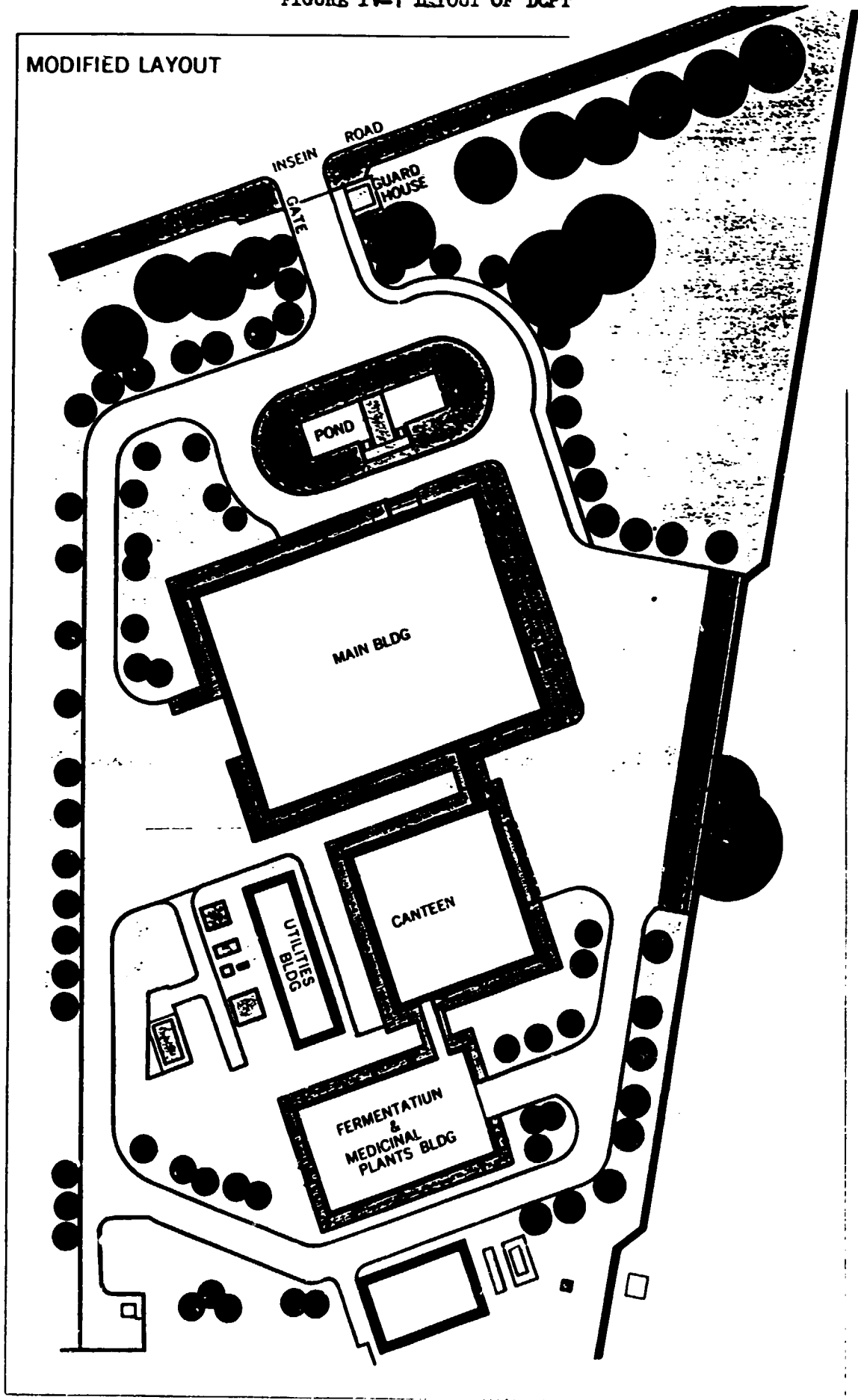
IV.3.

### The objectives of DCPT

The DCPT was established with the following objectives :

- (i) To undertake development and research in the promotion of pharmaceutical products in forms suited to typical national needs ;

FIGURE IV-1 LAYOUT OF DCPT



MAIN BUILDING

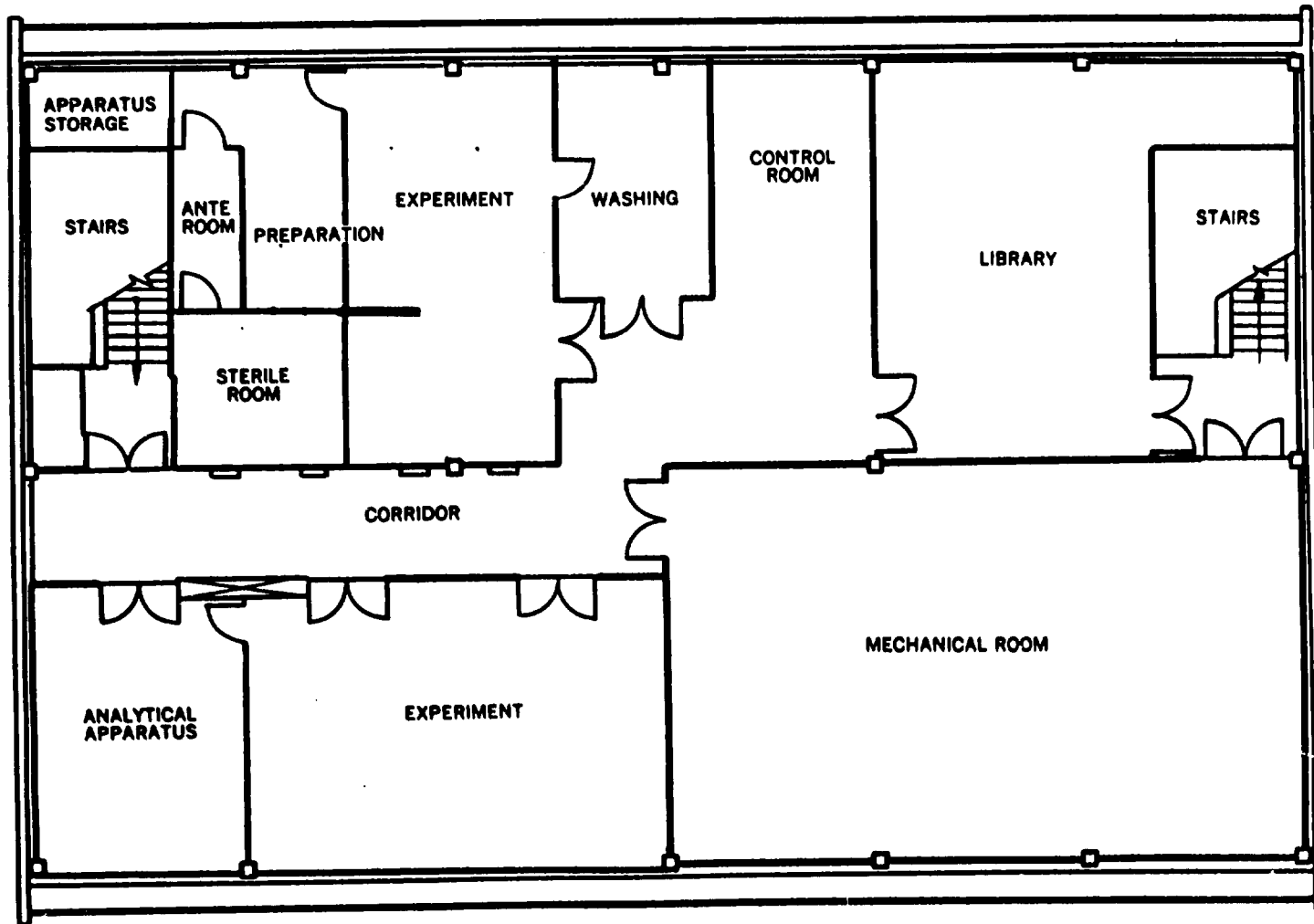
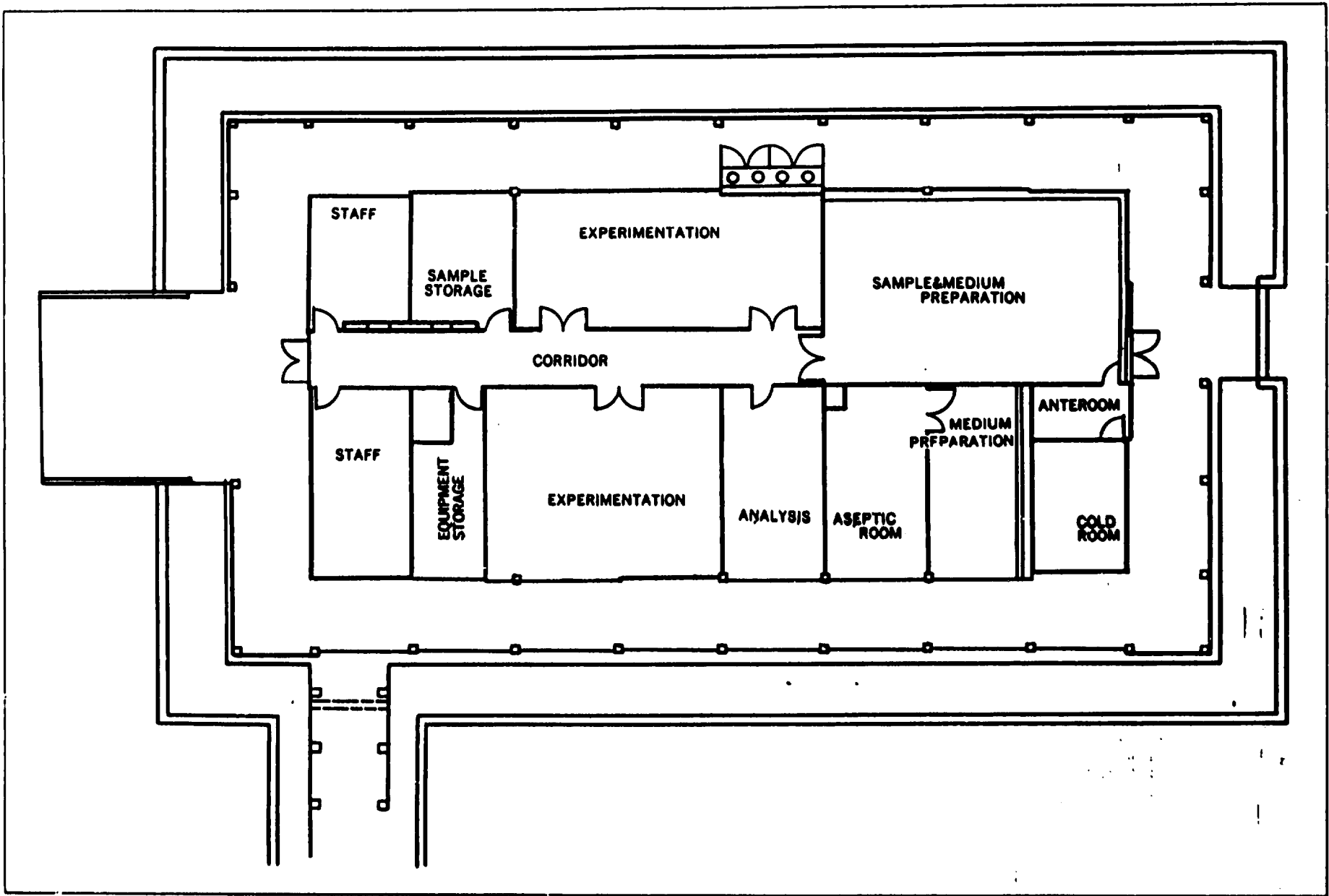


FIGURE IV-2 LAYOUT OF MAIN BUILDING (DCPT)

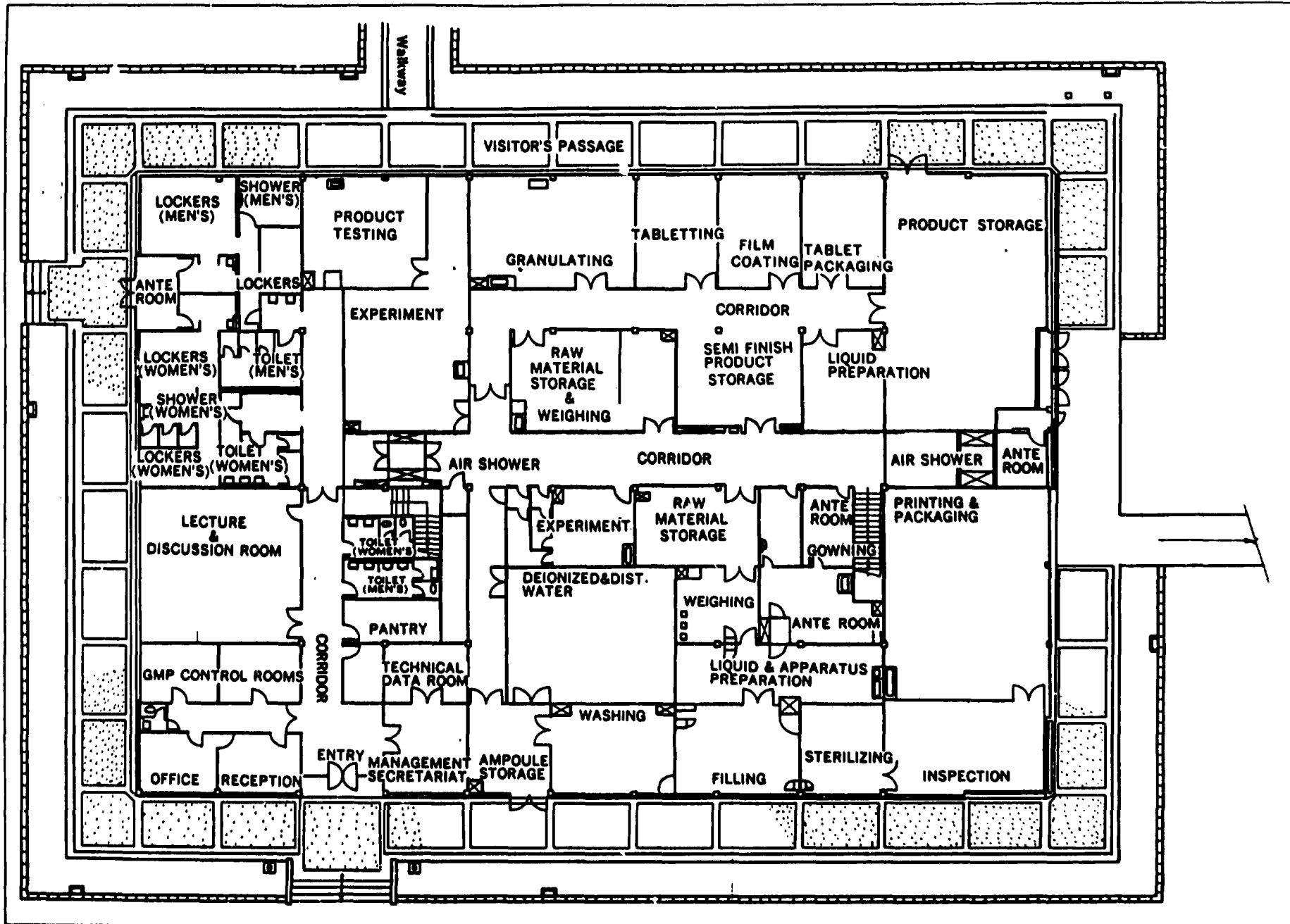
FIGURE IV-3 LAYOUT OF FERMENTATION AND MEDICINAL PLANTS BUILDING (DPT)



FERMENTATION & MEDICINAL PLANTS BUILDING



FIGURE IV-4 LAYOUT EQUIPMENT (DCPT)



**Table IV.1. DEVELOPMENT CENTRE FOR PHARMACEUTICAL TECHNOLOGY**  
**EXPENDITURE DURING CONSTRUCTION PERIOD**

Sr. No.	Particulars	1980-81				1981-82			
		Consultants Fees		Contractor		Consultant's Fees		Contractor	
		₹ Million	K Thousand	₹ Million	K Thousand	₹ Million	K Thousand	₹ Million	K Thousand
1.	Advance Payment 40%	58,400	1649.8 (18-9-80)	741,600	20,950.2 (27-10-80)				
2.	1st. instalment 30%	43,800	1237.3 (28-1-81)	556,200	15712.7 (26-2-81)				
3.	2nd. instalment 20%					29,200	824.9 (28-1-82)	370,800	10475.1 (17-7-81)
4.	Final instalment 10%					14,600	412.5 (8-3-82)	185,400	5237.5 (8-3-82)
		102,200	2,007.1	12,97,800	36,662.9	43,800	1237.4	556,200	15,712.6

Consultant's Fees	K Thousand	4,124.5	=	₹ Million	146
Contractors Fees		52,375.5	=		1854
Total for 1980-82		<u>56,500.0</u>			<u>2,000</u>

100 ₹ = K. 2.825

Table IV.2. DEVELOPMENT CENTRE FOR PHARMACEUTICAL TECHNOLOGY

ADDITIONAL EXPENDITURE AFTER CONSTRUCTION

<u>YEAR</u>	<u>1982-83</u>	<u>1983-84</u>	<u>1984-85</u>	<u>1985-86</u>	<u>1986-87</u>
<u>ADDITIONAL EXPENDITURE</u>	27,479,344	597,219	47,182,095	91,744,202	9,864,344
<u>TOTAL FOR 1982-87</u>	176,867,204				

- (ii) To undertake development and research in the utilization of indigenous resources for pharmaceutical products ;
- (iii) To undertake development and research in acquiring for production and control of drugs according to the Good Manufacturing Practice (GMP), and
- (iv) To train personnel in the fields of Pharmaceutical technology.

IV.4.

Facilities provided in DGPT

The details of equipment and facilities available in the fermentation department and utilities section are shown in Annexes IV.1. and 2 respectively.

IV.5.

Activities of DGPT

The following activities are normally carried out in DGPT :

- (i) Pharmaceutical Preparation Department  
Formulation and development of essential drugs in compliance with GMP and training in modern Production techniques ;
- (ii) Fermentation Department  
Research and Development in the utilization of indigenous resources to produce antibiotics by fermentation, collection of industrial microorganisms and training in basic fermentation technology ;
- (iii) Medicinal plants Department  
Training in basic and applied technology and research and development of indigenous medicinal plants ; and
- (iv) Quality control Department  
Development, research and training in chemical, microbiological and pharmacological procedures. Besides, DGPT has supporting departments including development and research planning, technical information service, administration and finance.

IV.6.

Technical assistance and training of Myanma

Personnel abroad

A resume of the Japanese expertise provided to DCPT and local staff trained in Japan is given in Annex IV.3. The details of training imparted to the local staff abroad are indicated in Annex IV.4. This training in Japan was supplemented by the visit of 2 Japanese experts for one month each during the early stage of DCPT operations, in the course of which the local staff were trained in basic fermentation technology, fermentation process of dihydro-streptomycin recovery and purification techniques and some theoretical aspects of antibiotics fermentation. Again in 1985, two Japanese experts visited for one month each and gave some lectures and did some laboratory work on fermentation technology and genetic engineering.

Subsequently under a separate bilateral arrangement with France four local Scientific personnel were given post graduate training in France leading to Doctorate degrees.

A resume of the academic qualifications and experience of Key technical personnel is given in Annex IV.5, from which it can be seen that all the Key technical and Scientific Staff are well qualified academically and they form the nucleus for carrying out the development work in DCPT.

IV.7.

The Development work already carried out by the  
Fermentation Department

IV.7.1.

Isolation of potential microbial cultures and maintenance

770 Soil samples from different parts of Myanmar were examined. Out of these 75 microorganisms were isolated. Among those, 52 isolates of Actinomycetes were found to be capable of producing antibacterial antibiotics and those were studied by morphological identification by using the International Streptomycin Project (ISP) reference. Some of the antibiotics produced were

observed to be of broad Spectrum and were strongly active against both gram positive and gram negative bacteria. Out of these some were identified as belonging to the genus Streptomyces based on morphological and physiological characteristics and the determination of antibiotic production in liquid media. Some strains were studied for preliminary antibiotic classification by using Summarized Paper Chromatography. In addition, some industrial strains including Aspergillus, Acetobacter and yeast were cultured. All the isolated strains have been maintained in freeze dried form.

IV.7.2. Strain improvement studies

After treatment of tetracycline and streptomycin Producers - *S. albobacillus* and *S. griseus* with mutagenic agents, that is, Nitrosoguanidine (NTG), the resulting strains are being studied.

IV.7.3. Experimental dihydrostreptomycin fermentation

The culture of *Streptomyces humidus* was grown on different media in shake flasks as well as 30 litre fermentor. A small quantity of antibiotic was recovered from the fermented broth and assayed. Effort was also made to substitute local soybean powder in place of the imported one with promising results.

IV.7.4. Import Substitution

Laboratory experiments were carried out involving the preparation of yeast extract, Corn starch, Corn steep liquor, Soybean meal and potato starch obtained from local sources for use as substitutes for imported materials in the fermentation media.

IV.7.5. Studies on industrial enzymes

IV.7.5.1. Studies on the Production of Amyloglucosidase by locally isolated strain of *Aspergillus niger*

The enzyme Amyloglucosidase was prepared from a locally isolated strain of *Aspergillus niger* in the laboratory. Some fermentation parameters were investigated using locally available raw materials alongside the imported ones. The optimum temperature for maximum enzyme activity was found to be 50°C and pH 3.5. The main Saccharifying enzyme

(Amyloglucosidase) hydrolysis of the substrate was done as an integrated form of the whole ethyl alcohol fermentation Process (that is, Simultaneous hydrolysis and fermentation). The substrates included soluble starch, Corn starch and locally available rice flour and tapioca starch. A maximum yield of 15.5% of ethyl alcohol was obtained. It is considered possible that with the above technology, a higher concentration - 30% of the locally available substrate could be used. The Scale-up study is now being carried out in Cooperation with MPI.

IV.7.5.2

Studies on the production of glutamic acid decarboxylase enzyme and trial application in glutamic acid analysis on a commercial Scale

Glutamic acid decarboxylase enzyme (GAD) was prepared locally from *E. coli* strain of Osaka origin at appropriate fermentation conditions both in shaker incubator and fermentor. Various methods for the recovery of the enzyme were tried. The locally produced enzyme was also evaluated in the manufacturing plant at Daik - U monosodium Glutamate (M.S.G) plant alongside an imported enzyme and the results were comparable. This is significant from the point of view of possible import substitution of the enzyme.

IV.7.5.3.

Penicillinase

Penicillinase enzyme production is being studied for use in the sterility testing of Penicillin at MPI in place of the imported enzyme.

IV.7.6.

Assistance to other organizations

Freeze dried Cultures, slant Cultures and starter Cultures were distributed to the Universities and the Development Centre for Food Technology. Assistance in fermentation studies, analysis etc. was given to the Post Graduate students of the University of Yangon and Yangon Institute of Technology.

IV.8.

The operating costs of DCPT

The operating costs of DCPT during the period 1986-87 to September, 1989 are shown in Table. IV.3. It is interesting to note that nearly 2/3 rd of the operating cost pertains to the cost of Services, which include Wages, Salaries, maintenance, raw materials for production and utilities.

DEVELOPMENT CENTRE FOR PHARMACEUTICAL TECHNOLOGY

Table IV.3.

( OPERATING COST )

(Kyats in thousand)

Sr. No.	Particulars	OPERATING COSTS				Remarks
		1986-87	1987-88	1988-89	Up to Sept. 1989	
1.	Costs of services	4378-89	4193-27	4536-70	2051-00	
2.	Administration Cost	1004-04	945-29	977-32	513-00	
3.	Research and Development	628-53	689-39	711-72	617-00	
4.	Total Operating Costs	6011-46	5827-95	6225-74	3181-00	
5.	Depreciation	3997-00	3980-10	4008-78	1638-00	
	Total Expenditure	2014-46	1847-85	2216-96	1543-00	

Chart:



IV.9. Assessment and Conclusions

Following is an assessment of the development work already carried out by the fermentation department of DCPT along with the Conclusions.

IV.9.1. Equipment and facilities

A perusal of the annexes IV.1. and 2. indicating the equipment and facilities in the fermentation department and utilities Section Shows that standard good quality equipment have been provided by the Japanese Agency within the frame work of the objectives of DCPT. Both the 30 litre Stainless Steel fermentors have been provided with Sophisticated instrumentation to carry out Small Scale fermentation experiments. The laboratories are adequate and well equipped with Sophisticated instrumentation. A limited quantity of Good quality equipment have been provided for some unit operations, which could be used in the recovery of fermentation products. It is understood that based on a specific request by the Myanma Authorities, Complete lines of industrial Scale equipment have been provided for some of the formulation operations. However, the equipment provided for the fermentation department is limited to the laboratory and some Small Scale Pilot Plant operations, probably to facilitate development work in general for the utilization of indigenous resources for pharmaceutical products as envisaged in the objectives. In other words, there is need to provide additional complementary equipment to undertake fermentation on a pilot plant scale, Such as additional equipment for the recovery of the fermentation Products and antibiotics in particular.

IV.9.2. Training

A review of Annexes IV 3,4 and 5 dealing with training and based on the discussions held with the technical Personnel concerned of DCPT, it is observed that the training imparted to the local technical staff in Japan as well as in France is adequate to handle microbial Cultures and related development work on a laboratory Scale within the frame work of DCPT objective. However, further practical training would be necessary in the production operations and engineering maintenance in fermentation plants and this aspect will be dealt with in subsequent chapters.

IV.9.3. Development work already carried out

IV.9.3.1. Isolation of microbial Cultures and Strain improvement

The fact that 770 Soil Samples have been examined resulting in the isolation of 52 Actinomycetes strains is encouraging. As far as the Strain improvement work is concerned, it appears that there is no Significant outcome. It is well known that the present day antibiotics industry in the industrialized Countries relies a great deal on the high yielding microbial strains to reduce costs and maintain their competitive position in the industry. Further, the industry spends large amounts of money towards strain improvement. Also there are some agencies available, which concentrate on strain improvement and sell these improved Commercial strains to the industry at a relatively high price. In view of this, it is desirable to Carryout strain improvement studies more intensively and on a much larger Scale. Instead of diversifying the limited facilities to work with several strains, it is desirable to concentrate on a few specific strains, keeping in view the demand in the Country for those Products and antibiotics in particular.

IV.9.3.2. Experimental Dihydrostreptomycin fermentation

As the Japanese Experts provided a strain Streptomyces humidus for the production of dihydro-Streptomycin 3 fermentation batches were completed in one of the 30 litre fermentors during 1983-1984. The fermentor broth assay ranged between 1000 - 2000  $\mu\text{g/ml}$ . Efforts were made to recover the antibiotic in the laboratory. About 8 grams of dihydrostreptomycin powder were obtained from all the three batches. The final product which was barely enough for testing, was analyzed using I.R. spectrum, thin layer chromatography and bioassay. The assay of different batches ranged between 440 to 759  $\mu\text{g/mg}$ . The above three batches cannot be considered standard runs, since samples from the running fermentor were obviously not tested for the absence of extraneous organisms and steam was not available on a continuous basis during the 7-8 days fermentation runs. The possible contamination of those batches could probably explain the very low recoveries and low potencies of the final product. This work was discontinued in 1984, as it is understood, that MPI was no longer interested in dihydrostreptomycin. Subsequently the same fermentor was utilized

for the fermentation relating to different enzymes during the period 1985-87. In all about 14 fermentation batches of enzymes were completed. The second 30 litre fermentor was not used for production so far.

The limited fermentation work carried out for dihydrostreptomycin sulphate and enzymes during the past 8 years served some purpose as far as training the staff in the laboratory and pilot plant in handling antibiotic and enzyme producing cultures are concerned. The decision to discontinue dihydrostreptomycin fermentation is the right one for the following reasons. First, dihydrostreptomycin sulphate has been banned in the industrialized countries several years ago on account of its adverse side effects and has been deleted from Pharmacopoeias. Second, the trend in several Countries is to move away from streptomycin sulphate for TB treatment. This was also confirmed during recent discussions with the Ministry of Health Authorities of Myanmar, during which it transpired that the trend here also is towards using Rifampicin in combination with Chemotherapeutic drugs for that purpose. In view of this, it is appropriate to start fermentation work relating to antibiotics, which are in demand and have prospects for increased demand in the future. This aspect will be discussed in the subsequent chapters.

#### IV.9.3.3.

##### Import substitution

As far as the work already carried out in DCPT is concerned, this has two broad aspects, that is, enzymes and agricultural raw materials. Regarding enzymes, the reports made available to the UNIDO expert show that the work carried out produced some encouraging results. In one case, the prepared enzyme has been evaluated in an industrial plant with satisfactory results and in another Scale up evaluation in a production plant is envisaged. In view of this, it is considered desirable to continue this work, carryout more test runs in the industrial plant with a view to ultimately replace the imported enzymes. A note of caution is necessary here. In current industrial practice in the developed Countries, the enzymes are immobilised on inert materials and are re-used several times to achieve cost reduction. It is desirable that work in this area be taken up in DCPT.

A review of the work done on the use of indigenous raw materials shows that the work to date is more of an academic nature and that too not much. It should be noted that the high yielding commercial strains used for industrial Scale fermentation are highly sophisticated in their raw material requirements. In view of this, the indigenously available crude raw materials require further processing for successful use in industrial Scale plants. This aspect will be discussed further in subsequent chapters.

IV.10. Further development work (including training) necessary

IV.10.1. Within the Capabilities of DCPT

IV.10.1.1. Equipment and facilities

As already pointed out, good quality equipment are available in the fermentation department and the attached laboratories. It is desirable that all these equipment are used on a regular and continuous basis. During the past eight years or so, only three batches of antibiotic fermentation and 14 batches of enzyme fermentation were carried out in one of the 30 litre fermentors. Even these batches could not be reckoned as standard fermentation runs due to the reasons mentioned in IV.9.3.2. above. It is obligatory that steam supply, compressed air and power supply should be available on a continuous basis throughout the fermentation runs. It is also necessary to draw samples from the running fermentors regularly to conduct physical, chemical and microbiological analyses and put for sterility test to ensure that no extraneous microbes are present. Similarly it is necessary to test the sterility of air at regular intervals.

It is recommended that the second 30 litre fermentor be taken up for carrying out production batches. Since both these fermentors are equipped with sophisticated instruments, different parameters including PH, dissolved oxygen, power input, aeration, should be continuously monitored and optimum parameters worked out. When both these 30 litre fermentors are operated on a continuous basis, there will be adequate fermentor broth to use the pilot plant equipment for the recovery of the product. The latter are scarcely used at present. It is learnt that shake flask incubators are used on a regular basis and this is encouraging. It is understood that some of the laboratory instruments

are out of order and efforts should be made to rectify them. This highlights the need to have an instrumentation engineer to maintain and repair the various instruments in the pilot plant as well as the laboratories. Lack of spareparts and the absence of planned preventive maintenance are important factors responsible for the low capacity utilization in general in the developing Countries. It is desirable that DGPT takes lead in this area to ensure uninterrupted functioning of equipment and instruments.

The DGPT authorities deserve credit for getting one 150 litre fermentor fabricated locally by cannibalising an obsolete stainless steel tank. UNIDO expert has been collaborating since December, 1989 to systematically test this fermenter and Commission the same for fermentation runs. When once this fermenter is taken into regular production, it will widen the Scope of the development work in fermentation. For example, two stage fermentation could be taken up using the 30 litre fermentor as the Seed Vessel and the 150 litre vessel as the fermentor. The design for the necessary piping installation for this purpose has been provided by the Unido expert. The 150 litre fermentor will also facilitate amongst other things, the meaningful development work relating to the import substitution of raw materials utilizing the indigenously available ones. This will also provide enough final product for a comprehensive analyses and evaluation. To facilitate the continuous use of all the equipment, it is necessary to plan and procure the required raw materials, chemicals, spare parts and auxiliaries in time.

#### IV.10.1.2.

##### Training

As already mentioned,,the nucleus technical staff of DGPT are well qualified academically and have adequate laboratory experience. However, the pilot plant fermentation operational staff is limited to one Deputy Research officer.(Head of the Department) assisted by one technician. This is totally inadequate for the continuous operation of the equipment. In the short term, it is recommended that the other nucleus technical and Scientific staff be trained in the pilot plant production operations. Although they had, some training in some industrial plants abroad, there is usually a limitation to allow trainees to engage in the actual plant operation for obvious reasons. The pilot plant operations in DGPT, therefore, will involve them more intimately with the process, which will also facilitate work in their

respective areas. Such involvement will in addition, provide supervisory staff for operations round the clock. Further, more technicians could be trained in the pilot plant operations. For example, two groups can be formed, one for fermentation and the other for recovery and purification. For training local staff, in addition to lectures it is necessary to prepare manuals and standard operational procedures in great detail so that operations are carried out in a uniform and consistent manner. Although one is dealing with a pilot plant at present, it is necessary to follow all the operational and Safety procedures followed in an industrial scale plant, Since this pilot plant with its staff will serve as a nucleus for the bigger pilot plant, which in its turn will be the nucleus for the industrial scale plant, as and when it is established at a future date. In other words, the plant discipline and working should be introduced from now on. Any departure even of a minor nature from the standard operational procedure should be viewed seriously. All operations should be logged in detail and maintained as permanent records. Such a discipline is vital in the fermentation industry.

IV .10.1.3. Development Work

IV .10.1.3.1. Isolation of microbial cultures and strain improvement

The importance of strain improvement has already been highlighted in IV .9.3.1. above. In view of this, it is desirable to intensify this work concentrating on microbes relating to the fermentation products of importance to the Country. It is in this context that the UNIDO expert advised DCPT in December 1989 to activate Penicillium culture from its type collection. No doubt the culture has been developed in the 50's but it is the only one available at DCPT. During the course of the present UNIP project, UNIDO expert could collaborate in this pilot plant work. Similarly, cultures relating to Tetracycline could also be activated. For strain improvement, several new techniques are available to screen several potential high yielding strains. This will facilitate the handling of a large number of mutants (strains) and selection of the potential ones. Having selected one, the fermentation parameters have to be worked out systematically both in the shake flask as well as the pilot fermentor. As regards enzyme development, it is suggested that the

strain improvement work could be taken up for the production of Enzyme Amidase from *E. Coli* or *Aspergillus orizae* cultures. This enzyme is specific for splitting Benzyl Penicillin chain to Yield pure GAPA which is the main intermediate for the production of Ampicillin. Since all the three antibiotics - Penicillin, Ampicillin and Tetracycline are in demand in Myanmar at present and are expected to be required in larger quantities in the future, the above mentioned strain improvement studies are recommended. The immobilization of the enzymes could also be worked out.

#### IV.10.1.3.2. Experimental antibiotic fermentation

As discussed in IV .9.3.2 and IV .10.1.3.1. above, work on Penicillium strain has been taken up by DCPT in December 1989 and is in progress. Similarly, experimental tetracycline production can be taken up. These two antibiotics are in demand at present and have potential for the future.

Having carried out fermentation in 30 litre fermentors, it is desirable to collect adequate quantity of the fermented broth and carryout recovery and purification of antibiotics using the available pilot plant equipment. This will facilitate obtaining adequate quantities for a comprehensive analysis and evaluation of the final product. The object should be to obtain product conforming to the specified Pharmacopoeal standards.

#### IV.10.1.3.3. Import Substitution

This is a very important area of work and constitutes one of the main objectives of DCPT, for which the Centre has been established. The major raw materials used in fermentation are agrobased and these include Soybean, Corn, Cotton Seed, Peanut, Starch, Vegetable oils and Sucrose and these materials are available in large quantities in Myanmar as can be seen from Annexes IV.7. and 8 showing acreages production and Acre Percentage under various groups of crops and their disposal. However, a lot of development work has to be carried out with these crude materials before they can serve as import substitutes. For example, Soybean has to be dehusked, flaked and solvent extracted to recover oil and solvent removed. The resulting Soybean meal has to be evaluated in the fermentation process. The limited work carried out to date in DCPT was with the crude raw materials and this is more of an academic nature. The

present day high yielding commercial strains are very specific in their nutritional requirements. It is, therefore, necessary to further process the available crude agricultural products. It is also desirable to identify the sources of major raw materials now and hold discussions with the producers concerning possibilities for further processing for use in fermentation. The processed materials have to be evaluated in the pilot plant, so that the required raw materials of indigenous origin will be available in the form required for the proposed pilot plant and at a future date for regular commercial production. There is a distinct possibility for the export of the Semi processed raw materials to earn much needed foreign exchange and this aspect will be elaborated in subsequent chapters.

#### IV.10.1.3.4. Incentives

It will be appreciated that research and development work in the fermentation field particularly at this stage of Myanmar's development needs a great deal of effort and dedication. Fortunately, DCPT has a nucleus technical staff, who are well qualified. With a view to motivate them further, it is recommended that some kind of incentives either in Cash or Kind be provided. The Unido mission appreciates the difficulties involved in rewarding one segment of the staff in a particular Public Sector unit, which could have repercussions in the other branches of the Public Sector. Still, it is hoped that a way would be found to provide the needed incentive to the Scientists, technologists, engineers and others concerned in the Centre in view of the special features of the development work involved.

#### IV.10.2. Further development work necessary outside the capabilities of DCPT

##### IV.10.2.1. Equipment and facilities

As discussed in IV .9.1. above, there is immediate need to procure a limited items of equipment for the recovery of fermentation products. For example, for the recovery of Penicillin, one small liquid-liquid extraction unit, some small stainless steel tanks with agitators and a small vacuum drier are required. A detailed list of equipment with specifications urgently needed is given in Annex IV.6 .



IV.10.2.2. Training

The Scope for additional training needed within DCPT has been discussed in IV.10.1.2. above. As pointed out, there is need for training in the actual plant operation and engineering maintenance. The training received so far appears practically limited to the laboratory and superficially to the plant. It is recommended to send <sup>2 microbiologists and</sup> / technologist and one chemical engineer for training in the fermentation operations and the recovery and purification operations respectively in an industrial Scale plant abroad for a period of six months in each case. So far no engineer has been trained in the mechanical maintenance of equipment in these areas, which are of a special nature unlike a standard chemical plant. In view of this, it is recommended that one mechanical engineer be sent along with the above two persons for training in engineering maintenance for a period of 6 months. It is not easy to get such facilities for actual practical training. It is recommended that UNDP/UNIDO may consider awarding fellowship and arrange training facilities for this purpose. As stated above, the emphasis should be to facilitate the trainees to engage in actual plant operations (Pilot plant as well as industrial Scale plant) and not merely watching the operations. For example, such facilities could be explored in Japan, South Korea, India, Italy, Yugoslavia, Portugal and Spain.

IV.10.2.3. Export Possibilities for Semi-processed agricultural products

The development work relating to the import substitution as outlined in IV.10.1.3.3. above, will involve the processing of the crude agricultural raw materials and testing for their suitability for the fermentation process. The Semi processed raw materials found suitable could be used in the fermentation pilotplant, in place of the imported ones (import substitution). Further, this work has a much greater significance. At present Myanmar is exporting Agricultural Products which are processed in the industrialized Countries for use in the fermentation industry. Instead of exporting the crude raw materials for the fermentation industry, Myanmar could organize processing on a large Scale based on the development work

carried out by DPT and could then export the Semi-processed agricultural products at a much higher, Price (Value added). This will not only bring in additional foreign exchange but will create employment in the rural areas, where these materials are grown.

V

TECHNOLOGY TRANSFER AT DCPT BY THE UNIDO CONSULTANT

V.1.

Penicillin G Production

Since no development work on any of the antibiotics currently in demand in Myanmar has yet been carried out at DCPT, the Unido Consultant considered it appropriate to transfer technology for Penicillin Production. Further none of the staff has so far been exposed to Penicillin production. The management readily agreed to this suggestion and provided necessary facilities. Following is a brief description of the work carried out in this connection.

V.1.1.

Microbial Culture Strain

Out of the *Penicillium chrysogenum* Thom Cultures from the American Type Culture Collection available at DCPT, the culture No.12688, M.P. Baccus, Wis F-3-64 (Wis 51-20 F<sub>3</sub>-64) (Mycologia 47: 429-463, 1955) was selected by the Unido Consultant for the technology transfer. This strain is nonpigmented and claimed to be of ' high yield ' in 1955. According to the Unido Consultant's experience, this particular strain had a productivity of around 2,000 Units/ml in 100 hours at that time. This particular strain was acquired by BPI some decades ago and was transferred to DCPT in 1982. Neither the record as to the storage conditions of this culture and power stoppages since its acquisition nor the technology for penicillin production is available at DCPT. The Unido Consultant therefore provided the necessary technology.

Since barley and millet normally used for the sporulation of the culture were not available, local rice and sticky rice with and without the addition of honey were used for the sporulation as substitutes. The sporulation in both the cases was Satisfactory (for example,  $3 \times 10^9$  spores were obtained per 20 grammes of rice). The quantity of spores was larger with the addition of honey.

V.1.2.

Fermentation

Fermentation was carried out in three stages in shake flasks of 200 ml, 500 ml and 1000 litre capacity respectively. The raw material composition and the fermentation parameters for each stage were provided. Locally available Soybean flour was used as

the main nitrogen source in all the three stages in place of imported corn steep liquor. A combination of lactose and sucrose was used as a carbohydrate source, in the absence of facilities for continuous addition of sucrose. Fermentation was carried out at 24°C in an incubator shaker. The optimum fermentation cycles for the first stage, the second stage and the third stage were 48, 24 and 144 hours respectively. 20 percent of the inoculum was transferred from the first stage to the second stage and 17 percent from the second to the third stage. Regular sampling was done at 24 hour intervals for assaying pH, biomass and penicillin potency by bioassay as well as chemical assay. Reducing sugar was also determined. The samples were directly observed under microscope with and without staining. Sterility tests to detect any extraneous microorganisms were also carried out. In all, 5 shake flask batches were carried out, based on which a standard graph was prepared for future follow up.

### V.1.3

#### Recovery and Purification

A detailed technological process for the recovery of Penicillin was provided. The recovery process was based on the use of Butyl acetate for the extraction of Penicillin from the filtered broth; washing the butyl acetate solution with buffer to remove the impurities; the extraction of Penicillin from the butyl acetate solution with potassium carbonate, followed by salting out with a saturated solution of potassium acetate and the purification of the resulting potassium penicillin G by washing with butyl alcohol and acetone and finally drying the product in vacuum.

A Power stoppage lasting as long as 2½ hours, during which the emergency diesel generator could not be commissioned ruined one large production batch earmarked for the recovery process. This high lights the need to ensure uninterrupted power supply to the fermentation unit.

The fermentation could not be carried out in 30 litre fermentors due to the nonavailability of imported raw materials, despite efforts made to procure them intime.

both  
It is gratifying to note that/the microbiologists have mastered  
the technology for the fermentation process within a relatively  
short period. Further training of the microbiologists in the  
Penicillin fermentation for a period of six months in a commer-  
cial plant abroad is strongly recommended to improve their skills.

V.2.

Commissioning of a 150 litre fermentor

As indicated in Chapter IV, DGPT got one 150 litre stainless steel fermentor fabricated locally by cannibalizing one obsolete stainless steel storage tank. However, this fermentor had yet to be properly aligned and tested. The Unido Consultant therefore, got the fermentor aligned properly. The mechanical seal of the agitator was checked and necessary adjustments were made. The fermentor was then subjected to hydraulic test (the jacket as well as the body) and was found to be in order. However, slight deformation occurred in the jacket, which highlighted the need to adjust the respective safety valves to avoid any hazards during the sterilization process. The adjustment was carried out.

On the completion of the mechanical alignment and mechanical testing, the fermentor was commissioned. At first it was run with water. Samples were drawn during the course of the operation for 6 hours and these were tested for sterility. Since compressed air and steam were not available round the clock, the test was discontinued. Next, the fermentor was run on a dilute nutrient medium containing 0.25 percent of soybean flour and 0.1 percent of yeast.

In this case also, the samples were drawn in the course of 6 hours and the test was discontinued due to the reasons mentioned above. In both the above cases, the samples remained sterile. To this extent, it can be stated that the fermentor is in an operational condition for taking up production runs. However, prior to this, it is necessary to run the fermentor for about 72 hours with continuous supply of air, steam, and agitation to establish the sterility beyond doubt.

As emphasized in Chapter IV, it is essential to have a continuous and uninterrupted supply of power, air and steam throughout the fermentation process, to safeguard sterility and optimum fermentation parameters.

The above tests also highlighted the need for Practical training in a commercial plant abroad for six months of at least one person, who will supervise the fermentation operations.

V.3.

Processing of agro-based products for use in fermentation

As discussed in Chapter IV, several agro-based products are available in Myanmar, some of which have a potential for use in the fermentation process. However, such products have to be processed further and evaluated in the pilot plant for establishing their suitability. In this connection, an effort was made by the Unido Consultant to transfer technology for the preparation of starch and corn steep liquor from the local maize. A brief description of the process is given below :

$\frac{1}{2}$  kg of local maize was steeped in water at 50°C in the course of ten days, maintaining a level of 100 P.P.M of sulphur dioxide. By then the maize <sup>was</sup> slightly swollen and soft. The soaked maize was separated from the water and the latter was concentrated under vacuum to obtain corn steep liquor of a light colour. The maize was suspended in water and crushed lightly, passed through a coarse sieve to separate the germs and husk. The resulting slurry containing starch and gluten was allowed to settle in a shallow tray. The supernatant liquid containing gluten was drained. The starch was again slurried with water and the process was repeated till the starch was free from the gluten. The starch was finally dried in a hot air oven. The recovery of starch was 52 percent. The corn steep liquor and starch obtained need to be evaluated in the pilot plant for their suitability in the fermentation process in place of the imported materials.

Normally hybrid corn is used for the manufacture of starch and corn steep liquor. Myanna maize appears rather hard for this purpose.

VI

POTENTIAL FOR THE UTILIZATION OF AGRO-BASED PRODUCTS  
IN THE FERMENTATION PROCESS - IMPORT SUBSTITUTION

As discussed on section IV.10.1.3.3, large quantities of agrobased raw materials are available in Myanmar and they have a potential for their utilization in the fermentation process, in place of imported raw materials. The need for carrying out development work and evaluation in the pilot plant to establish their suitability was also emphasized.

In this connection, the sources of some of the raw materials were identified, places visited and discussions were held with the concerned. The following is a Summary of such discussions.

VI.1.

Cotton Seed Cake

Processed Cotton Seed meal is an important raw material used in the fermentation process for Penicillin Production. It is known under trade names such as 'Pharma Media'. In this connection a cotton ginning and oil extraction plant at Myinttha, located 80 kilometers from Mandalay was visited. This factory which was established in 1986, is under the administrative control of the Textile Corporation of the Ministry of No.1 Industry. The ginning mill handles about 90 metric tons of cotton grown in the neighbourhood per year and delivers to the cotton Textile mills. The factory also purchases cotton seed from the neighbourhood.

In the oil extraction plant, the seed is passed through cold rollers and husk is sucked out. The kernels are then cooked in steam in four stages and the temperature reaches around 260°C. The cooked material is pushed through a screw expeller. The oil is passed through a filter press, neutralized, centrifuged and sent out for deodourizing. The oil cake, which contains less than 5-6 percent of oil is exported mainly to Belgium, Federal Republic of Germany and Japan. The factory can handle 30 tons of seed per day. The present out put is around 2,000 tons per year. A 2 kg sample of cotton seed cake was obtained.



Prior to the evaluation in the pilot plant, it is necessary to reduce the oil content to below 1 percent and inactivate gossypol, which is toxic.

## VI.2.

### Yeast, distillers solubles and barley

To explore the possibility of obtaining yeast and distillers solubles, Mandalay Beer factory was visited. This factory is under the administrative control of the Food Stuff Industry of the Ministry of No.1 Industry and has been established over 100 years ago. This factory produces, Beer, Rum, Brandy, Dry Gin and Baker's yeast. It produces annually 700,000 dozen bottles of beer of 24 ounces each and employs 360 persons. This is the only factory of its type in Myanmar and uses molasses as the main raw material. It imports hops. Now they are evaluating locally grown hops and barley. At present the still residue is drained. A sample of local barley was obtained.

Barley is to be evaluated at DGPT for the sporulation of *P. Chryso-genum* strain. The possibility of obtaining yeast and distillers solubles has to be further explored with IPI and Mandalay Beer factory.

## VI.3.

### Palm sugar syrup and sugar

With a view to investigate the possibility of using palm sugar syrup and sugar in place of cane sugar and imported glucose, Taungzin located 23 kilometers away from Pagan was visited. In this village, 80 percent of the households independently prepare palm sugar from the palm juice obtained in the neighbourhood. There are 10,000 such units in this village. The process used is rather primitive and comprises evaporation in 4 stages in open aluminium pans on open fire, to form a thick syrup, which is made into sugar balls each of 2 centimeters in diameter. Fresh juice is tapped twice a day from the palm trees and evaporated forthwith to avoid fermentation. The season lasts from February to August each year. The output of sugar balls is about 17 kg per palm tree per season. The household sells sugar at the rate of k 8 per kg to the local distributor.

Samples of palm sugar and syrup were collected for the evaluation at DCPT.

#### VI.4

##### Sorghum

With a view to explore the possibility of securing the supplies and evaluate the quality of Sorghum, Swesayan medicinal plant farm located 21 kilometers away from Mandalay was visited. This farm is under the administrative control of Myanna Pharmaceutical Industries of the Ministry No.I of Industry. This farm is spread over an area of 545 hectares and was started in 1973. Castor is grown in an area of 40 hectares and is the main crop.

Other medicinal plants grown include Mentha and Artemesia. Sorghum is grown in an area of 6 hectares and is used as cattle feed. Other crops include sugar cane and Sesame. About 35 kgs. of menthol oil are obtained per one hectare.

Sorghum is an important raw material used in the fermentation process. It is also used for the Sporulation of *P. chryso-*genum. Sorghum is widely grown in the neighbourhood.

A sample of Sorghum was collected for the evaluation at DCPT.

VII. ASSESSMENT OF TECHNICAL AND ECONOMIC FEASIBILITY OF SMALL SCALE PRODUCTION IN VIEW OF DEMAND AND DEMAND PROJECTION FOR FERMENTATION BASED PHARMACEUTICALS

VII.1 The demand - Supply Scenario

A review of Chapter III.3. relating to the Pharmaceutical subsector high lights the critical situation in Myanmar with regard to the supply of Pharmaceuticals vis a vis the demand (cf. Tables III.10 and III.11). First, the supply of Pharmaceuticals through domestic production and official imports falls much short of the demand. Second, the local supplies based on the import of Pharmaceutical active ingredients started a downward trend from 1982/83 onwards and declined steeply in 1987/88 due to non-availability of required foreign exchange. Since there is no local production of fermentation based active ingredients required for Pharmaceuticals, the domestic supply fluctuates widely depending on the vagaries of foreign exchange availability. As Pharmaceuticals constitute an essential commodity for the population next only in importance to food, it is necessary to ensure constant and continuous supply of the same.

Further more EPI has certain installed capacity for the production of pharmaceuticals and on account of non availability of adequate amount of foreign exchange, the sales in 1988/89 dwindled resulting in low utilization of capacity viz. 29 percent (cf. Annex III-26). Due to paucity of foreign exchange, some of the state agencies such as CSD and SSB were unable to import any Pharmaceuticals at all during recent years. The resulting vacuum in the official supply of pharmaceuticals has apparently been filled by receipts through illegal channels. This in its turn poses serious problems. First, some of the sick have necessarily to meet their medical needs through Purchases on the parallel market, often paying exorbitant prices. Second, the illegal supplies pose serious health hazard, since there is no local quality control on such supplies and they can as well be substandard, fake or time expired. The picture looks bleak when one considers the demand projection for Pharmaceuticals

in the year 2,000 and the likely gap that may arise between the demand and actual supplies (of Table III-11). Such a gap can only be filled by injecting massive doses of foreign exchange at the expense of other Sectors or illegal receipts. Further, a country can ill afford to depend entirely on imports for such an essential item i.e. pharmaceuticals.

An analysis of the above situation high lights the urgent need to set up small scale production of fermentation based pharmaceutical active ingredients required to meet the production needs of at least some essential pharmaceuticals.

## VII.2

### Technical feasibility of Small Scale Production

The development work carried out by the fermentation department of the Development Centre for Pharmaceutical Technology in the areas of isolation of microbial cultures, strain improvement, studies on streptomycin and Penicillin Production, industrial enzymes and import substitution has been reviewed in depth in Chapters IV and V. The Centre has also qualified microbiologists, technologists, chemists and engineers, several of them trained abroad in the fermentation field. Besides, the Centre has well equipped microbiological and chemical laboratories and trained staff. Further more the Centre has some equipment in the fermentation department, which needs to be strengthened ; has well equipped formulation department and utilities. As there is need to carryout additional development work in the areas mentioned above, recommendations were made by the Unido expert in Chapter IV with a view to arrive at meaningful conclusions facilitating further Scale up work. The recommendations pertain to work including training which could be carried out within the capabilities of DCPT as well as outside. After implementation of the above recommendations, necessary technical base will be available to take up Small Scale Production of fermentation based pharmaceuticals.

## VII.3

### Economic feasibility of Small Scale Production

When once the need for local production becomes imperative, then the question naturally arises as to the economically feasible level of Production. This would obviously depend on the existing demand

and the demand Projection up to the year 2,000. A perusal of Table III-11 presenting demand figures reveals that the requirements of fermentation based pharmaceuticals projected for the year 2,000 are still below the minimum economical size. For example, the minimum economical size for ampicillin based on data from a typical developing Country is 35 tons per year, that for Penicillin 122.5 tons per year and for tetracycline, it works out to 50 tons per year. As against these minimum economical levels, the imports by EPI during the period 1986/87 to 1988/89 and demand Projection are as follows :

Table VII-1 Comparison of actual imports of antibiotics in bulk by EPI Vis a Vis the respective minimum economical sizes and demand.

<u>S.No.</u>	<u>Product</u>	<u>Demand</u> 2,000 tons	<u>Imports by EPI tons</u>			<u>Minimum</u> <u>Economical</u> <u>Size</u> tons
			1986/87	1987/88	1988/89	
1.	Ampicillin	10.66	1.40	1.00	3.50	35.00
2.	Penicillin	21.72	2.25	nil	2.69	122.50
3.	Tetracycline	11.47	3.20	0.80	2.53	50.00

It can be surmised from Table VII-1 that large Scale commercial production in Myanmar seems uneconomical in the case of Ampicillin, Penicillin and Tetracycline taking into account even the Projected demand in the year 2,000 as the requirements of these antibiotics donot lend themselves to economy of Scale. As regards Streptomycin, the future trend in Myanmar is to discourage its main use in TB treatment in preference to rifampicin and chemotherapeutic drugs.

\* UNIDO, Report on Drugs from the National Drug list which because of their essentiality could be produced in the Developing Countries, ID/WG. 267/5, 1978.

VII.4 Need and Justification for a Fermentation Pilot Plant

VII.4.1 To create a technical base to carryout development work and to undertake Small Scale / large Scale Production

In view of the critical situation with respect to the supply of pharmaceuticals in Myanmar vis a vis the demand as discussed in the previous sections, it is desirable that necessary measures are taken early to move towards local production on a Small Scale with a view to attain some degree of self sufficiency in this vital Sector and to ensure continuous supply of certain essential pharmaceuticals. In this connection, the first step has already been taken with the establishment of DCPT in 1982. Recommendations for further work and training are contained in Chapter IV.

As already pointed out, the existing facilities are more in the nature of laboratory Scale set up and it is therefore, necessary to establish a full fledged pilot plant to create adequate technical base to undertake Small Scale production. The development work carried out in such pilot plant will lead to meaningful results to undertake Scale up work.

VII.4.2 To facilitate practical training:

The Small Scale production interalia requires trained staff. The Centre has well qualified Scientists, technologists and engineers but they need practical training to undertake Small Scale production. As already pointed out, it is almost impossible to obtain such practical training in large Scale commercial plants abroad for obvious reasons. Foreign training will involve foreign exchange and will also limit the number of trainees. The pilot plant will, therefore, offer facilities for training a larger number of persons at different levels with savings in foreign exchange.

VII.4.3 To evaluate indigenous raw materials for import substitution and export

As already discussed in Chapter IV.10.1.3.3., major raw materials needed for the production of fermentation based pharmaceuticals are agrobased and these include Soybean, Maize, Sorghum, Starch, groundnut and cotton Seed cakes, Sugar and Vegetable oils and these

are available in Myanmar in large quantities. Based on <sup>the</sup> Study in a typical developing Country, the raw materials in the case of Penicillin production account for 42 percent of the cost of production, out of which about 23 percent is contributed by agro based products.\* Similarly in the case of tetracycline the corresponding figures are 58 and 53 percent respectively. In view of this, the local agro based products are potential sources for import substitution facilitating economic feasibility and savings in foreign exchange. As pointed out earlier, the local agro based raw materials have to be processed for their suitability in the fermentation process and evaluated in the pilot plant. After establishing the suitability of the Semi-processed agrobased raw materials, the latter can also be exported to industrialized Countries to obtain added value and earn foreign exchange.

#### VII.4.4

##### Production of Small quantities of fermentation Products to support indigenous industry - import substitution :

The development work carried out by DCPT in the field of industrial enzymes Viz. Amyloglucosidase and glutamic acid decarboxylase has been described in Chapter IV.7.5. These enzymes have to be evaluated in the local commercial factories, for which sizeable quantities have to be produced. This could be done in the proposed Pilot plant. In the context of current industrial production needs in Myanmar, the annual requirements of such enzymes are not too large and it should be possible to meet the entire demand of the Country through Pilot Plant production using indigenous raw materials.

#### VII.4.5

##### Production of Small quantities of pharmaceuticals to support indigenous development work and investigations by other institutions or agencies

As discussed in Chapter III.3.1.2, the WHO " Myama Essential Drugs Project " under implementation requires Small quantities of Specific pharmaceuticals for assessing the total drug requirements in selected townships and these could be made available through pilot plant production. Similar is the case with other investigations.

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\* UNIDO, Ibid, 1978

VII.4.6

To Produce Small quantities of pharmaceuticals to meet total national needs in a specific area

As high lighted during the discussions with UNICEF, one million 5 gram tubes of Tetracycline ointment are required annually to meet the entire needs of the Country to cure a particular eye ailment. For this purpose, UNICEF supplied to HPI imported Tetracycline and packing materials. Such a limited production requires 50 kg. of Tetracycline per year and it should be possible to produce this Small quantity in the Pilot plant to meet the total demand of Myanmar. There are several such cases in which pilot plant production could meet the total needs of the Country.

VII.4.7

Evaluation and Adaptation of imported technology

Before acquiring imported Technology, it has to be evaluated. Such an evaluation can be carried out in a pilot plant and this will avoid the purchase of technologies, which may not prove useful later. Similarly, the imported technology has to be adapted to the local environment in the Pilot plant before it can be utilized in regular production at a future date. Adaptation in a pilot plant is less expensive than experimenting in a large scale Production factory.

VII.4.8

for  
Potential/meeting the present and projected demand in 2,000 of certain fermentation based pharmaceuticals

After establishing the technical base, training the required personnel, identifying local sources of raw materials after due evaluation and acquiring the necessary technology, the pilot plant would be in a position to meet the total needs of Myanmar of certain fermentation based pharmaceuticals. This aspect will be elaborated subsequently under Technology.

VIII.

PRELIMINARY DESIGN OF A FERMENTATION PILOT PLANT BASED ON DEMAND, WORK OF DCPT AND ASSESSMENT OF TECHNICAL AND ECONOMIC FEASIBILITY OF SMALL SCALE PRODUCTION

The design features of the Fermentation Pilot Plant are discussed below :



## VIII.1 FUNCTIONS OF THE PILOT PLANT

The main functions of the Fermentation Pilot plant have been discussed earlier in Chapter VII.4.1. under need and justification and these are listed below:

- (i) To create a technical base to carry out development work and to undertake Small Scale/ Large Scale production.
- (ii) To facilitate practical training.
- (iii) To evaluate indigenous raw materials for import substitution and export.
- (iv) To produce small quantities of fermentation products to support indigenous industry / import substitution.
- (v) To produce small quantities of pharmaceuticals to support development work and investigations by other institutions or agencies.
- (vi) To produce small quantities of pharmaceuticals to meet total national needs in a specific area.
- (vii) To evaluate and adapt imported technology.
- (viii) To have potential for meeting the present and projected demand in 2,000 of certain fermentation based pharmaceuticals.
- (ix) Service to other institutions

In addition to above, the Pilot Plant would be in a position to provide service to other institutions to carry out experiments, development work, training, small scale production etc. This will interalia promote the development of the other institutions and save foreign exchange needed to obtain such services abroad.

## VIII.2 CAPACITY (PRODUCTION)

Before proceeding to assess the production capacity of the pilot plant, it is appropriate at this stage to review briefly the process of production, on which the design is based. Typical flow sheets for production of Penicillin, Sodium Penicillin (sterile) and Ampicillin are presented in Figures VIII.1.1, VIII.1.2 and VIII.1.3 respectively.

FIGURE VIII-1.1

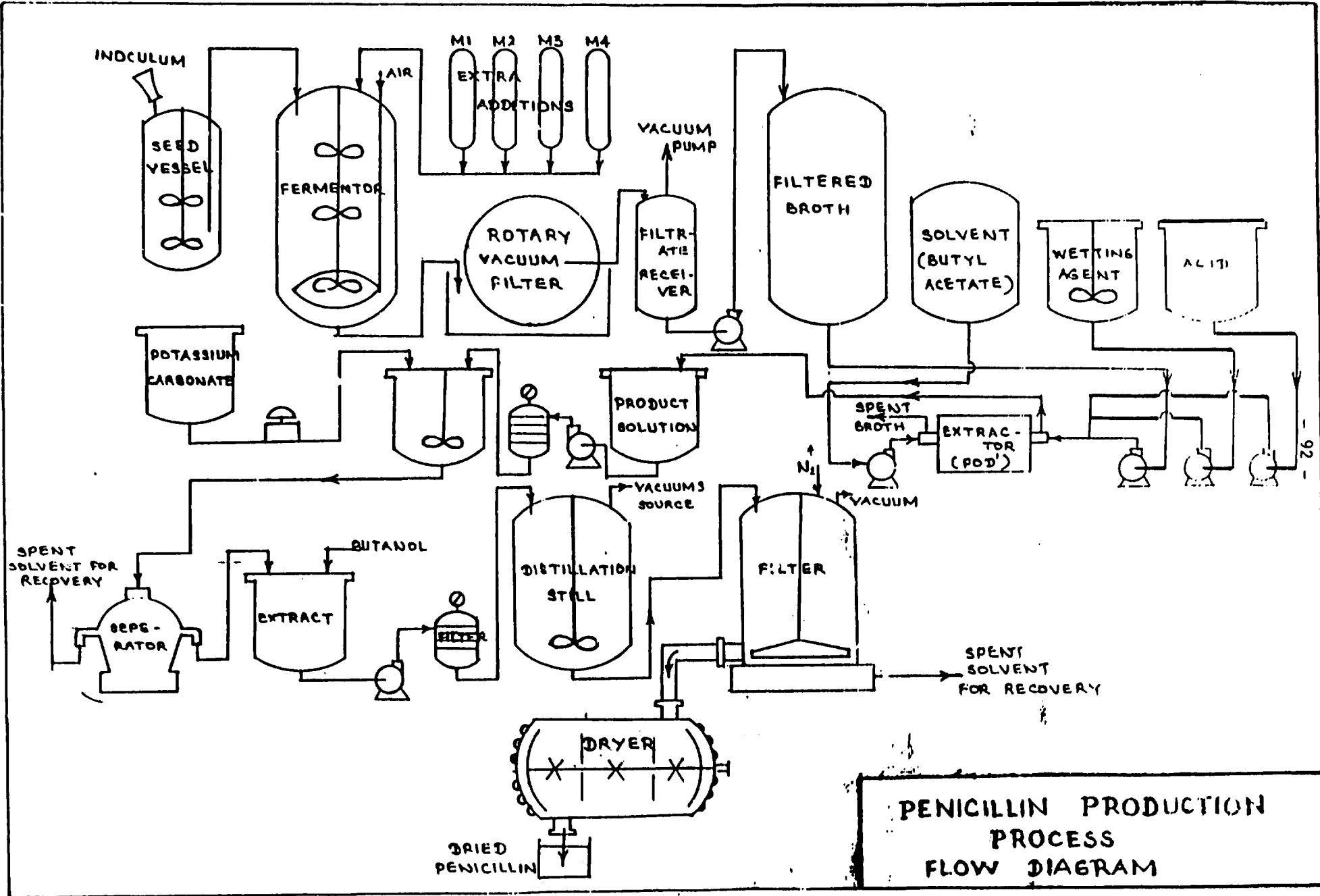
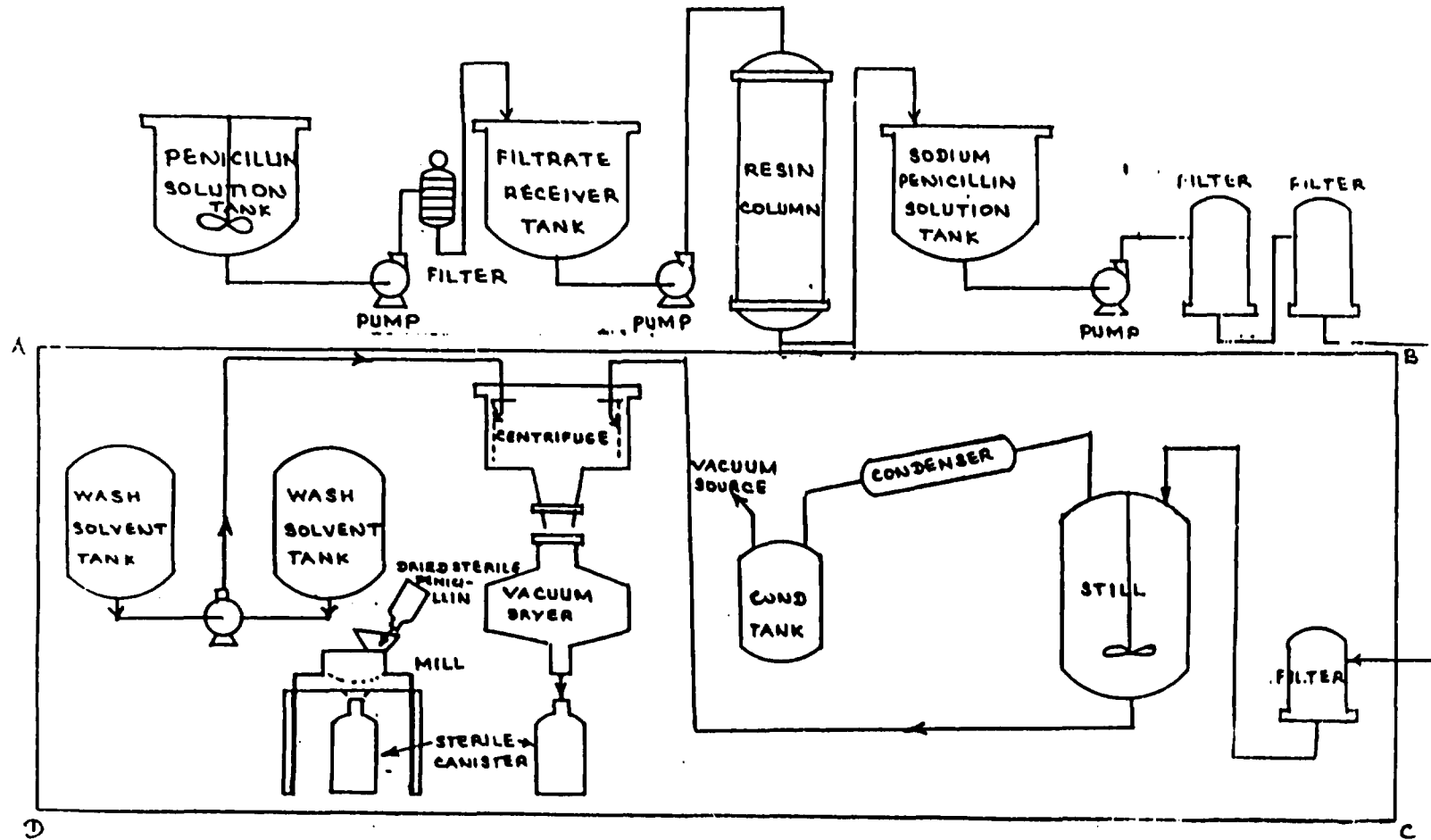


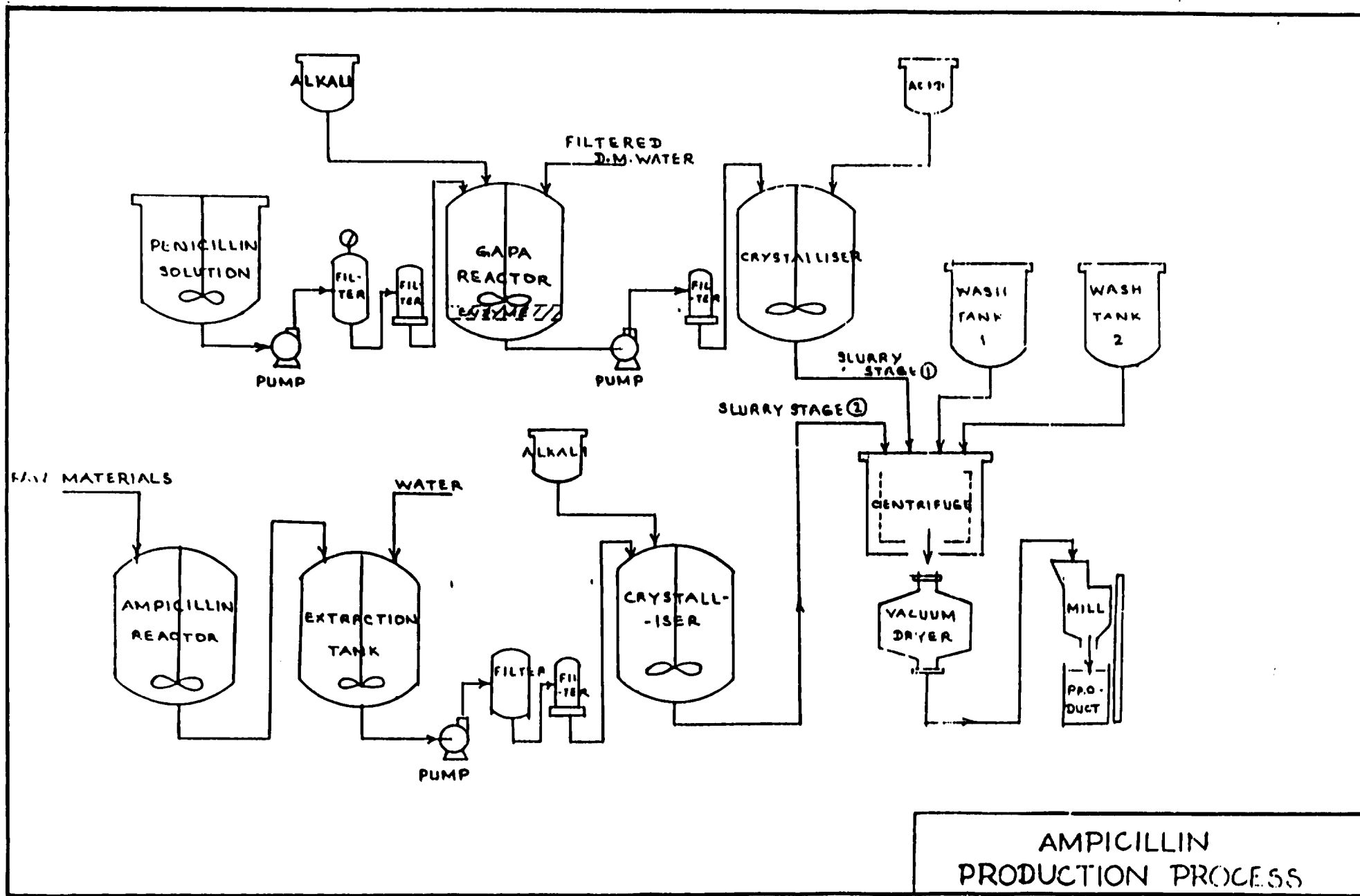
FIGURE VIII-1.2



AREA 'ABCD' - STERILE ROOMS

SODIUM PENICILLIN (STERILE)  
PRODUCTION PROCESS  
FLOW DIAGRAM

FIGURE VIII-1.3



A brief description of the production processes for Penicillin, Sodium Penicillin (sterile) and Ampicillin is given below.

A. Penicillin 'G' or 'V' Non-Sterile Bulk

Penicillin producing master culture is preserved with necessary care. Lyophilis are prepared and tested on shake flask for productivity and sterility. Inoculum is prepared and transferred to sterile production media in a tank. The seed is grown under optimum conditions of temperature, air flow, pressure and agitation. The seed is checked at regular intervals and transferred to sterile medium held in fermentor (seed volume 10% to 12% of fermentor volume). The fermentation is carried out under optimum conditions of temperature, air flow, back pressure. Levels of (1) D.O, (2) Ammonia nitrogen, (3) pH, (4) Carbohydrates, (5) packed cell volume are maintained by regulating extra additions, (a) Sugar, (b) PAA, (c) Ammonia, Urea and (d) oil. The fermentation is terminated when productivity is maximum and filtered via rotary vacuum filter. The filtered broth, solvent (Butyl acetate), wetting and coagulating agent, are fed into counter-current extractor. The product layer (rich acetate) is collected, treated with potassium carbonate solution and continuously extracted. The spent solvent from above two steps is sent for recycling, after recovery or directly after a caustic wash. The potassium carbonate extract is distilled in presence of butanol azeotropically till slurry forms. The slurry is filtered in a closed super filter, washed with butanol, acetone and dried in a paddle dryer. The dried penicillin 'G' or 'V' non-sterile bulk is packed into suitable containers weighed, labelled and sampled.

B. Sodium Penicillin Sterile Bulk

Potassium penicillin is dissolved in distilled water, filtered and fed into a resin column containing cationic resin to replace sodium ion with potassium ion. The sodium salt solution is filtered through clarity grade and sterility grade filters and collected in a sterile batch distillation still in sterile area. The batch is azeotropically distilled with butanol till good slurry forms. The slurry is filtered, washed and dried in a sterile double cone vacuum filter. The dried powder is milled under sterile conditions and packed into sterile canisters and sealed. The samples are checked for

all specifications as per pharmacopoeial specifications.

C. Ampicillin Trihydrate Non-sterile Bulk

**1st Step - 6 APA Production**

Potassium penicillin 'G' or 'V' is taken as starting material depending on the specificity of penicillin acylase enzyme (immobilized) nature. The penicillin solution is filtered and pumped into 6-APA reactor containing immobilized enzyme (above the reactor bottom retention screen). The pH and temperature are continuously monitored. The alkali necessary to maintain pH is filtered through fine filter and held. After the reaction, the filtrate from reactor is transferred into crystallizer through another filter. Required quantity of solvent and acid are added. The 6-APA slurry is filtered, washed and dried in vacuum dryer, milled, packed and sampled.

**2nd Step - Ampicillin Production**

The Ampicillin reactor is made bone dry. Required Solvent, Chemicals, 6-APA are added. The reaction is monitored at various temperature levels with the addition of additional chemicals such as D (-) alpha phenyl glycyl hydrochloride. When the reaction is complete the reaction mass is transferred into chilled, filtered dist/DM water. The product, aqueous layer is filtered through primary and fine filters, precipitated with filtered alkali, centrifuged washed and dried. The dried crystals are milled and packed into suitable containers. The product sample is analyzed for all specifications as per relevant pharmacopoeial standards.

The requirements of other fermentation products are for below minimum economical size (cf. Table III-11)

Having ruled out the economic feasibility of commercial Production, the need for Small Scale Pilot plant production and its economic feasibility have to be examined.

At this juncture, it is pertinent to take a look at the global pharmaceutical market scenario. Due to the introduction of high yielding microbial culture strains and advances in engineering and technology, large scale commercial production of fermentation based pharmaceutical active ingredients became economically feasible in the industrialized Countries due to reduction in production costs. Such an advantage will not be available in the case of Small Scale Pilot plant production in the absence of economy of Scale. It is, therefore, obvious that Small Scale production is being considered on account of other important factors but not primarily on the basis of economic feasibility. Further more, the price at which a particular pharmaceutical active ingredient can be purchased on the international market at a given time by a given Country does not necessarily reflect its cost of production and the price can vary for the same product for Country to Country and from time to time due to interplay of market forces. The question of prices of drugs has been examined in great depth by Unido and discussed at length in the Unido pharmaceutical consultations from time to time. For example, the price of Reserpine manufactured by the same Company and of the same quality was purchased in a given period by different Countries and the prices ranged in the ratio of 1 : 11. So it is practically impossible to find out what the actual Cost of Reserpine in question could have been. Much less, a developing country with Small Scale production and inferior technology should not judge the economic feasibility of its own production on the basis of the lowest price of a particular pharmaceutical active ingredient at which it can purchase on the international market at a given time. This leads us to the question of need and justification for a Small Scale Pilot Plant.

VIII.3.

Technology

As already pointed out, technology plays perhaps the most crucial role in the fermentation industry. In this technology package are included the microbial culture strains and their maintenance, raw material quality, composition and mode of addition; fermenter design and size operational parameters and controls; recovery and purification process. The level and efficiency of technology influence the economical performance of the industry to a large extent. In view of this, large sums are allocated for research and development by the enterprises in the industrialized Countries to develop sophisticated technology. There are also some Companies specializing in developing and selling the complete technology package to the industry. For example in the case of Penicillin, the culture strains were producing about 2,000 Units/ml in the fifties. Now it is learnt that improved culture strains are available in some industrialized Countries with a productivity of 90,000 Units/ml i.e. 45 times the productivity of the fifties. One can imagine the tremendous impact on the cost of production when more efficient technology is used. Such technologies are rather expensive, as can be seen below :

Table VIII-2: Sophisticated technologies and their prices in the International market

<u>S.No.</u>	<u>Product</u>	<u>Productivity</u>	<u>Price range of Technology Package (U.S. Dollars)</u>
1.	Penicillin	55,000 Units/ml	300,000 to 500,000
2.	Tetracycline	25g./litre	300,000 to 400,000
3.	Erythromycin	6g./litre	300,000
4.	Cephalosporin C	25g./litre	500,000

Such technologies are purchased by large industrial enterprises. Examples of companies selling Technology packages are Pan Labs Inc., Taiwan and J.C.P. Martin and Associates, Channel Islands, U.K.



As far as the proposed Pilot plant is concerned, there are some microbial culture strains at DCPT mostly acquired from American Type culture collection and these strains have been developed decades ago as can be seen from Table below :

Table VIII-3: Microbial culture strains available at DCPT

<u>S.No.</u>	<u>Product</u>	<u>Year of Development of Strain</u>
1.	Penicillin	1955
2.	Streptomycin	1944
3.	Chlortetracycline	1948
4.	Oxytetracycline	1960

As already discussed in section VIII-3, strain is only one part of technology package and its productivity cannot be derived fully without the other parts. DCPT does not possess the technology for the above strains. The culture strains available with DCPT, therefore, are more of an academic interest, except for Penicillin, in the case of which technology has been transferred by the UNIDO Expert as described in Chapter V.

In view of this, further development work can be carried out by DCPT utilizing the Penicillin culture strain and technology.

#### VIII.4.

##### Theoretical Potential capacity of the Pilot Plant to meet the Projected demand of fermentation based Pharmaceuticals

The design of the pilot plant is also based on the assumption that it could meet the Country's Projected total annual requirement up to 2,000 of Penicillin, and Ampicillin, when the Pilot plant acquires Sophisticated technology and operates continuously round the year, exclusively for the production of Penicillin and Ampicillin. Similar is the case with Tetracycline. This aspect is illustrated in Table VIII- 4 below :

**Table VIII-4 Theoretical Potential Production Capacity of the Pilot Plant to meet the Projected demand of Penicillin and Ampicillin**

S.No.	Productivity of Penicillin (Average yield) Units/ml	Annual Production Capacity of Potassium Penicillin G		Annual Production Capacity of Ampicillin †	
		Alternative I *	Alternative II **	Alternative I *	Alternative II **
1.	20,000	7.53	9.19	5.12	6.25
2.	35,000	13.18	16.08	8.97	10.94
3.	55,000	20.71	25.27	14.09	17.19

\* Alternative I : Pilot plant operation during the course of 250 days per year leaving 115 days for maintenance, equipment changes etc.

\*\*Alternative II : Pilot plant operation during the course of 305 days per year allowing 30 days for annual maintenance and 30 days for routine maintenance and untoward stoppages.

† 1.47 kg of Potassium Penicillin G are required for 1 kg of Ampicillin.

The above production figures are to be viewed in the context of the demand projection for the year 2,000 of 21.72 tons for Penicillins and 10.66 tons for ampicillin respectively. The detailed working for arriving at the above capacities is presented in Annexes VIII-2. Similar data for Tetracycline are presented in Annexes VIII.3 and 4.

**VIII.5.**

**Is it a Pilot Plant or Production Plant ?**

When once certain theoretical possibilities for production capacity exist as discussed in section VIII.4 above, the question naturally arises as to whether the proposed unit constitutes a Pilot Plant and not a production plant. The answer is emphatically 'Yes' for the following reasons : First, the commercial plants in the industrialized Countries have large Scale production Capacities and use Sophisticated technologies. For example, the size of the fermentor Capacity in such cases generally varies from 80,000 litres to 300,000 litres each, while optimum economical size is considered to be

Broadly speaking the process for the production of fermentation based pharmaceuticals and other products comprises two stages viz. (1) Fermentation and (2) Recovery and purification. In the fermentation process, the fermenter, usually a stainless steel reactor with arrangements for agitation, cooling, heating, aeration, control of temperature, pH etc. is the heart of the process. The fermentation process is carried out under aseptic conditions. The equipment used in this process is more or less the same for different products. So the capacity of the pilot plant depends primarily on the capacity of the fermenters with a given technology.

The medium for the fermentation process differs from product to product. Similarly the microbial culture strains used in fermentation also differ. The medium for the fermentation process consists of agro based products, inorganic and organic chemicals. These are mixed in water and the contents are sterilized either in the fermentor or outside and transferred to the fermentor and cooled. The specific microbial culture strain is grown in stages starting with a small fermentor and is transferred to bigger fermentor, both of which are kept under continuous aeration, agitation and constant temperature (submerged fermentation). Different parameters are monitored throughout the process. After a predetermined period (fermentation cycle), the fermentor is harvested for recovery and purification. In most cases, the required product is in the filtrate. In some cases, however, the product is in the microbial mass.

The recovery and purification process is in the nature of a chemical process based on the chemical configuration of the product and therefore, differs from product to product. Although unit operations such as filtration, extraction, adsorption, centrifuging, distillation, evaporation, <sup>and</sup> drying are involved, the grouping of equipment depends on the particular product. The capacity of equipment is matched to the capacity of the fermentor. In other words, the capacity of the pilot plant, as already discussed depends primarily on the capacity of the fermenters with a given technology. For example, in the case of Penicillin the product is in the form of a solution in the filtrate from which it is recovered through counter current liquid - liquid extraction using an immiscible solvent such as Butyl acetate. In the case of streptomycin, the product is recovered from the filtrate through adsorption on

resin beds packed in columns. In the case of tetracycline, the product is recovered from the filtrate by precipitation with chemicals. Similarly further purification differs from product to product. In some cases, the final product is produced under sterile conditions. The entire operations should conform to Good Pharmaceutical Manufacturing Practice (GMP).

From the above, it is seen that the production capacity depends primarily on the size of fermentor used. As can be seen from the provisional list of equipment for the pilot plant (cf. Annex VIII-1) the fermenter sizes vary from 30 litres to 20,000 litres each. So does the capacity.

For a given product, the production capacity of the pilot plant depends on the fermentor capacity as well as technology. The latter including microbial culture strains, plays a crucial role in the fermentation industry. The aspect of technology will be further elaborated in the subsequent section. As regards capacity, two examples are given below in Table VIII-5 concerning Penicillin and Tetracycline Production using certain technology packages.

Table VIII-5 Range of Capacities available in the Pilot Plant with certain technology packages

<u>S.No.</u>	<u>Product</u>	<u>Technology Package</u>	<u>PRODUCTION CAPACITY</u>	
			<u>Per fermentor per batch</u>	
			<u>( KILOS )</u>	
			<u>30 litre fermentor</u>	<u>20,000 litre fermentor</u>
1.	Penicillin	20,000U/ml in 192 hours	0.187	128
2.	Tetracycline	10g/litre in 192 hours	0.156	102

It can be seen from the above that a great deal of flexibility is built into the pilot plant not only to produce different types of fermentation based products but widely varying quantities of the same to facilitate different functions.

around 125,000 litres each. As against these, the size of the fermentor in the proposed pilot plant varies from 30 litres to 20,000 litres each and these sizes could not be reckoned as commercially viable capacities. A fermentor of 20,000 litres will facilitate the various functions listed in section VIII-1 above and large enough to give meaningful results for further scale up in a regular commercial plant at a future date. Second, Sophisticated technology is not proposed for the pilot plant since such a technology package is rather expensive as discussed in VIII-3 and could not be justified on economical grounds. The pilot plant should acquire less Sophisticated technology at much less cost as for example, the technology discarded by some of the large industrial undertakings and yet is good enough to carry out the pilot plant's functions. In view this, the proposed unit is a pilot plant and production, if any, is incidental and could be readily used by RPI in place of the imported pharmaceutical active ingredients. At the same time, it has the theoretical potential capacity to meet the Country's needs with respect to certain fermentation based pharmaceuticals, in case factors other than purely economical feasibility such as urgent health needs necessitate the use of the pilot plant exclusively round the year for such a production.

#### VIII.6.

##### Can different fermentation based pharmaceuticals be produced simultaneously ?

As already indicated the production operations should conform to Good Pharmaceutical Manufacturing Practice (GMP).

According to the latter, for example, Penicillin and Penicillin products such as ampicillin should be produced exclusively in a given production facility at a time to avoid cross contamination and possible health hazards. In certain other cases, there is no such health hazard and production of two products could perhaps be undertaken simultaneously. This aspect should be carefully examined before taking up production.

In general, it is desirable to handle one product at a time to avoid mix up and cross contamination. The system should be thoroughly cleaned to get rid of even minute traces of the previous product before taking up the production of another product.

VIII-7

Potential for the utilization of fermentation based pharmaceuticals from the pilot plant for the captive consumption of DCPT

As indicated earlier, some sophisticated equipment are available at DCPT for the Production of pharmaceutical formulations, as can be seen from Annex VIII-5. Such equipment are meant for commercial scale production of tablets and injectible ampoules. At present, they are mostly idle due to nonavailability of imported active ingredients on account of Scarcity of foreign exchange. In view of this, the output of fermentation based pharmaceutical active ingredients from the pilot plant could be utilized for the production of tablets, ampoules etc. This will facilitate the use of the concerned equipment to produce pharmaceuticals, which have a ready market.

Further the production of pharmaceutical formulations will also improve the economical feasibility of the proposed pilot plant.

VIII-8

Equipment

The list of major equipment along with specifications for the pilot plant is presented in Annex VIII-1.

VIII-8-1.

Basis for the sizing of equipment

As discussed in section VIII-2, the fermenter is the heart of the fermentation process on which depends the capacity of the pilot plant, with a given technology package. The equipment in the recovery and purification section are geared to the respective capacities of the fermenters. The sizing of the fermenters has been done to facilitate various functions of the pilot plant, as described in section VIII.1. The following sizes of fermenters are provided :

Table VIII- 6. The capacity and number of fermenters in the Pilot plant

<u>S.No.</u>	<u>Capacity</u> Litres	<u>Number of fermenters</u>
1.	30	2
2.	300	2
3.	1,000	2
4.	3,000	2
5.	20,000	2

The fermenters ranging in capacity from 30 litres to 3,000 litres can either be used as production fermenters depending on the specific function or they can also be used as intermediate fermenters to grow seed (Microbial Culturemass ) in stages for the larger fermenters. For example, in the case of Penicillin fermentation, 30 litre fermenter can be used as the first stage (inoculator), 300 litre fermenter as the second stage (Seed tank) and 3,000 litre fermenter as the third stage production fermenter. All these fermenters are interconnected for aseptic transfer from one to the other.

The fermenters are also equipped with agitators, individual air filters, pH and temperature recorders and regulators, dissolved oxygen and absorbed potency monitors, foam control probes, air flow meters, continuous monitoring of oxygen and carbondioxide of

vented air besides heating and cooling arrangement. All these devices will facilitate the monitoring and control of various parameters in the fermentation process according to the set regime. In the industrialized Countries, some large enterprises utilize computer programming and monitoring to ensure strict adherence to the regime and also to save labour.

The equipment in the recovery and purification are geared to the respective fermenter sizes. Equipment for different unit operations are also provided. The grouping of these equipment is geared to the specific product. The equipment in each unit operation in their turn are versatile to handle different process needs. For example, for drying different types of dryers are provided such as vacuum shelf dryer, rotary vacuum dryer, fluid bed dryer, spray drier rotary hot air dryer and simple hot air circulating oven. Similar is the case with other unit operations.

The equipment provided take into account the existing facilities at DCPT in order to avoid duplication to integrate where feasible and to strengthen in other cases. The equipment proposed for utilities are also based on all the above considerations. For example the existing water circulation system with minor additions could also serve the needs of the proposed pilot plant.

Important attention was given to the recovery of solvents used in the process, since solvents are expensive, imported at present. Their recovery will not only improve the economy but save valuable foreign exchange.

Particular emphasis was placed on the treatment of effluents in view of the global awareness of its impact on environment. There is a small unit provided in DCPT for this purpose and this will be supplemented by another unit and improved to serve the pilot plant needs.

The possibility of fabricating some of the above equipment locally was explored and it appears that except for some carbon steel storage tanks all the rest of the equipment have to be imported.



## VIII.9.

### PREMISES

The design and layout of the pilot plant take into account the latest trends in the fermentation industry.

The layout of the Pilot plant is presented in Figure VIII-2. The Pilot plant complex includes the following main buildings and installations :

- Production block
- Utilities block and cooling tower
- Solvent Recovery Unit
- Sotores
- Mycelium dryer and incinerator
- Effluent treatment Unit

### VIII.9.1.

#### Production block

The Production block is the main building and is the nerve centre of the pilot plant. The rest of the buildings and installations cater to the needs of the Production block.

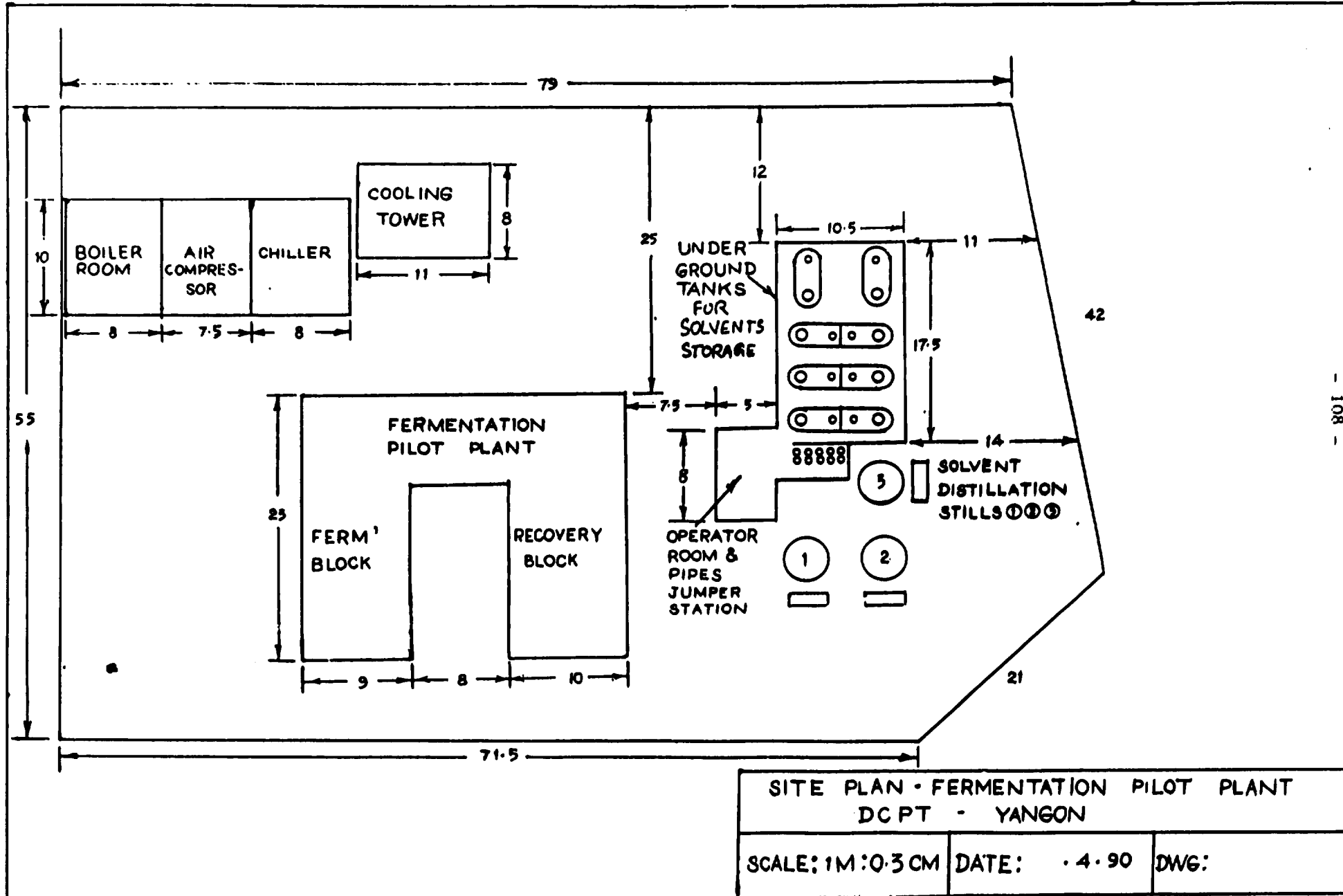
The latter is a U shaped building of three floors. The fermentation section is located in one wing and the recovery and purification section in the other, in order to separate these operations. The layouts of the Production block at the levels 0, 3.7 M and 6.7 M are shown in Figures VIII-3, 4 and 5 respectively.

### VIII.9.1.1.

#### Fermentation Section

As can be seen from the above layouts, both the 20,000 litre fermenters and 10,000 litre Media mixing tank are mounted at level 0 M. The operating level for the media mixing tank is level 3.7 M and that for the fermenters is level 6.7 M. The fermentation raw material substore is located at level 0 M. The rotary vacuum filter and filter press are also located at level 0 M to facilitate the transport of the waste materials. The floor at level 3.7 M is primarily meant for the storage of materials for a single fermenter batch and for mixing the same in the media mixing tank. The rest of the space at level 3.7 M is open. The remaining fermenters, auxiliary vessels, air filters and some pumps are located at level 6.7 M; to facilitate operations and savings in labour. The elevation of fermentation wing is indicated in Figure VIII-6.

Figure VIII-2: Layout of Pilot Plant



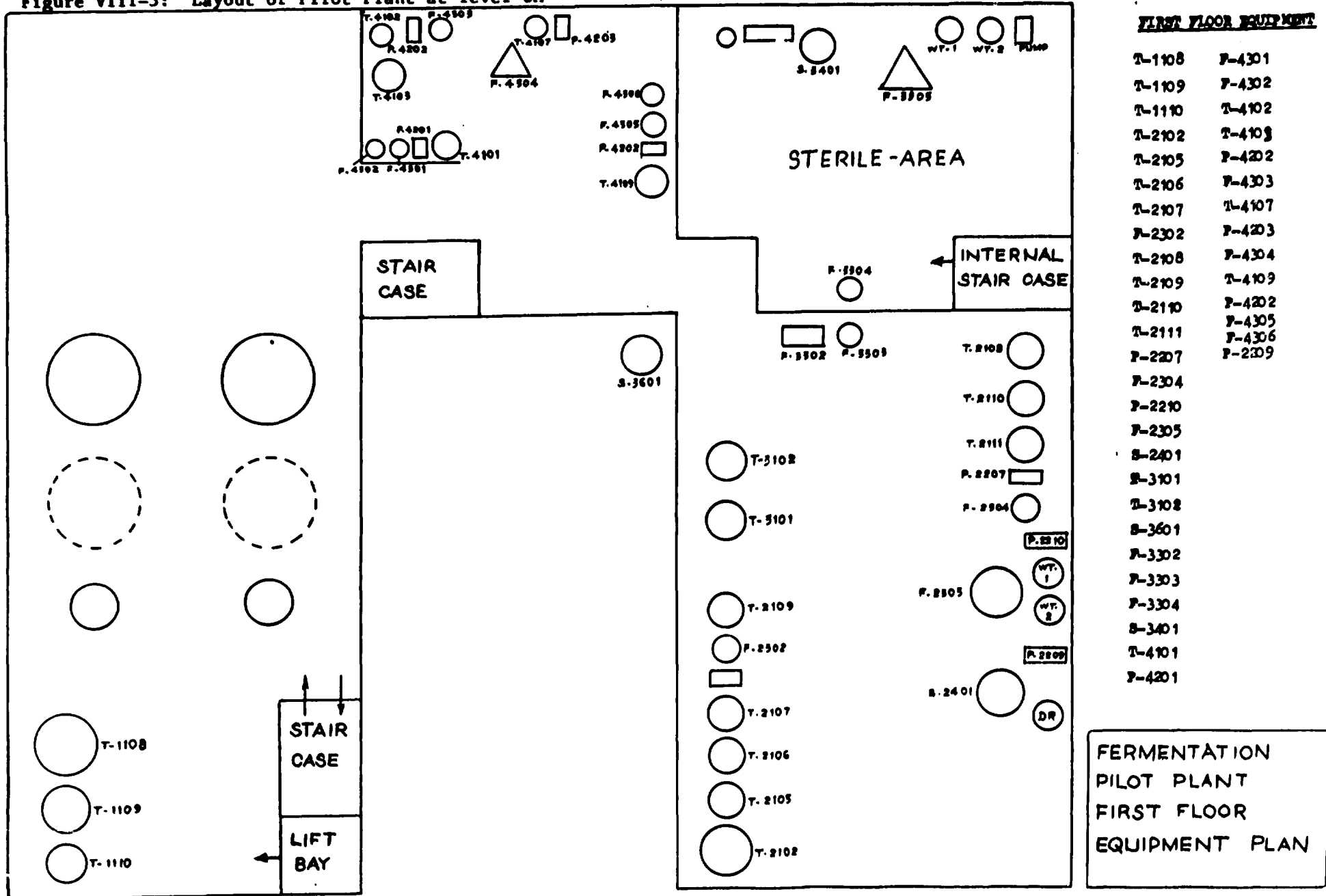
SITE PLAN - FERMENTATION PILOT PLANT  
DC PT - YANGON

SCALE: 1M:0.3 CM

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DWG:

Figure VIII-3: Layout of Pilot Plant at level OM



**FIRST FLOOR EQUIPMENT**

- T-1108 F-4301
- T-1109 F-4302
- T-1110 T-4102
- T-2102 T-4103
- T-2105 F-4202
- T-2106 F-4303
- T-2107 T-4107
- F-2302 F-4203
- T-2108 F-4304
- T-2109 T-4109
- T-2110 F-4202
- T-2111 F-4305
- F-2207 F-4306
- F-2304 F-2209
- F-2210
- F-2305
- S-2401
- S-3101
- T-3102
- S-3601
- F-3302
- F-3303
- F-3304
- S-3401
- T-4101
- F-4201

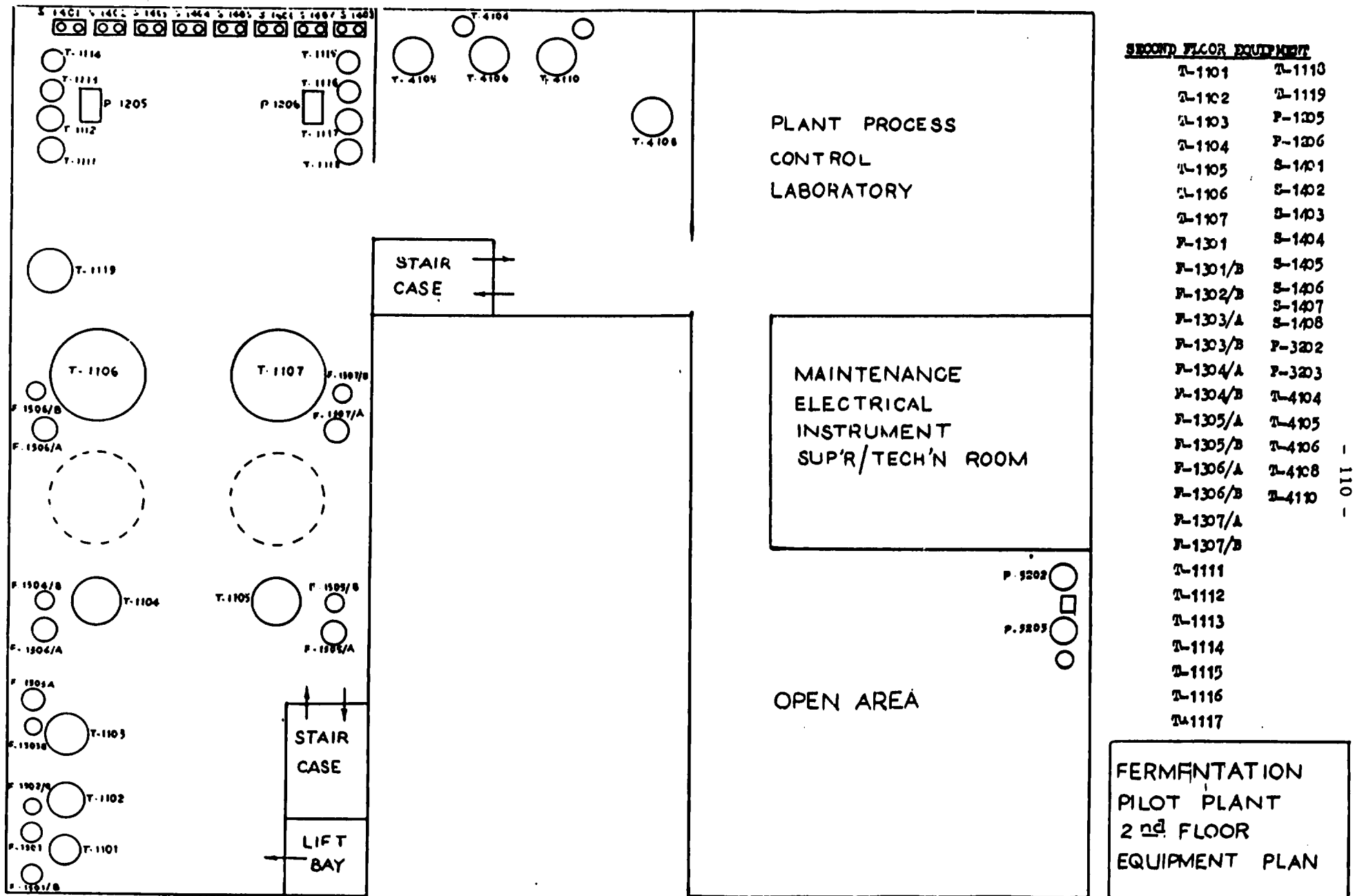
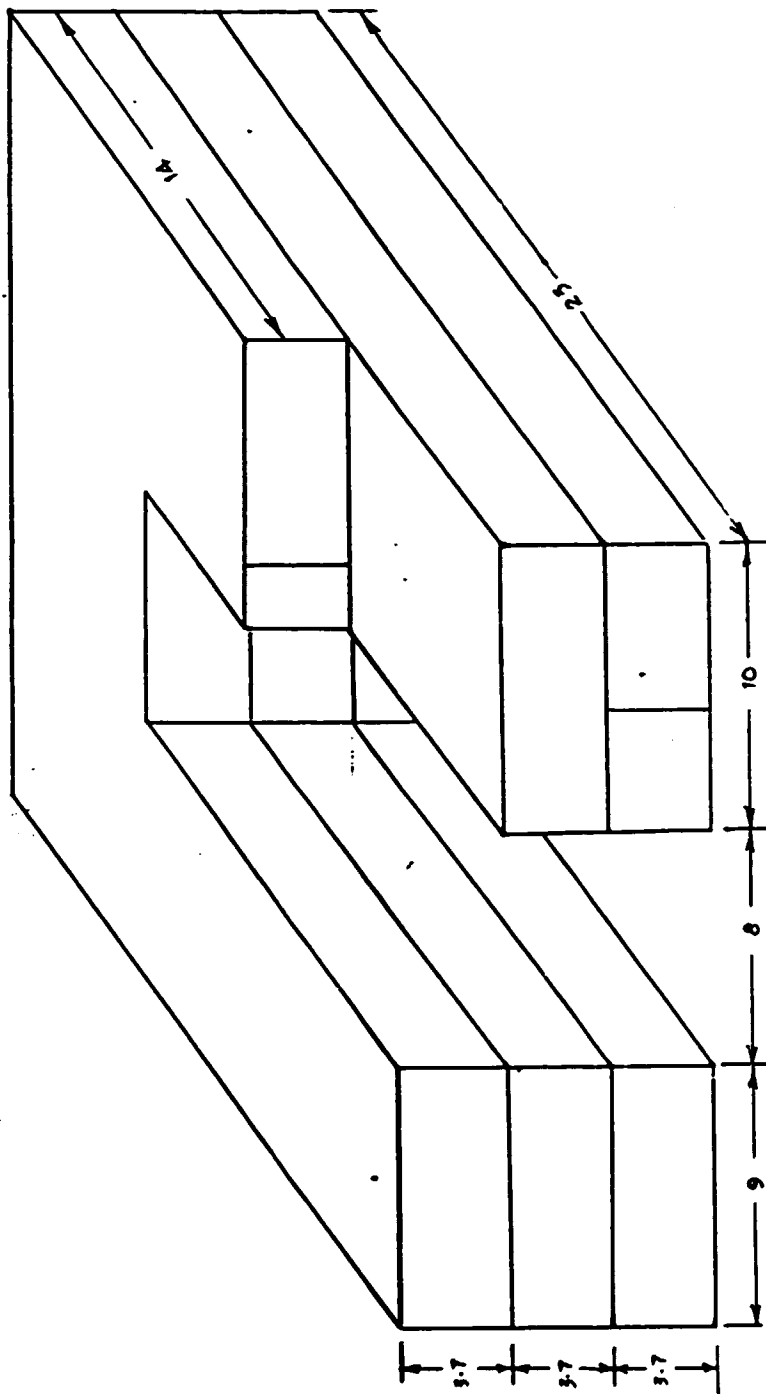


Figure VIII-4: Layout of Pilot Plant at level 3.7M



Figure VIII- 6: Elevation of Fermentation Pilot Plant



FERMENTATION PILOT PLANT BUILDING  
ELEVATION

VIII.9.1.2.

Recovery and Purification Section

The floors at all the three levels are fully built. The layout of equipment is based on gravity flow principle as well as the special needs of the process. Several storage tanks are installed at level 0 M. The Counter-Current extractor for Penicillin and the filter press are also located at this level along with some pumps. The final product stores is located at level 0 M.

Most of the dryers are installed at level 3.7 M. The sterile area is also located on this level. At level 6.7 M, the crystallizer, Stainless Steel and glass lined reactors and centrifuges are located. Some of the processed materials from here are conveyed to level 3.7 M for finishing and drying.

VIII.9.1.3.

The engineering maintenance workshop and stores are located at level 3.7 M. The laboratories and offices are located at level 6.7 M.

VIII.9.1.4.

Central storage yard

The open area between the fermentation and recovery and purification wings is used for the location of big storage tanks, filter broth tank and ion-exchange resin columns. The waste materials from the Production block are transported from this open area.

VIII.9.1.5.

Constructional features of Production block

With a view to ascertain the local constructional features and available building materials, discussions were held with the concerned officials of the Architect Group of the State Public Works Department. Based on these discussions, the following constructional features are specified for the Production block. The building will be of Reinforced cement concrete construction, for which steel, cement and other materials are available locally. Since a flat roof will cause problems during the heavy rains and the water proofing

material has to be imported, a sloping roof is specified with steel trusses and asbestos sheet roofing. In case of possible hazard with asbestos, galvanized iron sheets could be used. At levels 3.7 and 6.7 M, a flooring of terrazzo in-situ with plastic, copper or Aluminum strips is specified. Except for the strips all other materials are available locally.

Glazed tiles for the walls, acid proof tiles, glazed stone ware pipe, PVC pipe of large sizes are not available locally at present and will have to be imported. In regards to windows and doors, they use wood for local construction. Since wood cannot be used due to the handling of inflammable solvents and needs of sterility, aluminum frames and glasses have to be imported. Steel frames are also not fabricated locally.

Although grill is preferable at level 3.7 M in the fermentation wing, it is not fabricated locally. It is, therefore decided to use one half floor of R.C.C. and keep the other half open.

#### NOTES

- A. Production block is  $\Gamma$  shaped. The floor wise drawings enclosed.
- B. The solvent recovery unit will need one control room (drawn to scale and enclosed) equipping instruments for the three stills. All the inlet and outlet pipes from and to solvent tanks, and column feed lines, are drawn to jumper station adjacent to control room and are provided with female kamlok joints. Hose pipes (armoured type) are connected with male kamloks. This will provide all the needed flexibility and ease for this multistill, multitank solvent yard.
- C. Utilities - Boiler house, chilled water, tower water, and compressor houses are drawn to scale. The brine unit has been located on the ground floor of recovery block. This will help in reducing (1) additional building cost, (2) heavy losses on refrigeration due to heat picked up during transportation, and (3) high costs of piping and cold insulation.

**VIII.9.2. DEMINERALIZED WATER, WATER TREATMENT AND EFFLUENT TREATMENT (A brief description of demineralized water, water treatment and effluent treatment is given below.)**



A special mention has to be made about the effluent treatment. Since the production processes involve fermentation and recovery and purification, the effluent is rich in organic and inorganic materials. It is, therefore, necessary that the effluent is treated properly to avoid adverse effect on the environment.

A. Demineralized water

In the existing system the iron content from the tube well water is removed to a greater extent. This water is fed into a double bed cationic and anionic regenerated resin column where demineralization takes place due to removal of cationic and anionic impurities through adsorption.

**Chemistry of ion removal**

Operating on the hydrogen cycle the cation exchanger converts the ionizable salts in the solution to their respective acids. In the following anionic exchanger hydroxyl (OH<sup>-</sup>) group replaces the negative radical in the acid, removing the anion and leaving only water as the effluent (flow diagram enclosed). The resin columns are regenerated at regular intervals with good quality hydrochloric acid and caustic solutions.

B. **WATER SUPPLY AND TREATMENT**

Additional source of water is necessary to meet the demand. Two more tube wells to supply additional 24 M<sup>3</sup>/hr. are suggested with a parallel system of iron remover. The quality of treated demineralized water should pass following specifications before it is used as boiler feed water or feed water for production process.

Hardness	- Nil
Silica	- 5PPM Max.
Turbidity	- Less than 5PPM
pH	- 7.0 to 8.0
Alkalinity	- Passes the test

C. **EFFLUENT TREATMENT (Detailed flow sheet enclosed.)**

Briefly the process of effluent treatment for a fermentation plant consists of the following steps.

The incoming effluent is screened by means of bar screens to eliminate large pieces of floating debris. It is then passed through a grit chamber for removal of grit. The effluent is passed to reaction tank,

Figure VIII-7

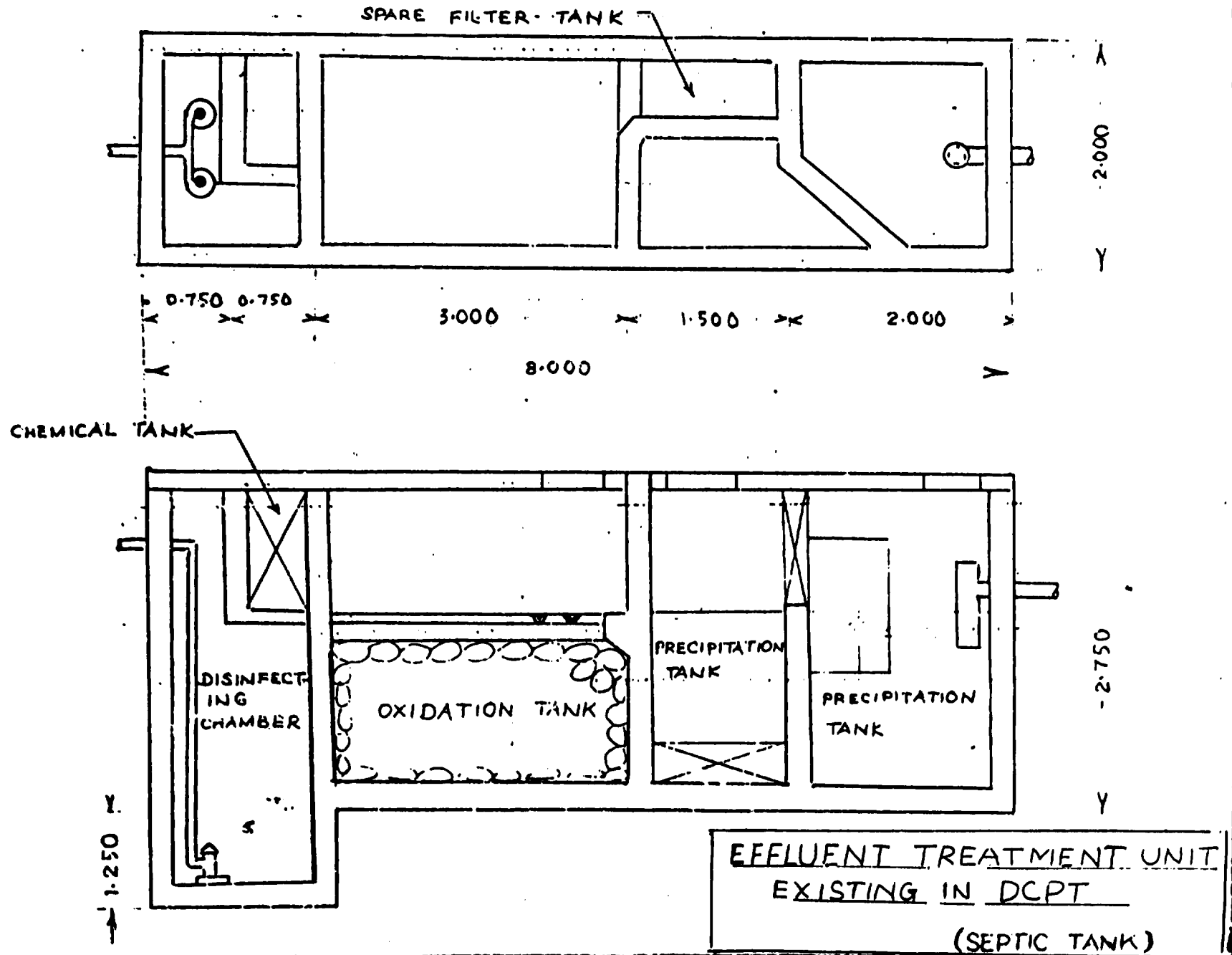
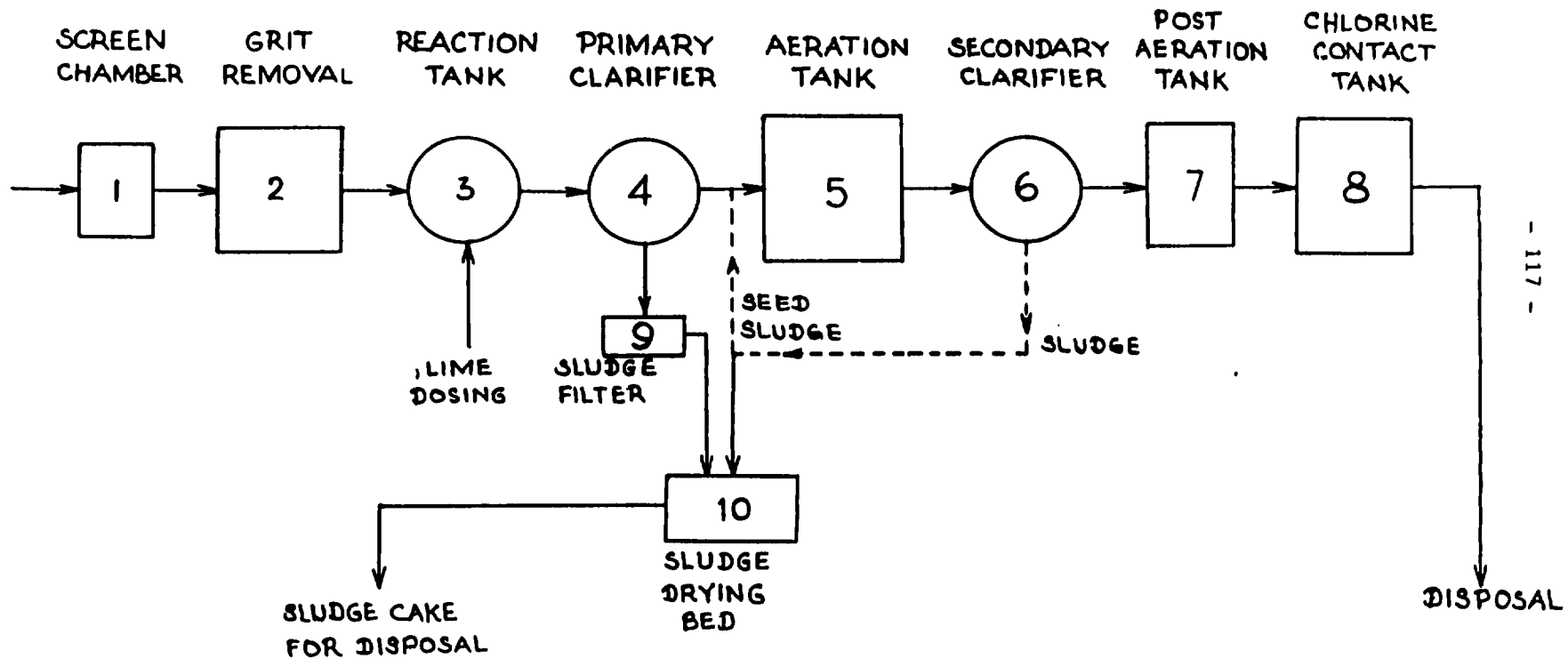


Figure VIII-8



**EFFLUENT TREATMENT AND DISPOSAL PLANT FOR FUTURE EXPANSION PLAN**

neutralized with lime slurry under air sparging for mixing. Then it is passed through clarifier to remove suspended solids by settling. From there the stream is led into aeration chamber for biological treatment of the dissolved oxygen matter before final disposal. The sludge collected can be sold as bio-fertilizer. The treated effluent can be used for irrigation of near-by fields.

It is observed the existing effluent treatment system (known as septic tank) of DCPT Yangon is very near to the proposed pilot plant. With its spare filter tank the existing septic tank should be able to take care of the effluent coming out of the plant.

Rate of effluent flow

1. One fermentor batch and wash water/30,000lits (as spent broth from solvent recovery)
2. Neutral hot water stream from 6 - APA ML distillation column/ 1,000lits per batch
3. Other miscellaneous uses like columns  
regeneration, tank washings }  
} /5,000lits  
}

Total effluent for treatment at peakload /50,000lits per day (Max.), i.e., 2083lits per hour.

This is a small quantity and hence the present set up of DCPT can take care of this effluent treatment. Specifications for treated effluent before final discharge

1. BOD Mg/lit - 30
2. COD Mg/lit - 250
3. Suspended solids Mg/lit - 30

Total solids loading per day (at peak load) - 1.5 kg.

VIII-10

TABLE VIII.7-COST OF BUILDINGS

- BASIS (1) RCC local construction cost K.4821/-per SQ.MTS including stair case liftbay.  
 (2) M.S. Doors and windows (imported) cost \$16.10 per SQ.MTS.  
 (3) Aluminum panel (imported) Cost \$52.80 per SQ.MTS.

Sr. No.	Description	Component	Cost	
			Local Kyats(K)	Imported \$
1.	<b>Production Building</b>			
(A)	Fermentation block ground floor 9 x 23 207SQ.MTS	RCC structure Doors(2) Windows(12)	997,947/	697/
	first floor 9 x 23 207SQ.MTS	RCC structure Doors(2) Windows(12)	997,947/	697/
	second floor 9 x 23 207SQ.MTS	RCC structure Doors(1) Windows(12)	997,947/	637/
(B)	Ampicillin block ground floor 8 x 8 64SQ.MTS	RCC structure Doors(1) Windows(4)	308,544/	254/
	first floor 8 x 8 64SQ.MTS	RCC structure Doors(1) Windows(4)	308,544/	254/
	second floor 8 x 8 64SQ.MTS	RCC structure Doors(1) Windows(4)	308,544/	254/
(C)	Recovery block ground floor 10 x 23 230SQ.MTS	RCC structure Doors(3) Windows(11)	1,108,830/	712/
	first floor 10 x 23 230SQ.MTS	RCC structure Doors(3) Windows(12)	1,108,830/	697/
	second floor 10 x 14 140SQ.MTS	RCC structure Doors(3) Windows(6)	674,940/	471/
(D)	Sterile area Aluminum Frames & panels Two floors 96SQ.MTS	Aluminum panels and doors 96SQ.MTS		5068/
(E)	Electric lift for raw materials fermentation block	Liftage pulley motor, and other accessories		33,334/

Sr No.	Description	Component	Cost	
			Local Rates(K)	Imported \$
2.	<b>SOLVENT RECOVERY</b> Operator cabin/control room 5 x 6 (30 SQ.MTS)	RCC structure Doors(2) Windows(4)	144,630/	314/
3.	<b>UTILITIES</b> Boiler house 8 x 8 (64 SQ.MTS) Air compressor house 8 x 8 (64 SQ.MTS) Total 128 SQ.MTS Cooling tower water	RCC structure Doors(4) Windows(6)	617,088	435
4.	<b>WATER TREATMENT AND EFFLUENT TREATMENT PLANTS</b>			
<b>TOTAL</b>			<b>7,573,791</b>	<b>43,824</b>
U.S. \$ (1 \$ = 6.52 K)			<b>1,161,624</b>	<b>43,824</b>
<b>TOTAL COST (US \$)</b>			<b>1,205,448</b>	

## VIII.II MANPOWER AND TRAINING

The requirement of manpower is shown in Annex VIII-6. As indicated therein, the figures mentioned represent the maximum personnel required for continuous production around the year. It is desirable, however, to start with about one half of the total number mentioned and increase gradually as necessary.

Since the pilot plant involves sophisticated microbiological fermentation processes, manpower training assumes great importance. Guidelines for training different categories of personnel are described below. A typical organization chart for the personnel working in the Production department in shifts round the clock is also discussed below.

Organization chart for fermentation pilot plant floor operations, from section officer to lower grades.

Section officer (Production planning and control)

FERMENTATION BLOCK

RECOVERY BLOCK

Shift supervisor

Shift supervisor

<u>Operator 1</u>	<u>Operator 2</u>	<u>Operator 3</u>	<u>Operator 4</u>	<u>Operator 5</u>
Operations	Operations	Operations	Operations	
1. Seed Vessels	1. Fermentor	on penicillin	on penicillin	Solvent
2. Media mixing	2. Sampling	recovery stream	from RA collection	recovery
3. Other	3. Rotary	up to RA collect-	to potassium	
miscellaneous	vacuum filter	ion or operations	penicillin	
jobs		Ampicillin plant	crystals or	
			operations in	
			sodium penicillin	
			(sterile area)	

For convenience floor staff from shift supervisors and below will be grouped in 4 groups and will work round the clock.

Group	Category		Helping Hand (semi-skilled)	Scientific Assistant Chemistry
	Shift Supervisor	Operator (skilled)		
A	2	5	4	1
B	2	5	4	1
C	2	5	4	1
D	2	5	4	1
<b>Total</b>	<b>8</b>	<b>20</b>	<b>16</b>	<b>4</b>

Three groups will work in three shifts while the fourth group will take weekly offs.

Shift Timings	1st shift 0600 to 1400hr	2nd shift 1400 to 2200hr	3rd shift 2200hr to 0600hr	Weekly Off
Monday	A	B	C	D
Tuesday	A	B	C	D
Wednesday	D	B	C	A
Thursday	D	B	C	A
Friday	D	A	C	B
Saturday	D	A	C	B
Sunday	D	A	B	C

- Note:
1. Each group will have to work for 6 days before taking weekly offs.
  2. The additional working days have to be compensated with an additional off after every 5 weeks.  
This can be adjusted by reducing 3rd shift man power to minimum on those days.
  3. Scientific assistant mycology can work only in 1st and 2nd shifts, when situation demands.
  4. Maintenance and instrument technicians can work in 1st and 2nd shifts, when situation demands.
  5. Plant utilities technicians will have to work round the clock along with other production staff.

#### TRAINING NEEDS FOR THE PLANT STAFF

1. Section Officer
  - a. Thorough knowledge of production unit operations and all types of equipment in section.
  - b. Production plan for the month with set targets for raw material consumption, utilities consumption and production stage wise efficiencies.
  - c. Inventory control especially w.r.t. raw materials.
  - d. Effective utilization of equipment and man power.
  - e. Strict control over operations of critical and hazardous nature.
  - f. Preparation of standard operation procedures for each unit operation with time cycles and



all inputs.

- g. Preparation of suitable batch record sheets with efficiencies standard charts and graphs.
- h. Control over man power with required human relations for better communications and understanding.
- i. Knowledge of safety requirements and aids.
- j. Section cleanliness and housekeeping.

2. Supervisor

- a. He should be trained in all above mentioned lines with special attention to his shift work planning and control.
- b. Alertness in case of interruptions such as power failures.
- c. Direct and close supervision of operations of critical nature.

3. Operator

- a. Thorough working knowledge of the operations on hand.
- b. Close follow-up of batch ticket, standard operation procedures.
- c. Adherence to standardized process time cycles.
- d. Knowledge of safety aids and safety requirements.
- e. Filling batch data, records, with relevant details.
- f. Knowledge of emergency operations to ensure safety and minimize product loss during calamities such as power failure, etc.

4. Helping Hand

- a. Clear understanding of the job he is expected to carry out.
- b. Training in use of safety aids.
- c. He should work under the guidance of operator and/or supervisor.

5. Laboratory assistant (Chemistry)

- a. Qualitative, Quantitative analysis of all samples which are the guiding factor for process controls.
- b. Required working knowledge in the use of instruments such as HPLC.

Spectrophotometer.

- c. Knowledge of specifications of all materials and products, connected with production plant.

6. Laboratory assistant (Mycology)

- a. Strain preservation and re-isolation work.
- b. Preparation of lyophilis from master culture.
- c. Preparation of inoculum, sterility testing procedures.
- d. Staining methods and identification of contaminants.
- e. Sterilization of laboratory equipment.
- f. Checking of growth parameter for advising seed transfer, checking productivity, etc.

7. Technician (Mechanical)

- a. Knowledge of maintenance requirements for all equipment.
- b. Use of proper safety aids when required.
- c. Maintenance of minimum spares needed for critical instruments.

8. Technician (Instrumentation)

- a. Required working knowledge of all instruments in section.
- b. Maintenance of minimum spares needed for critical instruments.

9. Technician (Boiler House) (Qualified boiler certificate holder)

- a. Knowledge of boiler firing, steady and peak load generation.
- b. Knowledge of flue gas analysis to ascertain proper firing (fuel to air ratio, proper working of burners) and blow down of boiler operations.
- c. Well versed in boiler shut off operations, calculations of boiler efficiency and running costs.
- d. Safety requirements.

10. Technician (Services) Chilled water, brine, compressed air and tower water.

- a. Maintenance of parameters on each working unit.
- b. Quick follow-up of standard procedures during equipment breakdown.

**VIII.12 UTILITIES**

The requirement of utilities for the pilot plant is indicated in Annex VIII.15.

**VIII.13 REQUIREMENT OF PRINCIPAL RAW MATERIALS**

The requirement of principal raw materials for the production of antibiotics in the pilot plant is shown in Annex VIII.16.

**VIII.14 COST OF PRODUCTION**

The provisional cost of different antibiotics is described in Annex VIII.17.

**VIII.15 LOCATION OF SITE FOR THE PILOT PLANT**

Since the Proposed pilot plant is complementary to DCPT and as the fermentation based pharmaceuticals produced in the Pilot Plant will primarily be used by BPI in place of the imported ones, it is desirable to locate the pilot plant in the territory of DCPT, adjacent to BPI. Furthermore, the technical personnel of DCPT will form the nucleus staff of the proposed pilot plant. The existing laboratories of DCPT will also serve the pilot plant. Similar is the case with some of the utilities such as the water circulation system. Further, there are well laid out communication system, roads and other infrastructure available at DCPT.

In view of the above advantageous factors, the possibility of locating the Pilot plant in the DCPT territory was explored in association with the DCPT authorities. There is adequate space in the south side of DCPT adjacent to fermentation section, which is at present lying vacant. In case the Government so decides, this area could be used for the location of the Pilot plant, as can be seen from Figures VIII.7 and 8. Further details for the location of various units of the Pilot plant in the above space can be worked out, when once the Project is approved and an administrative decision taken to use the vacant space at DCPT for the location of the Proposed Pilot Plant.

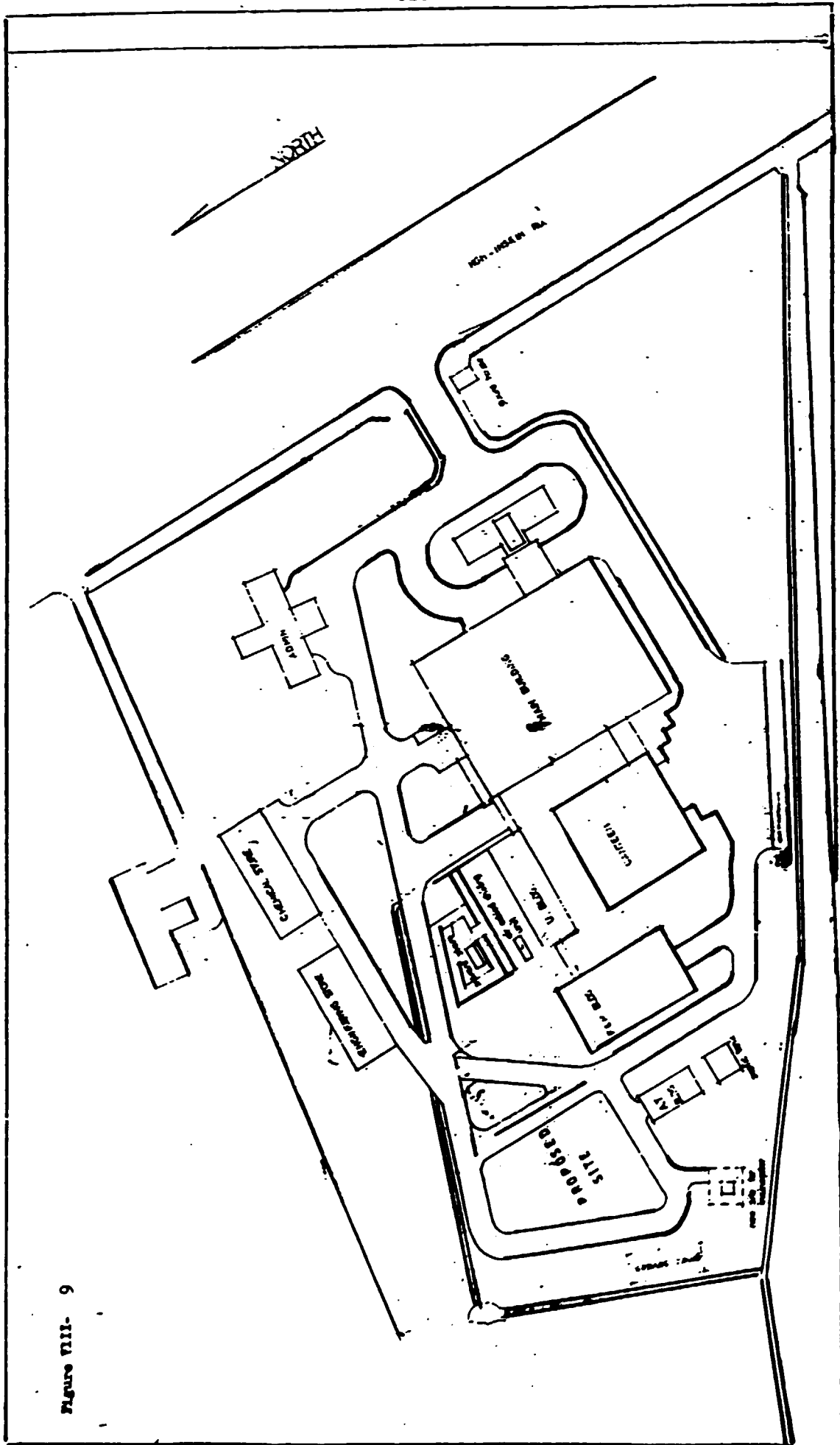
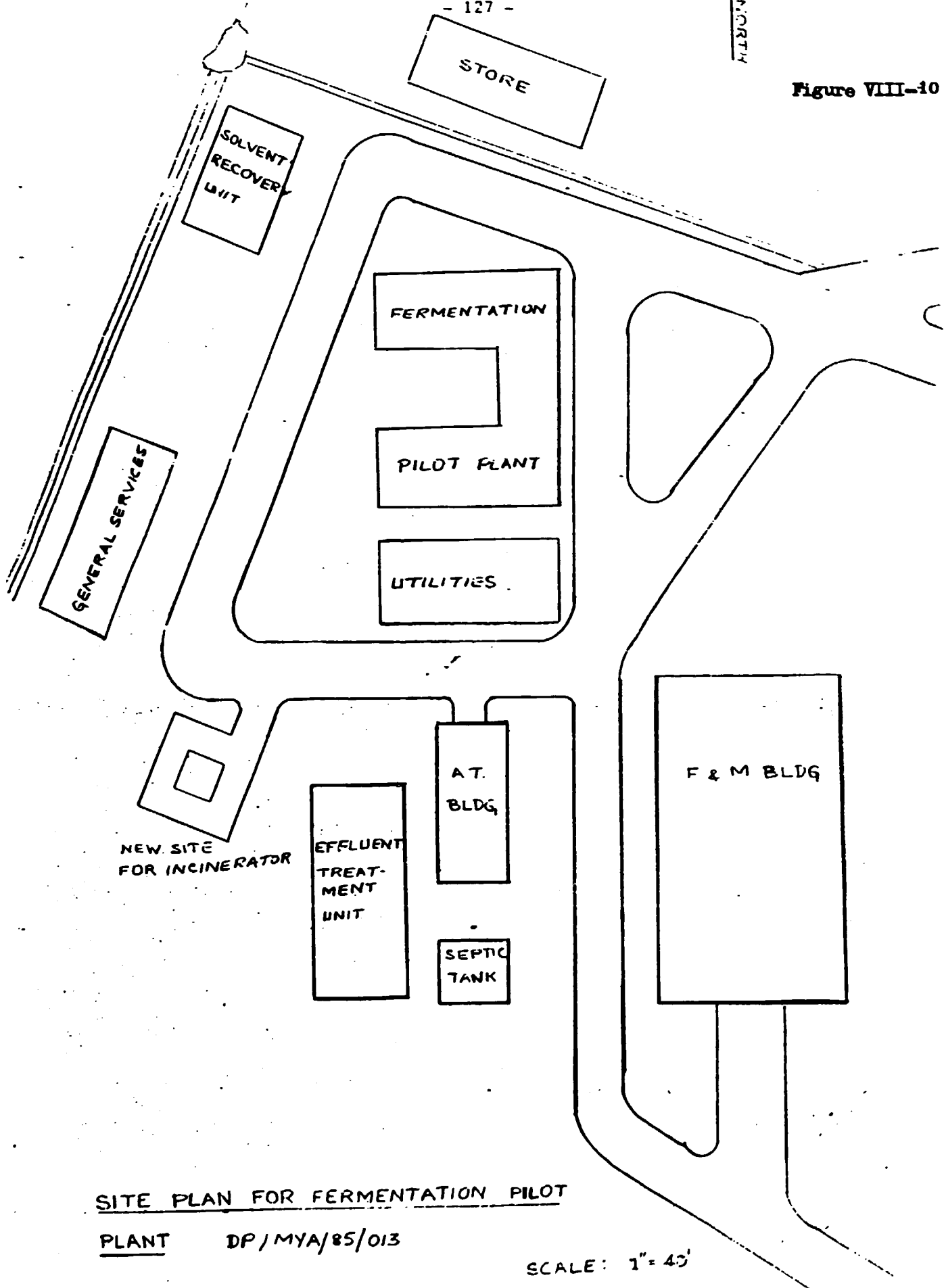


Figure VIII- 9

SITE PLAN FOR FERMENTATION PILOT PLANT

Figure VIII-10



SITE PLAN FOR FERMENTATION PILOT

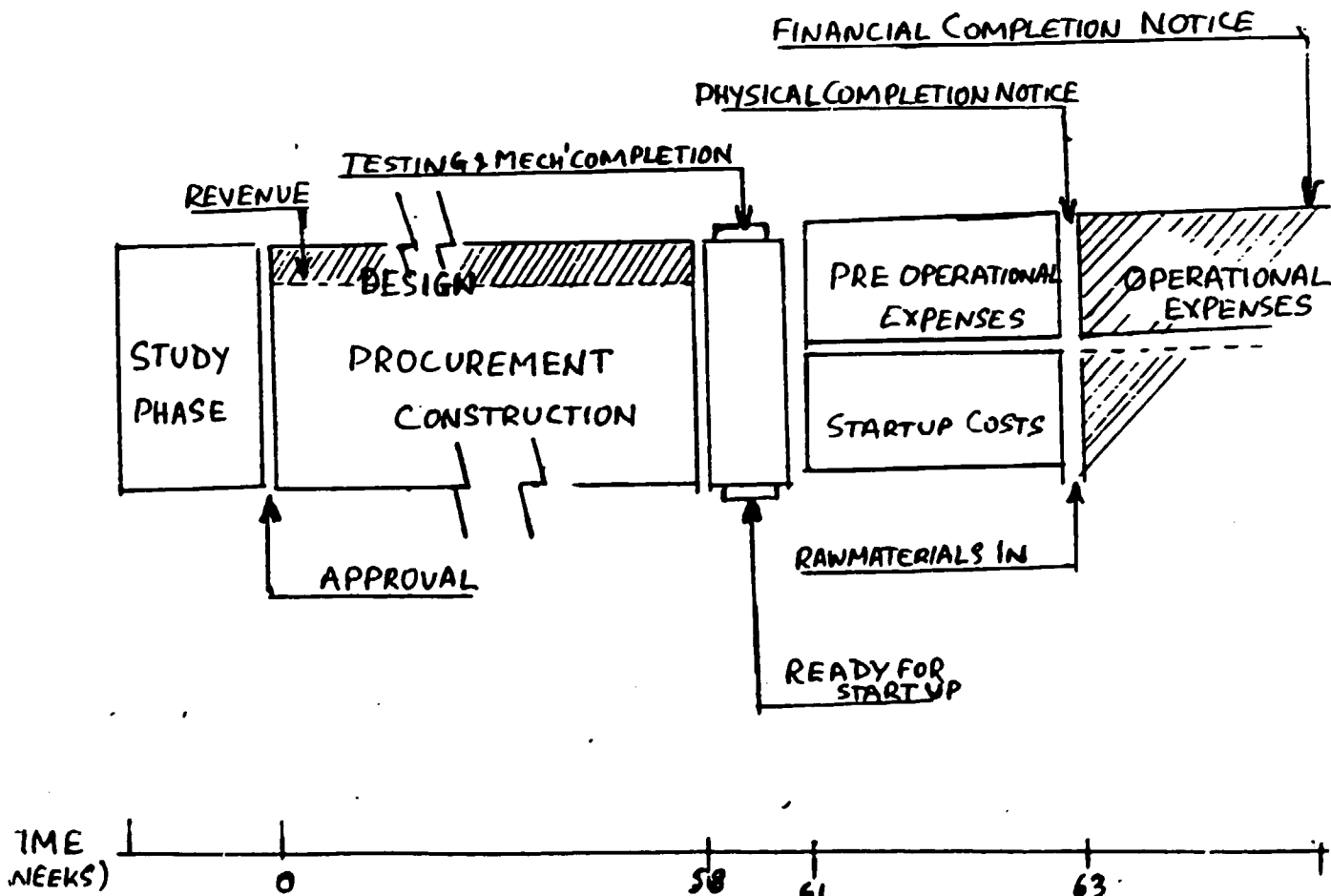
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SCALE: 1" = 40'

16. PILOT PLANT PROJECT EXECUTION

There are various stages through which a project moves from conception to operation stage. While the function stages are well defined, in the time frame there is a certain amount of over lap. Good management of the project aims at smooth movement from stage to stage, noticing the interdependence of these functions. The project engineer incharge will be totally responsible for managing the project including the Cost control factor. It is advised a task force be drawn including heads of all disciplines for effective control and close monitoring.

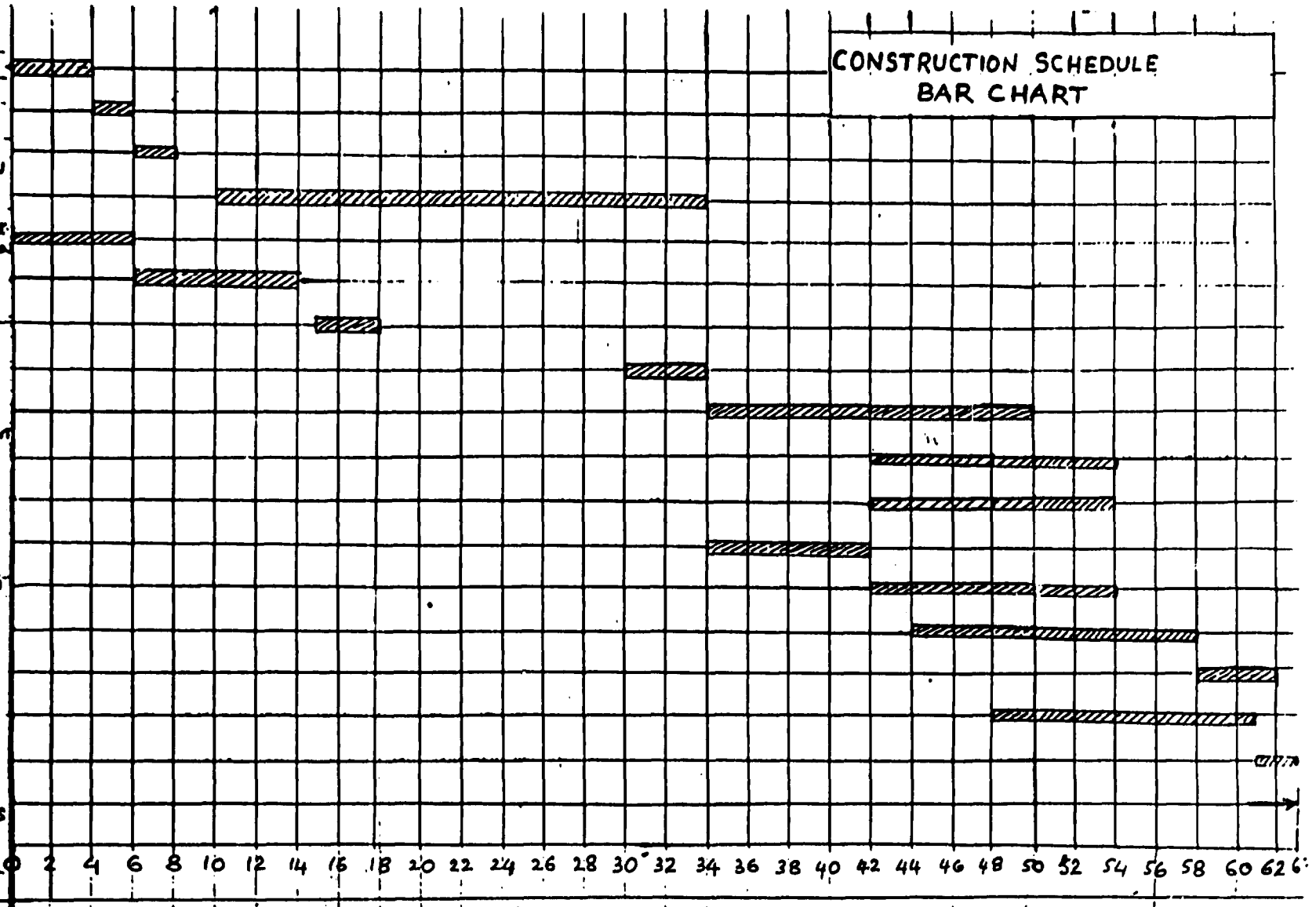
PROJECT ACTIVITIES CHART



**① MAIN BUILDINGS**

1. INVITE TENDERS FOR SELECTION OF RATE CONTRACTOR
  2. SELECTION OF RATE CONTRACTOR
  3. DECISION ON EQUIPMENT LOCATION
  4. BUILDINGS CONSTRUCTION
  5. DETAILED PROCESSING & EQUIPMENT DESIGN
  6. GLOBAL TENDERS FOR EQUIPMENT
  7. SELECTION AND ORDERING EQUIPMENT
  8. EQUIPMENT DELIVERY
  9. TESTING AND ERECTION OF EQUIPMENT
  10. INSTRUMENTATION
  11. ELECTRICAL
- ② UTILITIES**
12. CIVIL WORK
  13. ERECTION TESTING
- ③**
14. PIPING LAGGING PAINTING
  15. MECHANICAL TESTING
  16. RAW MATERIALS PROCUREMENT & TESTING
  17. WATER TRIALS
  18. REGULAR PRODUCTION RUNS

**CONSTRUCTION SCHEDULE BAR CHART**



**VII.17 PRODUCTION PLAN**

Trial production and Production plan are discussed below:

Refer to the *BARChart*. The plant can go into production in 65 weeks from the time the project is approved and funds allotted.

For any Commercial scale plant the return on investment, payout time (pay back time) are worked out to know the minimum period of pay back. For commercial viability discount cash flow is calculated. However, this pilot plant being a plant for trying new technologies and process development with a multi product mix, a production plan is worked out for the three years from the time of commissioning.

**TABLE VIII.8 PRODUCTION PLAN**

Year	Products	Yield (Kg)
First	(1) Penicillin (First 6 months one fermentor, later 6 months two fermentors in commission), yield 25000 U/ml overall efficiency 65%. Total 57 batches	12,041
	(2) Ampicillin, (input: -8028 kg penicillin) overall efficiency -72.25%	6,283
	(3) Sodium penicillin, input: -4013 Penicillin efficiency-75%	3,010
Second	(1) Penicillin 2 fermentors, yield-35000 U/ml, efficiency: -65%, 78 batches	23,068
	(2) Ampicillin, (input: -15379 kg penicillin)	12,037
	(3) Sodium penicillin, (input: -7689 kg penicillin)	5,767



It is evident from the table, conversion of total penicillin to the high cost product Ampicillin will result in better returns. This is in turn guided by two important factors (1) the technology must be good to increase yields and lower the cost of production, and (2) marketability of the product (Local and export) must be ensured to maintain minimum inventory of finished product, even when production is at its peak level.

**VIII.18 CAPITAL INVESTMENT AND MAINTENANCE COSTS**

The capital investment costs and those of routine and preventive maintenance are described below.

**Table VIII-9 Fermentation Pilot Plant-Total Investment**

Sr. No	Item	Cost		Total Cost in US \$ at conversion rate 1 US \$=6.52 K Z
		Local (K)	Imported (US \$)	
1.	Production Buildings (including Solvent recovery control room and electrical lift)	6,956,703	43,389	1,110,368
2.	Production equipment		1,077,320	1,077,320
3.	Utilities buildings	617,088	435	95,080
4.	Utilities equipment with instrumentation		898,070	898,070
5.	Instrumentation (5% of equipment cost)		53,866	53,866
6.	Electrical wiring with explosion proof and ordinary fittings as per requirement (5% equipment cost)		53,866	53,866
<b>TOTAL</b>		<b>7,573,791</b>	<b>2,126,946</b>	<b>3,288,570</b>

Costs of Routine and Preventive Maintenance

The plant equipment is categorized as critical and non-critical equipment.

---

Third	(1) Penicillin 2 fermentors, yield-55000 U/ml	39,039
	efficiency: -70%, 78 batches	
	(2) Ampicillin (input:-26026 kg penicillin)	20,864
	overall efficiency: -74%	
	(3) Sodium penicillin (input:-15013 kg penicillin)	10,020
	overall efficiency:-77%	

---

The following table gives interesting details on 'pay back' on a product mis.

Basis:	Cost of penicillin	\$30 per kg
	Cost of Ampicillin	\$90 per kg
	Cost of Sod. penicillin	\$50 per kg

---

		Product Cost in \$		
		1st year	2nd year	3rd year
A.	If all penicillin produced is sold directly	361,230	692,000	1,171,170
B.	If 66.6% penicillin is converted to Ampicillin and 33.3% to Sodium penicillin	715,970	1,371,680	2,378,760
C.	If all penicillin is converted to Ampicillin	848,204	1,624,979	2,816,675

---

The spares needed for all rotating parts such as bearings, seals packings sleeves proper nuts and bolts. special and ordinary grease. lubricating oil of the grades required for machinery must be kept in readiness to avoid time and production loss.

The corrosive liquid tanks and lines corrode faster. Frequency of repair occurrence must be examined to check the needs and to take further remedial actions which will extend the life of equipment.

A new plant with all its equipment new and in condition require minimum maintenance. The maintenance expenditure is likely to increase to a level of 4% equipment cost and beyond from 3rd year. Preventive maintenance will help reduce the break down maintenance costs and production losses. Preventive maintenance schedules must be drawn and adhered to strictly. However, a balance has to be maintained while drawing preventive maintenance schedules as over maintenance often proved to be uneconomical and nonproductive.

#### VIII.19 JUSTIFICATION FOR PARALLEL DIRECT POWER LINE

When the production work is in full-swing following process equipment will be in commission at any given time.

(1) Seed vessels, (2) Fermentors, (3) 6-APA or Ampicillin reactor, (4) Sodium penicillin (sterile product) distillation still and (5) Minimum one solvent distillation still. Total power failure can result in huge production and monetary loss, as the damage caused to the product in process is irreversible. A very huge generator with very high capital investment, high running and maintenance costs, will be uneconomical as it lies idle most of the time.

It is observed the power failures extending over a considerable period of time are not uncommon. In view of this it is recommended to have a parallel direct power line from a different main power generation source. Declaration of DCPT pilot plant production as "Essential services unit" should help in meeting the requirements.

## VIII.20 SAFETY REQUIREMENTS

### PLANT SAFETY AND FIRE PROTECTION

1. Design of structures and equipment must be calculated with full awareness and careful assessment of special situations and risk involved.
2. Equipment and individual items must be examined not only for normal service but also for emergency demands.
3. Reliable automatic safety devices such as pressure safety valves must be provided.
4. Operators must have necessary training and standard operating instructions must be clear. Operators must be fully aware of the potential situations for which safety depends on their alertness.
5. Means to delay the penetration of heat such as "Quick closing metallic flame proof fire safety doors" for isolating the area under fire, must be installed for preventing spread of fire.
6. Corrosive harmful materials storage tanks should have 'dike wall' to retain the accidental release or leakages (Volume of the largest tank + 10% volume of the remaining tanks in dike).
7. Equipment within processes units should be located with due consideration to potential hazard.
8. Explosions of flammable materials may occur as a result of minor spark discharge of STA ELECTRICITY. To protect against hazard due to static electricity (a) Metal parts of vessels and connecting pipes should be electrically grounded and the use of air for mixing flammable liquid should be restricted or avoided, (b) Tank trucks for flammable liquids and their filling connections must be grounded, (c) Steam air and water hoses used in areas where inflammable materials are present must be grounded.
9. TO ENTER A PROCESS TANK FOR CHECK UP OR MAINTENANCE
  - A. Purge process material completely.
  - B. Provide adequate oxygen.
  - C. Switch off mains of agitator or other electrical equipment connected with process tank.
  - D. Isolate in coming and out going process lines on the vessel.
  - E. Provide safety gas mask and life belt.

10. Provide suitable GUARDS for all rotating equipment.

11. FIRE PROTECTION

A. Identify the fire extinguishing needed for the particular area (carbondioxide/dry chemicals/ chemical foam/mechanical foam, etc).

Keep in readiness and within easy reach.

12. Housekeeping of process plants will often reflect the general presence or absence of safety hazards. As a rule a well kept plant is usually a safe plant.

## FINANCIAL AND ECONOMIC ANALYSIS

### Chapter I. Financial Analysis

#### 1. Introduction

##### 1.1 Objectives

The objectives of the proposed pilot plant are listed on p.91 of the main report. None of these objectives refers to financial feasibility, and indeed on p.93 reference to major producers and their economies of scale leads to the statement that "the economic feasibility of commercial production can be ruled out". The focus is therefore on the economic and social aspects of the project, i.e. the introduction of technology and training, evaluation of local resources, and the provision of a reliable domestic source of products of acceptable quality. This does not detract from the importance of establishing a financial analysis of the project to determine the capital commitment required and the extent to which it may be able to cover its costs; but it does emphasise that the financial return should not be the sole or even the main criterion by which the project should be assessed.

##### 1.2 Product Selection

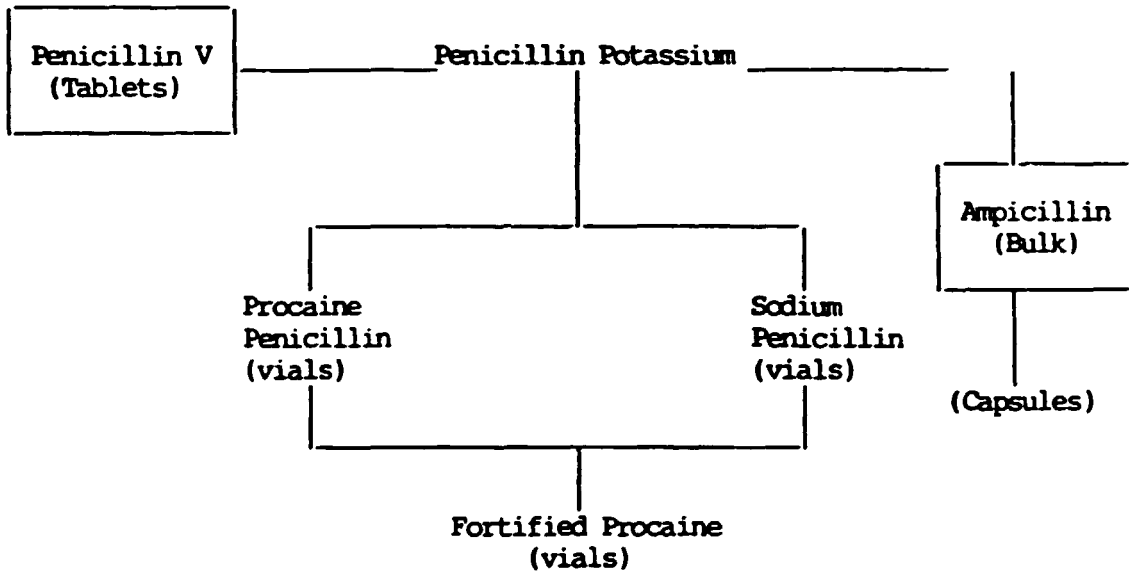
Demand for pharmaceuticals in Myanmar has been analysed in detail in Section III-3 of the main report, and estimates of projected demand combined with considerations of minimum economic size have been taken into account in Section VII-3. These considerations are the basis for the product selection.

Although it is possible to produce a wide variety of products in the pilot plant, and some flexibility of production

will be desirable to meet national needs and to provide for experimentation, the two products which have been selected as a basis for the Study are Penicillin V and Ampicillin, for which there is a basic demand, and which offer a basis for determining the costs and benefits of the study. To assume the production of a wider variety of products entails allowing for production delays while cleaning takes place to avoid product contamination, and results in appreciably higher production costs. The selection of two products therefore simplifies the production process and provides a better indication of the potential returns of the project.

It is assumed that Penicillin V will be produced in tablet form for packaging by BPI and Ampicillin will be produced in bulk for further processing by BPI.

### PRODUCT SELECTION



### 1.3 Product Pricing

The demand analysis is also the basis of the projected output of penicillin and ampicillin on which the financial projections have been made, and for the economic analysis. It also provides the background for the price estimates on which the feasibility is calculated.

The main Report concludes that substantial unsatisfied demand exists for pharmaceutical products in the domestic market, and that this is exaggerated by erratic supplies through formal channels due to Forex problems. Pharmaceutical products are imported illegally and are of variable and doubtful quality. High prices are paid in the market for the more reputable products both domestic and imported. The mark-up on BPI products by the Trade Corporation is shown in Tables D and E, and a comparison of official and unofficial prices is shown in Table E, from which it appears that there is a considerable disparity between the Government (BPI) and unofficial prices. Questions concerning the current systems of pricing were described by officials as related to Government policy and therefore inadmissible, and they were not prepared to comment. Why this should be so was not clear, but it would be useful to the project to know what is the basis for the present pricing system and whether it is likely to continue. Price is a prime determinant of feasibility, and from available information a variety of pricing possibilities present themselves which are summarized in Table C.

Historic prices of imported product plus transport insurance and duties suggest "landed" costs of Penicillin V = K312 per kg and Ampicillin = K856 per kg. These prices appear to be



realistic in view of the almost identical prices supplied by BPI through DCPT which DCPT notified by Telex in April 1990.

However, according to the detailed costings obtained from BPI the costs used for the imported "landed" penicillin are K456 per kg and ampicillin K1266 per kg. The reason for this difference is not known. These costs are used to calculate prices charged by BPI and are those illustrated in Table E, i.e. Penicillin @ K0.425 and Ampicillin K0.635 per tablet packaged. But these are not the prices which apply in the market. These products are supplied to the Trade Corporation for sale, and substantially higher prices are then charged (Table D). If the prices of the packaged products are calculated overall, there is an increase of approximately 50% in the Trade Corporation's prices over those at which it is supplied by BPI. Applying an increase of approximately 50% to prices charged by BPI suggests official prices in the market of K684 per kg of penicillin V and K1899 per kg of ampicillin. At these prices substantial profits would be made, though a proportion of BPI's products are distributed free of charge through hospitals and clinics so that it is not clear at what average price the products become profitable. What is evident from Table E is that there is a shortage of product, and the prices for BPI products in the market are very much higher than the official prices, even when enhanced by the margins imposed by the Trade Corporation. It is unclear to what extent an increase in supply would affect market prices, but it may be assumed that it would be an acceptable objective of the project to reduce unofficial prices and if possible eliminate sales of unreliable material.

Although the use of cif prices is appropriate for economic analysis, major world producers are able to manipulate prices to an extent that it is difficult to determine what a world equilibrium price, if any, should be. While this manipulation could result in a high degree of uncertainty the improvements in technology and increasingly large scale production have resulted in the prices of penicillin and ampicillin being relatively stable over the past ten years (Annex VIII-12). There is no guarantee that cif prices of these products will remain consistent in future, but the reasons for their past stability suggests that they are unlikely to change appreciably over the life of the project. This situation also suggests that as mentioned in the main part of the report, no direct competition is possible on price with the major international suppliers.

A decision on the prices to be used for the products is crucial in determining the degree of financial feasibility or otherwise of the project.

Ampicillin would be supplied by the project to BPI in bulk containers for tableting and packaging by BPI. The price that could be charged by the project would not be a retail price, but an intermediate price related to what BPI is paying for imports. When import prices are quoted independently (Table C (1) and (2)), they do not correspond with the price shown in detailed costs provided by BPI (Table B), and are substantially less. If the foreign cost element in Table B is adopted it results in substantial profit for the project. The cost of Ampicillin to BPI in Table B is approximately K1266 per kg. Using this as the price to be charged by the project produces a substantial profit,

so a compromise of K1000 per kg is used which is just less than half the difference between what BPI indicate that they pay for imported material, and the cost they attribute to the same material in their cost details (Table B). This is compared to the use of the landed cost of imported material.

The proposal to develop indigenous raw materials to substitute for imports would result in cost reductions. However although an indication is given in the main report p.89, that up to 23% of raw materials are agro based and could be available locally, it would be difficult to predict the speed at which these materials could be developed and introduced into the project. It has been assumed that 5% by value could be introduced in year 4, 15% in year 5, and the full 23% thereafter. This substitution, has not been shown in Table J because it is not possible to anticipate the cost at which these materials could be introduced. However, if it is assumed that the indigenous materials cost very little, (and no cost is attributed to them), the difference in the return of 6% in Table K(1) would only be an additional 1%, but a 7% return under these circumstances would be creditable. The impact of the substitution of indigenous materials is of course much greater in the economic analysis.

Penicillin V tablets would be supplied to BPI for packaging only. The costs in Table A do not provide the detail necessary to isolate the packaging only costs, and although it was suggested by BPI that they would expect to pay K35.50 per 100 tablets, this would not permit them any margin as they appear to sell on at this price (Tables D and E). Two prices have therefore been used, K35 and K30 per 100 tablets. Both prices

produce attractive returns to the project. As the cost of packaging 100 tablets costs proportionality less than packaging 20, the difference of K5 should adequately cover the additional costs. However if this margin is not considered sufficient the returns available would permit a further reduction in price to the project.

#### 1.4 Data Sources

Manning levels, product selection and production levels, conversion factors and some costs have been drawn from the main report, particularly Annex VIII and the cost of new building, plant and equipment is taken from the Technical Report. Most of the cost data has been obtained from BPI by the counterpart staff of DPTC, who also provided the breakdown of data for the tableting department.

#### 1.5 Inflation

The change in Government policy in the period 1987/88-1988/89 resulted in a sudden upsurge in prices which may be regarded as abnormal. This does not provide guidance for the continuing situation for the next 5 years. The prices of imported raw materials have been stable over a long period, and for reasons already given there is no reason to assume that this will change. The materials to be purchased locally will be in relatively small quantities, and labour, administration and utilities costs will remain the main domestic costs. It is assumed that these costs will remain approximately in line with changes in domestic prices generally, and with changes in the prices of the product.

## 1.6 Risk and Sensitivity

### 1.6.1 Management

In view of the development work which the project is intended to provide, it is important that management should be sufficiently motivated to carry out the trials of new materials and have the flexibility to produce a variety of products. The delay and contamination problems created by a flexible multi-product operation will require a high level of efficiency which in turn will require management capable of responding to the challenge. Consideration should be given to providing appropriate incentives plus the introduction of monitoring controls.

### 1.6.2 Raw Materials and Products

Imported raw materials are expected to remain accessible at stable prices, in view of the record of the past 10 years, and similarly the products are expected to remain in demand at prices which will continue to be managed at levels appropriate to the costs of production.

Current uncertainty concerning domestic product prices has been allowed for by varying the price of Ampicillin from K600 per kg, K860 per kg and K1000 per kg to produce an IRR of 6% at K860 per kg and 11% at K1000 per kg. For Penicillin V 100 tablets priced at K35 and K30 give IRRs of 38% and 31% respectively.

A change in capital cost for Ampicillin has been considered with an increase of 10% only, in view of the 11% return (Table K(2)) and this results in a fall of 1%, to 10%. There is more scope to consider capital cost increases in the production of Penicillin V, and an increase of 30% produces a return of 30%

down 8%. This suggests that even if the capital costs escalate substantially, the project would be financially feasible.

Although feasibility is indicated particularly in the production of Penicillin V tablets it would be misleading to base calculations of break-even on these figures, because the intention is clearly to produce a variety of products, necessitating stoppages for changeover and decontamination. Where financial viability might be affected it should be compensated for by managing the product mix to provide higher value products.

**Table A Penicillin V 100 Tablet Bottle**  
(250 mg tablets)

K

Foreign	11.46
Packing material	)
Direct Labour	)
V/C	)
F/C	)
Admin. Cost	)
Distribution selling	) <u>19.28</u>
Total Cost	<u>30.74</u>
Profit 10%	<u>3.07</u>
Ex Factory Cost	33.81
Turnover Tax 5%	<u>1.69</u>
	<u>35.50</u>
	=====

**Table B Ampicillin 100 Capsule Bottle**  
(250 mg capsules)

K

Foreign	31.65
Packing material	)
Direct Labour	)
V/C	)
F/C	)
Adm. Exp.	)
Dis. sell.	) <u>23.33</u>
	<u>54.98</u>
10% profit	<u>5.50</u>
Ex Factory Cost	60.48
5% Commodity Fee	<u>3.02</u>
	<u>63.50</u>

SOURCE: BPI, 1989.

Table C Penicillin-Ampicillin Prices per Kg

	<u>Penicillin \$ K</u>		<u>Ampicillin \$ K</u>	
(1) BPI 1989 App.VII-12 (Penicillin B Potassium)			(Ampicillin Compound)	
FOB	29.64	190	81.20	520
CIF (+ 16%)		220		603
Landed (+ 42%)		312		856
(2) BPI (DCPT Telex) 1990				
CIF	34.41	220	94.27	603
Landed (+ 42%)	48.91	313	133.98	857
(3) BPI 1989 Detailed Accounts, Tables A + B. These prices refer to the cost of foreign product which includes "other chemicals"		456		1266
(4) Prices used Table J				
CIF				600
Landed				860
Adjusted from (3) above (Table B)				1000
(5) Price used in Table L note 14		35 per 100		



Table D Distribution and Pricing

Prices in K per tablet packed.

		0.51 (100s)		
		0.65 (20s)		
	Trade Corpn.		Medical	private
		2.00 (16s)	retail shops	practitioners
		0.97 (100s)		(prescriptions can
				be given for govt.
				clinics)
Penicillin V	0.425 (20s)			
	0.355 (100s)			
BPI				
		<sup>1</sup> CMSD	Civil Hospital &	
			Govt. Clinics	
Ampicillin	1.294 (16s)			
	0.635 (100s)			
	0.675 (500s)			
		<sup>2</sup> AMSOD	Military Hospital	

1. CMSD - Central Medical Stores Dept.
2. AMSOD - Army Medical Stores Dept.  
(Ref. p.37 Report)

**Table E Domestic Market Prices**  
(K per 250 mg packed)

Official Prices

	<u>Penicillin V</u>	<u>Ampicillin</u>
BPI	0.425 (20s) 0.355 (100s)	1.294 (16s) 0.635 (100s)
Trade Corpn.	0.510 (100s) 0.650 (20s)	2.000 (16s) 0.970 (100s)
UNICEF	FREE	FREE

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Unofficial Prices

BPI	2.000 (20s)	4.5 (16s)
Chinese	0.500 (20s)	2.0 (16s)
Thai	0.400 (20s)	
UNICEF	1.400 (20s)	2.0 (16s)
Bangladesh	-	1.5
Japanese	-	4.0
German (Helm AG)	-	3.0
Italian (Bayer)	-	2.5

Table F Proposed Manning and Labour Costs

	Production	Utilities	Laboratories	Admin	Miscellaneous	Rate per month	Total per month	Total Annually
1. Manager				1		1300	1300	15,600
2. Supervisor (Asst.Mgr)	1	1	1	1		1250	5000	60,000
3. Shift Supervisor (graduate)	4	4	4	2	2	1125	18000	216,000
4. Shift Technician (Charge Hand)	16	8	-	4	3	1000	31000	372,000
5. Skilled Worker (Grade 1)	4	-	2	-	-	875	5250	63,000
6. Semiskilled Worker (Grade 3)	4	4			4	750	9000	108,000
								834,600
Employers Social Contribution						5.2	364	4,368

- Note: i) Staff requirements from Annex VIII-6  
 ii) For purposes of calculating wages it is assumed that the whole staff complement will be employed throughout, because although there will be a production build-up over 3 years, an essential objective is training.

Table G Duties and Taxes (%)

	Pharmaceuticals and Chemicals	Machinery	Parts	Mild Steel	Stainless	Electrical	Air Cond.
FOB and Freight	15						
Insurance	1						
CIF and Customs	15	15	15	15	75	15	100
Commodity Tax	5	15	30	30	20	30	60
Licence Fees	5						
Port Duties	2						
Bank charges	0.5						
Transport and Handling	3						

Business Taxes

Turnover Tax	5
Profits Tax )	
State Contribution)	30

Source: BPI documents and DCPT procurement dept.

Although the above figures were officially quoted, the difference between the cif and landed cost of penicillin and ampicillin appears to be 42%. This amount has been used to apply to the costs of imports in Table J, 2. 11. 13. (from App.VIII-8 + 11).

Although the Foreign Investment Law of 1988 gives tax exemptions on equipment and materials imported by foreign investors, it is understood that the project would not benefit from this concession. However, this would almost certainly depend on the main source of finance, and taxes have not been added to the estimated capital cost.

It would be expected that the project would not declare profits.

**Table H Capital Costs - Ampicillin (000s K)**

Year	1	2	3
Buildings domestic	7,574	-	-
imported	280	-	-
Plant domestic	-	-	-
imported	6,666	6,666	-
	14,520	6,666	-

Depreciation

Building domestic	114	114	114
imported	4	4	4
Plant domestic	-	-	-
imported	500	1,000	1,000
	618	1,118	1,118

1. No duties have been added to imports.
2. Imports are converted @ K6.4 = \$1
3. Depreciation is assumed to begin in year 3, year 1 of operation.

Depreciation buildings 1.5%  
Plant and equipment 7.5%

Penicillin V (000's K)

Year 6

Equipment imported 10,000

4. Depreciation is assumed to begin in year 6.

**Table I Working Capital - Ampicillin/Penicillin V**

	Year	3	4	5	6
1. <u>Work in progress</u>		505147	655104	846424	-
12 days fermentation					
3 days stage 1					
3 days final product					
24 days quality control					
40 days total operation					
of 305 p.a.(production					
costs less depreciation)					
2. <u>Stocks of finished products</u>		-	-	-	-
These are distributed immediately.					
3. <u>Stocks of raw materials</u>		1057102	1586157	2114204	-
Table J 2 + 13. Half year supply.					
4. <u>Stores and spare parts</u>		-	-	-	383280
These are included in the new equipment cost (13331980) to year 5. After which 4% of equipment cost is held less the 150,000 allowance made in Table J (13,181,980)					
<b>Annual Total</b>		<b>1562249</b>	<b>2241261</b>	<b>2960628</b>	<b>383280</b>
<b>Working Capital Requirement</b>		<b>1562249 + 679012 + 719367 + 383280</b>			
<b>Accumulated Total</b>					<b>3343908</b>

There are no debtors or creditors.

It is assumed that the working capital for Penicillin V will be the same. This will overstate the cost of Penicillin V. A charge of 4% for spares is also included in the P&L A/c under maintenance and spares from year 8, plus 1% charged to domestic costs. No addition is made to working capital under this heading.

Table J Ampicillin Profit and Loss - Alternative II Strain 2 (35000 V/ml)

Year	3		4		5		6		7		8	
	Dom.	Import	Dom.	Import	Dom.	Import	Dom.	Import	Dom.	Import	Dom.	Import
1. Production - Penicillin (kgs)	8,040		12,060		16,080		16,080		16,080		16,080	
Costs in K												
2. Raw Materials (imports) and duties (dom)	299,752	713,695	449,628	1,070,542	599,503	1,427,389	599,503	1,427,389	599,503	1,427,389	599,503	1,427,389
3. Labour	834,600	-	834,600	-	834,600	-	834,600	-	834,600	-	834,600	-
4. Social benefit	4,370	-	4,370	-	4,370	-	4,370	-	4,370	-	4,370	-
5. Utilities including fuel	74,610	-	111,920	-	149,220	-	149,220	-	149,220	-	149,220	-
6. Administration	472,900	-	472,900	-	472,900	-	472,900	-	472,900	-	472,900	-
7. Maintenance & Repairs	-	-	-	-	150,000	150,000	150,000	150,000	150,000	150,000	150,000	150,000
8. Insurance	184,320	-	184,320	-	184,320	-	184,320	-	184,320	-	184,320	-
9. Depreciation	113,607	1,004,105	113,607	1,004,105	113,607	1,004,105	113,607	1,004,105	113,607	1,004,105	113,607	1,004,105
	1,984,159	1,717,800	2,171,345	2,074,647	2,508,520	2,581,494	2,508,520	2,581,494	2,508,520	2,581,494	2,508,520	2,581,494
Cost of Penicillin production	3,701,959		4,245,992		5,090,014		5,090,014		5,090,014		5,090,014	
10. Equivalent Output Ampicillin (kgs)	5,470		8,210		10,940		10,940		10,940		10,940	
11. Packaging (bulk containers) + duties	10,505	25,013	5,283	12,530	5,243	12,483	-	-	-	-	-	-
12. Utilities	131,220	-	196,950	-	262,440	-	262,440	-	262,440	-	262,440	-
13. Chemicals & Duties	325,576	775,182	488,662	1,163,482	651,153	1,550,384	651,153	1,550,384	651,153	1,550,384	651,153	1,550,384
	467,301	800,195	690,875	1,176,012	918,838	1,562,847	913,593	1,550,384	913,593	1,550,384	913,593	1,550,384
Cost of Ampicillin production	1,267,499		1,866,887		2,461,663		2,463,957		2,463,957		2,463,957	
14. Total Cost Ampicillin Production	4,969,455		6,112,879		7,571,697		7,553,971		7,553,971		7,553,971	
15. (1) Revenue @ world price cif (K600)	3,282,000		4,926,000		6,564,000		6,564,000		6,564,000		6,564,000	
(2) Revenue @ cif price including duties (K860)	4,704,200		7,060,600		9,408,400		9,408,400		9,408,400		9,408,400	
(Gross Surplus 15 (2)-14	(	(265,255)		947,721		1,838,703		1,854,429		1,854,429		1,854,429
(Depreciation added back	(	1,117,712		1,117,712		1,117,712		1,117,712		1,117,712		1,117,712
(Pre depreciation surplus	(	852,457		2,065,433		2,954,415		2,972,141		2,972,141		2,972,141
(3) Revenue @ BPI price K1000 per kg	5,470,000		8,210,000		10,940,000		10,940,000		10,940,000		10,940,000	
Gross Surplus 15(3)-14	500,545		2,097,121		3,368,303		3,386,029		3,386,029		3,386,029	
Pre-depreciation Surplus	1,618,257		3,214,833		4,486,015		4,503,741		4,503,741		4,503,741	

Notes to Table J

1. Annex VIII-10
2. Annex VIII-11. \$13.87 per kg. An additional 42% has been added for duties. DCPT telex April 1990.
3. Annex VIII-6.
4. Annex VIII-6.
5. Annex VIII-11 \$1.45 per kg.
6. Estimate based on 25% of DCPT overheads net of labour.
7. These costs are included in new equipment costs for years 1 and 2; with K300,000, half domestic half imported in subsequent years. Additional spare parts are allowed in the working capital.
8. At K0.87 per K100 assets. Quote from State Insurance Corporation.
9. Ref. Table H.
10. Annex VIII-10.
11. Annex VIII-8. It is assumed that this packaging will be aluminium containers, re-usable for the project's life in 6 monthly cycles.
12. Annex VIII-8, 9.
13. Annex VIII-8 \$22.143 per kg. An additional 42% duties.
15. Annex VIII-12; and Table C.
16. No substitution of indigenous raw materials has been included.



Table K(1) Cash Flow - Ampicillin (K 000s)

	1	2	3	4	5	6	7	8	9	10	11	12
1. Revenue	-	-	852	2,065	2,954	2,372	2,972	2,972	2,972	2,972	2,972	2,972
2. Residual Capital												10,006
3. Balance		(15,032)	(22,697)	(23,908)	(22,522)	(20,287)	(17,842)	(14,870)	(11,898)	(8,926)	(5,954)	(2,982)
4. Total Inflow	-	(15,032)	(21,845)	(21,843)	(19,568)	(17,315)	(14,870)	(11,898)	(8,926)	(5,954)	(2,982)	9,996
5. Buildings	7,854											
6. Plant and equipment	6,666	6,666										
7. Expatriates and Training	512	999	501									
3. Working capital			1,562	679	719	527						(3,344)
9. Total outflow	15,032	7,665	2,063	679	719	517	-	-	-	-	-	(3,344)
10. Cash Flow	(15,032)	(22,697)	(23,908)	(22,522)	(20,287)	(17,842)	(14,870)	(11,898)	(8,926)	(5,954)	(2,982)	13,340

Note: No assumptions have been made about financing. The cash flow is .'. indicative of funds required.  
IRR = 6%

1. Table J Based on the price of K860 per kg. 15 (2)
2. Table N.
5. Table H.
6. Table H.
7. Table O.
8. Table I.

Table K(2) Cash Flow - Ampicillin (K 000s)

	1	2	3	4	5	6	7	8	9	10	11	12
1. Revenue	-	-	1618	3215	4486	4504	4504	4504	4504	4504	4504	4504
2. Residual Capital		-										10006
3. Balance		(15032)	(22697)	(23142)	(20606)	(16839)	(12862)	(8358)	(3854)	650	5154	9658
4. Total Inflow		(15032)	(21079)	(19927)	(16120)	(12335)	(8358)	(3854)	650	5154	9658	24168
5. Buildings	7854											
6. Plant & Equipment	6666	6666										
7. Expatriates & Training	512	999	501									
8. Working Capital		-	1562	679	719	527						(3344)
9. Total Outflow	15032	7665	2063	679	719	527						(3344)
10. Cash Flow	(15032)	(22697)	(23142)	(20606)	(16839)	(12862)	(8358)	(3854)	650	5154	9658	27512

Note: No assumptions have been made about financing. The cash flow is .'. indicative of the funds required.

IRR = 11.0%.

1. Table J. Based on the price of K1000 per kg. 15(3)
2. Table N.
5. Table H.
6. Table H.
7. Table O.
8. Table I.

Table L Penicillin V - Tablets - Profit and Loss Account

Years	3		4		5		6		7		8	
	Dom.	Import	Dom.	Import	Dom.	Import	Dom.	Import	Dom.	Import	Dom.	Import
1. Production Pen. V. kg.	8,040		12,060		16,080		16,080		16,080		16,080	
2. Production Pen.V. Tablets kg.	7,799		11,698		15,598		15,598		15,598		15,598	
3. Production Cost Pen.V.	1,984,159	1,717,800	2,171,345	2,074,647	2,508,520	2,581,494	2,508,520	2,581,494	2,508,520	2,581,494	2,508,520	2,581,494
4. Total Production Cost Pen.V.	3,701,959		4,245,992		5,090,014		5,090,014		5,090,014		5,090,014	
5. COSTS TABLET DEPT.												
6. Labour	233,400		233,400		233,400		233,400		233,400		233,400	
7. Social Security	1,370		1,370		1,370		1,370		1,370		1,370	
8. Utilities	271,640		407,460		543,300		543,300		543,300		543,300	
9. Maintenance and repair	25,000	400,000	25,000	400,000	25,000	400,000	-	-	-	-	100,000	400,000
10. Admin. including insurance	100,000		100,000		100,000		100,000		100,000		100,000	
11. Depreciation	-	-	-	-	-	-	750,000		750,000		750,000	
	631,410	400,000	767,230	400,000	903,070	400,000	878,070	750,000	878,070	750,000	978,070	1,150,000
12.	1,031,410		1,167,230		1,303,070		1,628,070		1,628,070		2,128,070	
13. Total Production Cost	4,733,369		5,413,222		6,393,084		6,718,084		6,718,084		7,218,084	
14. Total Revenue @ K35 per 100	10,918,600		16,377,200		21,837,200		21,837,200		21,837,200		21,837,200	
15. Gross Surplus (including depn.)	6,185,231		10,963,976		15,444,116		15,119,116		15,119,116		14,619,116	
16. Gross Surplus pre-depreciation	7,302,943		12,081,690		16,561,828		16,986,828		16,986,828		16,486,828	

1. The tablet department of DCPT has capacity of 16500 kg on one shift per annum.
2. Material reduction of 3% on tablet process (rounded) DCPT telex 31.8.90 suggested 2 to 3%.
3. 4. From Table J. (Includes depreciation).
6. Labour cost of tablet department DCPT 1989/90 fully staffed - DCPT written note March 1990.
11. Utilities total cost DCPT 1989/90 54370 @ 10% capacity pro rated. (DCPT Telex 19.4.90) on capacity assumed to be 16080 kg.
9. Maintenance @ 4% on current equipment asset value of K8.5 m. Plus 1% domestic cost.
10. Reduced to nominal K100,000 p.a. from 489,000.
11. Depreciation ignored for 3 years. Replacement of equipment in year 6 at K10m and charged at 7.5% p.a. No depreciation of buildings. New buildings and plant depreciated in the production cost of penicillin.
14. Assuming K35 per 100 tablets unpacked. Although BPI sell to The Trade Corporation @ K35.5 per 100 these are packed. The Trade Corporation resells @ K51 per 100.

Table M Cash Flow - Penicillin V tablets (K000s)

	1	2	3	4	5	6	7	8	9	10	11	12
1. Revenue @ K35 per 100			7,303	12,082	16,562	16,987	16,987	16,487	16,487	16,487	16,487	16,487
2. Residual Value												14,756
3. Balance		(15,302)	(22,697)	(17,457)	(6,054)	9,789	16,393	33,380	49,867	66,354	82,841	99,328
4. Total Inflow		(15,032)	(15,394)	(5,375)	10,508	26,776	33,380	49,867	66,354	82,841	99,328	130,571
5. Buildings	7,854											
6. Plant and equipment	6,666	6,666				10,000						
7. Expatriates and training	512	999	501									
8. Working capital			1,562	679	719	383						(3,344)
9. Total outflow	15,032	7,665	2,063	679	719	10,383	-	-	-	-	-	(3,344)
10. Cash flow	(15,032)	(22,697)	(17,457)	(6,054)	9,789	16,393	33,380	49,867	66,354	82,841	99,328	133,915

Note: No assumptions have been made about financing. The Cash flow is .\*. indicative of the funds required.

IRR = 38%

1. Table L.
2. Table N.
5. Table H.
6. Table N.
7. Table O.
8. Table I.

**Table N Residual Values (K)**

Penicillin Capital Costs		Depreciation 10 years		Residual year 12
Buildings	7,854,000	118,000	1,180,000	6,674,000
Plant	13,332,000	1,000,000	10,000,000	3,332,000
		<hr/>		
		1,118,000	11,800,000	10,006,000
Tabletting Capital Costs		7 years		
Equipment in year 6	10,000,000	750,000	5,250,000	4,750,000
		<hr/>		
				14,756,000
		<hr/>		
Working Capital - Ampicillin/Penicillin V				3,343,908

Existing equipment, stores and spares are used in years 3, 4 and 5 for tabletting, and charges for maintenance and repair are in the P&L A/c. From year 8 the cost of spares and maintenance is also included on an annual basis without addition to the working capital. These cost are not recoverable.

**Table O Expatriate Support Costs (K 000)**

Year	1		2		3	
	m/m	K	m/m	K	m/m	K
<b>Expatriates:</b>						
Construction Engineer	3	167				
Chemical Engineer	-	-	6	334	3	167
Fermentation Technologist			3	167	3	167
Pharmacist					3	167
Component total	3	167	9	501	9	501
<b>Local personnel:</b>						
Individual Fellowships	12	307	18	460	-	-
Study Forms	1	38	1	38	-	-
Component Total	13	345	19	498	-	-
Overall Total	16	512	28	999	9	501

Converted from \$ estimates @ K6.4 = \$1.

It is assumed that all these costs are incurred in foreign currency.

## Chapter II Economic Evaluation

### 1. Introduction

It would be difficult to over-estimate the problems of data collection currently encountered in Myanmar. The government is primarily concerned with the maintenance of law and order, and since the change in policies in 1988 policy-making appears to be in abeyance. Officials are not readily accessible, with appointments taking 3 weeks to arrange; such appointments resulting in neither explanations of government policy nor expressions of opinion. In the period in the field only one such meeting was arranged, during which it was stated that "legally one cannot speculate about the rate of interest". As no data is collected for the purpose of economic evaluation, and with access to official opinion so curtailed, any economic criteria applied to an investment proposal such as this must be more than usually subjective.

An essential part of an economic evaluation is an understanding of Government policies, with a view to assessing possible changes in the medium term. Implementation of the project is expected to take 2 years, and if some time is allowed for consideration and decision-making a 5 year view would seem reasonable. Unfortunately at the present time it would seem that no view can be taken. To quote UNIDO Mission of June 1989; "...a time characterized by many uncertainties. Specially it has not been possible to ascertain in sufficient detail the economic and industrial policies which the country's authorities wish to adopt and pursue in the years to come".

"The switch in policy from centrally planned and isolationist, to a more market orientated and open economic policy framework", does not indicate what the government's own programme will be.

"The present government has officially abolished all existing long-term economic plans in favour of short-term economic planning on the basis of annual plans. This is done however, without any clear coherent notion of both the macro policies and the industrial priorities required in the future"<sup>1</sup>.

It was not possible to elicit from officials what government policy is or would be in the near future; nor any suggestions for establishing economic parameters. Under the circumstances a simplified economic evaluation is adopted. For this purpose rules of thumb have been used based on the UNIDO domestic price system of economic shadow pricing.

## 2. Potential Indirect Benefits

The project would produce a range of pharmaceutical products which would go some way to meeting national needs. Raw materials would be processed for BPI which would otherwise be imported directly in processed form. Ampicillin would be supplied to BPI in bulk for BPI to package, and Penicillin V would be supplied to BPI in tablet form also for packaging.

Given the limited availability of Forex, any allocation of Forex to purchase raw materials for the project may affect the amounts of other materials purchased by BPI, so it is not clear to what extent the output from the project will overlap with or

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1. UNIDO Ind-Sector Review Mission to Myanmar October 1989.



augment the output from BPI, and it is possible that in the short term there would be no overall increase in output, nor a change in product prices. Although BPI is currently operating below capacity this is due essentially to a shortage of Forex. If the project can be funded through foreign sources there will be an addition to national output as a result of the project.

A shortage of pharmaceutical products exists. To give an impression of the market situation to which the project would contribute, there was an estimated demand in 1981 for

14 tons Penicillin G and V, and  
7 tons Ampicillin; and an actual import in 1985/86 of:  
10 tons Penicillin G and V  
2 tons Ampicillin

There was a decline in output from BPI between 1982/83 and 1988/89 of approximately 26% (Fig. II-4 and Table III-10, the main Report). Unofficial prices for Ampicillin are twice the price charged by the Trade Corporation, and three times the price for Penicillin V (Table E). At full capacity the project is expected to produce

16 tons of Penicillin V or,  
11 tons of Ampicillin, or a combination of the two or others, which would not become available until year 5 of the project in these quantities. It is anticipated that the project will have a direct and beneficial effect on the supply or price of products to the consumers, but to an unquantifiable extent. It is also possible that the saving in Forex could induce an increase in the quantity of products imported, though in present circumstances that is unlikely. What is possible is that the

gradual introduction of new locally produced raw materials would lead to cheaper and increased supplies, but despite the importance of this as a direct benefit to the public, these benefits cannot be quantified.

In these circumstances it is particularly difficult to decide on the parameters to be applied, particularly when the principal objectives of the project are the creation of economic and social benefits, which under normal circumstances are difficult to quantify. A restatement of the objectives serves to underline the difficulty.

1. The ultimate objective is to secure an improvement in the reliability of the supply of basic medicines at lower prices for the people. As there will be some overlap with current supply and the possibility exists of alternative uses of foreign exchange affected by the project, the net impact on consumers cannot be quantified. Nevertheless the importance of an improvement in supply cannot be over-estimated.
2. The immediate objective is to reduce dependence on foreign exchange by a) substituting imports of less processed active ingredients for formulated products; and b) substituting indigenous materials for imports.
3. These objectives can only be achieved through the introduction of more sophisticated technology and the upgrading and development of the skills of local staff. This may however be regarded as a separate and additional object in itself.

The introduction of sophisticated technology and the training of local staff, while valuable in itself, is the essential means by which the project can succeed. Training would involve not only staff recruited for the project, but also the upgrading of the skills of the staff at DCPT. This contributes to overall development, making successive opportunities more accessible, and promoting independence and self-reliance; but no attempt has been made to quantify this.

### 3. Direct Benefits

The substitution of indigenous materials and skills for imported products is intended to reduce dependence on scarce foreign exchange, and a valuation of the benefits derived from this is the main quantifiable economic benefit of the project. (The economic value of the gross direct benefits of the project is treated as the border price value of the output of the project expressed at the shadow exchange rate.)

#### **Foreign Exchange - economic value**

Although the amounts involved can be estimated, there are no official guidelines to suggest the scarcity value which foreign exchange justifies at the present time. Published trade figures must be increasingly unreliable as a substantial proportion of trade follows unofficial channels.

This situation suggests that a shadow exchange rate cannot be derived from the trade figures; first because the reliability of the trade figures themselves is doubtful; but secondly because the duties and taxes on traded goods are not fully responsible for the total distortion in domestic prices. The

unofficial market rates may be regarded as extreme; reflecting an unstable if temporary situation, though a previous study in 1988 considered an unofficial rate of K30 = \$1 as a reasonable assumption, and using a figure from the trade formula settled on K21 = \$1. In a meeting at the Ministry of Planning and Finance, reference was made to new official arrangements which permit traders to use export earnings to purchase imports, which can be sold at rates of approximately K50 = \$1. This has been possible since 1st March 1990 and is believed to have had the effect of bringing the unofficial rates down to below K50 = \$1.

Unofficial trade is being conducted at exchange rates of K50 = \$1, and possibly as high as K60 = \$1, compared with the official rate of K6.4 = \$1, and these rates are reflected in a wide range of products on local markets. Luxury products can be sold for K60 = \$1; clothing at K50 = \$1. Shortages in the supply of domestic products are openly reflected in official and unofficial prices. Beer is available in government outlets for K20, elsewhere for K70. The difference in prices for pharmaceuticals has been illustrated in Table E. Under the circumstances, where foreign exchange appears to be increasingly scarce, it is assumed that K38.4 = \$1, or 6 times the official rate, should be used.

No attempt has been made to breakdown all the inputs into traded and nontraded categories. A premium of 600% has been applied to products which can be readily identified as imports, import substitutes, or exports at untaxed cif/fob border prices.

It is assumed that 5% of the agro-based raw material imported will be replaced by indigenous materials in year 4; 15%

main Report p.89.)

#### 4. Economic Discount Rate

If current government attitudes to planning can be inferred from the quotations referred to above, government cannot be expected to take an active role in investment in new projects. This was emphasised by officials of Myanmar Pharmaceutical Corporation who expressed concern that projects should be attractive on commercial grounds. There is concern for the rehabilitation of existing projects, many of which are in difficulties due to scarcity of capital, particularly Forex. However some industries have been designated state monopolies, and in these the investment initiative, whether resulting in government or other investor participation, will remain with government. Shortage of investment funds, and especially Forex is resulting in the breakdown of existing industries, so that funds are not readily available for new projects under any system of allocation; and under these circumstances it is suggested that only projects which are particularly attractive, ie. with high returns, are likely to be considered. This situation suggests at most a supportive government role. No evidence was available to indicate the EDR, though clearly it may have been overlooked, and it may be reasonably assumed that projects were not being selected by government on the basis of the Economic Internal Rate of Return. In discussion with the Ministry of Planning and Finance no suggestions were forthcoming, and indeed it was pointed out that "it is illegal to speculate about the rate of interest". The Myanmar Investment and Commercial Bank stated that the long term savings deposit rate was 10%, and the

stated that the long term savings deposit rate was 10%, and the minimum IRR was also 10%. No explanation supported these statements, and in view of the foregoing comment it is inappropriate to speculate on a rate.

#### 5. Shadow Wage Rate

Official salaries and wages are considered to be inadequate to meet basic living costs by up to 50%. The salary of a highly qualified recruit would be K1250 monthly, and it is currently estimated that a basic minimum wage to keep a family of four would be K1500 excluding rent. Only the most senior government officials get subsidised housing, otherwise the rent for a family apartment is likely to cost K1000 a month. This suggests that K2500 a month represents the basic living costs for a family of four compared with official wages which are as low as K750 a month. Official wages are therefore supplemented by a wife's income and moonlighting. Productivity is low and many employers use the obstacles presented by the bureaucracy and other informal means to supplement their salaries. Despite this situation there are many qualified people in search of jobs, and many professionally qualified are actively seeking emigration.

It is anticipated that there would be no difficulty in recruiting staff for the project. The manager would be on transfer from another government post, with direct recruitment for other posts. The situation is changing however, with qualified people emigrating and leaving public service for the private sector, so that it is possible that recruitment would be more difficult in future. Qualified personnel are least likely to be productively employed, but there is a potential loss to the

country through emigration. Skilled and semi-skilled workers are in demand and are considered to be able to earn close to government rates. In these circumstances it is difficult to see that the opportunity cost of labour to the project would be much if any less than the wages on offer. It would also be reasonable to expect that whatever is earned will also be consumed.

It is assumed that labour recruited for the project is not in its alternative occupations producing goods which would carry a foreign exchange premium, so that no adjustment is made to the proposed salaries and wages used in the financial analysis.

**TABLE P Working Capital - Economic Cost/Benefit**

<b>Ampicillin</b>				
Year	3	4	5	6
1. Work in progress Production cost - depreciation $\times \frac{40}{305}$	1,414,473	1,962,390	2,572,409	-
2. Stocks of finished product	-	-	-	-
3. Stocks of raw material (half year) and chemicals	4,466,631	6,541,491	8,290,934	-
4. Stores and spares 4% equipment cost - 150000 $\times$ 6				2,299,674
<b>Total Each Year</b>	<b>5,881,104</b>	<b>8,503,881</b>	<b>10,863,343</b>	<b>2,299,674</b>
<b>Working Capital Commitment</b>	<b>5,881,104</b>	<b>2,622,777</b>	<b>2,359,462</b>	<b>2,299,674</b>
<b>Accumulated Total</b>				<b>13,163,017</b>

<b>Penicillin V</b>				
1. Work in progress production cost - depreciation $\times \frac{40}{305}$	1,165,164	1,426,548	1,741,398	-
2. Stocks of finished	-	-	-	-
3. Stocks of raw material (half year) and chemicals	2,141,085	3,051,045	3,639,842	-
4. Stores and spares (Equipment as for penicillin. Tabletting equipment spares included in P&L account)				2,299,674
<b>Total each year</b>	<b>3,306,249</b>	<b>4,477,593</b>	<b>5,381,240</b>	<b>2,299,674</b>
<b>Annual Commitment</b>	<b>3,306,249</b>	<b>1,171,344</b>	<b>903,647</b>	<b>2,299,674</b>
<b>Accumulated Total</b>				<b>7,680,914</b>



TABLE Q Economic Cost-benefit - Ampicillin (K)

	3	4	5	6	7	8
1.*Raw Material	4,282,170	6,102,090	7,279,684	6,594,540	6,594,540	6,594,540
2.+Labour	834,600	834,600	834,600	834,600	834,600	834,600
3. Social Benefits	4,370	4,370	4,370	4,370	4,370	4,370
4. Utilities	74,610	111,920	149,220	149,220	149,220	149,220
5. Administration	472,900	472,900	472,900	472,900	472,900	472,900
6. Maintenance and Repairs	-	-	150,000 900,000	150,000 900,000	150,000 900,000	150,000 900,000
7. Insurance	184,320	184,320	184,320	184,320	184,320	184,320
Depreciation Foreign	6,024,630	6,024,630	6,024,630	6,024,630	6,024,630	6,024,630
Domestic	113,607	113,607	113,607	113,607	113,607	113,607
8. Depreciation Total	6,138,237	6,138,237	6,138,237	6,138,237	6,138,237	6,138,237
9. Packages	150,078	75,180	74,898	-	-	-
10. Utilities	131,220	196,950	262,440	262,440	262,440	262,440
11. Chemicals	4,651,092	6,980,892	9,302,184	9,302,184	9,302,184	9,302,184
12. Total Production Cost	16,923,597	21,101,459	25,752,853	24,992,811	24,992,811	24,992,811
13. Ampicillin Revenue @ K600	19,692,000	29,556,000	39,384,000	39,384,000	39,384,000	39,384,000
14. Cost excluding depreciation	10,785,360	14,963,222	19,614,616	18,854,574	18,854,574	18,854,574
15. Gross Revenue (excluding depreciation)	8,906,640	14,592,778	19,769,384	20,529,426	20,529,426	20,529,426

Note: Based on Table J.

Duties and Taxes excluded.

+ Shadow wage adjustment applied-none.

Forex factor applied

\* Local material substitution - year 4, 5%, year 5, 15%, year 6, 23%.

TABLE R Economic Discount Schedule - Ampicillin (K 000s)

	1	2	3	4	5	6	7	8	9	10	11	12
1. Revenue			8,907	14,593	19,769	20,529	20,529	20,520	20,529	20,529	20,529	20,529
2. Residual Value Balance												26,666
Total Inflow												47,195
3. Buildings	7,854											
4. Plant and Equipment	39,996	39,996										
5. Expatriates and Training	3,072	5,994	3,006									
6. Working Capital			5,881	2,623	2,359	2,300						(13,163)
Total Outflow	50,922	45,990	8,887	2,623	2,359	2,300						(13,163)
Balance of Resources	(50,922)	(45,990)	20	11,970	17,410	18,229	20,529	20,529	20,529	20,529	20,529	60,358

IRR = 11.5%

Residual Value, Forex premium applied to the equipment and plant.

Residual value buildings 6674 + (3332 x 6).

Building assumed to be entirely a domestic cost.

Forex premium applied to plant and equipment.

Forex premium applied to expatriate experts and training.

Forex premium applied to working capital.

Duties are excluded from working capital. Production cost-depreciation-duties x  $\frac{40}{305}$  6

TABLE S Economic Cost Benefit - Penicillin V (K)

	3	4	5	6	7	8
1. Production of Penicillin V. Kg.	8,040	12,060	16,080	16,080	16,080	16,080
2. Production of Penicillin V tablets kg.	7,799	11,698	15,598	15,598	15,598	15,598
3. Cost of Production - Penicillin (including depreciation)	11,991,207	13,848,437	16,113,331	15,428,187	15,428,187	15,428,187
4. Costs as for Penicillin (excluding depreciation)	5,852,970	7,710,200	9,975,094	9,289,950	9,289,950	9,289,950
<u>Tabletting</u>						
5. Labour	233,400	233,400	233,400	233,400	233,400	233,400
6. Social Security	1,370	1,370	1,370	1,370	1,370	1,370
7. Utilities	271,640	407,460	543,300	543,300	543,300	543,300
8. Maintenance & Repairs Foreign	2,400,000	2,400,000	2,400,000			2,400,000
Domestic	25,000	25,000	25,000	-	-	100,000
9. Administration (including insurance)	100,000	100,000	100,000	100,000	100,000	100,000
10. Depreciation	-	-	-	4,500,000	4,500,000	4,500,000
11. Tablet Production Cost (including depreciation)	3,031,410	3,167,230	3,303,070	5,378,070	5,378,070	7,878,070
12. Tablet Production Cost (excluding depreciation)	3,031,410	3,167,230	3,303,070	878,070	878,070	3,378,070
13. Total Cost (including depreciation)	15,022,617	17,015,667	19,416,401	20,806,257	20,806,257	23,306,257
14. Total Cost (excluding depreciation)	8,884,380	10,877,430	13,278,164	10,168,020	10,168,020	12,668,020
15.*Revenue @ K220 per kg (1) x 6	10,612,800	15,919,200	21,225,600	21,225,600	21,225,600	21,225,600
16.*Cost of tablet production(11).	3,031,410	3,167,230	3,303,070	5,378,070	5,378,070	7,878,070
17.*REVENUE (15 + 16)	13,644,210	19,086,430	24,528,670	26,603,670	26,603,670	29,103,670
18. GROSS SURPLUS EXCLUDING DEPRECIATION	4,759,830	8,209,000	11,250,506	16,435,650	16,435,650	16,435,650
19.+REVENUE @ K549 per kg (2) x 6	25,689,906	38,533,212	51,379,812	51,379,812	51,379,812	51,379,812
20.+Gross Surplus excluding depreciation	16,805,526	27,655,782	38,101,648	41,211,792	41,211,792	38,711,792

3.4. Costs from Table P allow for domestic raw material substitution from year 4.

4. Table P 1-7 inclusive.

- \*15.16.17 Penicillin V is not imported in tablet form. CIF Penicillin V is \$34,41/K220 per kg (before reduction). To get a cif price for 100 tablets it is assumed that the above cost of tabletting is added to the cif cost of Penicillin V.
18. A quotation from a UK supplier cif Yangon Sept. 1990, 100 tonnes x 250 mg tablets in 1000 tablet containers was \$85.8 per kg, or K549 per kg, (applied to actual tablets produced), (2).
- +19.20

TABLE T (1) Economic Discount Schedule - Penicillin V (K 000's)

	1	2	3	4	5	6	7	8	9	10	11	12
Revenue			4,760	8,209	11,251	16,436	16,436	16,436	16,436	16,436	16,436	16,436
Residual Value												55,166
Balance												
Total Inflow												
Buildings	7,854											
Plant and Equipment	39,996	39,996				60,000						
Expatriates and Training	3,072	5,994	3,006									
Working Capital			3,306	1,172	903	2,300						(7,681)
Total Outflow	50,922	45,990	6,312	1,172	903	62,300						(7,681)
Balance of Resources	(50,922)	(45,990)	(1,552)	7,037	10,348	(45,864)	16,436	16,436	16,436	16,436	16,436	79,283

The assumption \* on Table S produces an almost breakeven position in economic terms.

TABLE T (2) Economic Discount Schedule - Penicillin V (K 000's)

	1	2	3	4	5	6	7	8	9	10	11	12
Revenue	-	-	16,806	27,656	38,102	41,212	41,212	38,712	38,712	38,712	38,712	38,712
Residual Value												55,166
Balance												
Total Inflow												
Buildings	7,854											
Plant and Equipment	39,996	39,996				60,000						
Expatriates and Training	3,072	5,994	3,006									
Working Capital			3,306	1,172	903	2,300						(7,681)
Total Outflow	50,922	45,990	6,312	1,172	903	62,300						(7,681)
Balance of Resources	(50,922)	(45,990)	(10,494)	26,484	37,199	(21,088)	41,212	38,712	38,712	38,712	38,712	101,559

The use of the quotation cif Yangon produces an IRR of 21%.

PERSONS MET

1. Myanmar Pharmaceutical Industries, Yangon  
Colonel Soe Lwin (Retd.)  
Managing Director  
U Ban Yi  
Planning Director
2. Development Centre for Pharmaceutical Technology, Yangon  
Dr. Ko Zo Gyi, Director  
U Kyaw Sein, Deputy Director.  
U Hsin Co, Dy. Research Officer, Fermentation Department  
Daw Eyi Eyi Pyone, Head, Finance Department  
U Soe Myint, Administrative Officer
3. Burma Pharmaceutical Industry  
U Mya Sein, General Manager  
U Thein, Dy. General Manager (Planning)  
U Htun Aung, Chief Accountant
4. Pharmaceutical Raw Materials Plant Hnawbi  
Ngwe Thein, Dy. General Manager  
Kyaw Shwe, Production Manager
5. Ministry of Health, Yangon  
Prof. Hla Tun, Director General, Dept. of Indigenous medicine  
Dr. U Kyint Thein, Director, Health Dept.  
Dr. U Ohn Han, Dy. Director, Health Dept.  
Dr. U Naw Thein, Dy. Director, CMBD, Health Dept.  
Dr. U Ohn Kyaw, Asst. Director, Med. Care Dept.
6. Shwessayan Medicinal Plant farm, BFI  
U Kyaw Swe Lin, Incharge  
U Saw Pawlar, Plantation Manager
7. Myanmar Textile Corporation, Cotton Seed factory Myinttha  
U Hla Myint, Manager  
U Ko Zo Aung, Asst. Manager  
U Hla Zin, Mechanical Engineer

8. Institute of Traditional Medicine, Mandalay  
Dr. Hla Myint, Principal
9. Mandalay Beer Factory, Mandalay, Food Stuff Industry  
U Win Myint, General Manager  
U Thung Myint, Chief Brewer  
U Kwin Maung, Chief Distiller  
U Kyaw Than, Head of Administration Dept.  
U Sai Aung Kyi, Head of Planning Dept.
10. State Public Works, Architect Group II  
U Tin U, Group Leader
11. Industrial Training Centre, Syrian  
U Khin Maung Tha, In charge  
U Tin Myint
12. Chemical Engineer's Cooperative, Yangon  
Daw Khin Myo Hin, Vice chairman  
Daw Khin Khin, Chemical Engineer
13. Central Research Organization, Chemical Engineering group  
~~Ministry of~~ Industry, Yangon
14. United Nations Development Programme, Yangon  
Mr. K. Kitatani Resident Representative  
Mr. Bjorn Carlsson, Dy. Resident Representative  
Mr. M. Gauthier, Dy. Resident Representative  
U Htin Aung, Programme Officer
15. United Nations Children's Fund  
Mr. M. Bajaj, Dy. Resident Representative  
Mr. LaRoche, Programme Officer
16. World Health Organization  
Dr. R. Roy Chowdhary, Representative  
Dr. U Than Sein, Programme Officer  
Dr. Khin Kwi Kyi, National Consultant
17. Food and Agricultural Organization

18. Ministry of Planning and Finance

Das Yi Yi Thwe, Director

U Htan Kote, Additional Director

U Than Han, Deputy Director

J Thin Myint Han, Asst. Director



**Fermentation Pilot Plant Study**

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**PART - II**

**THE PROJECT**

**A. Development Objective**

To expand the volume and the range of pharmaceuticals in support of the public health programmes.

**B. Immediate Objective**

To assess the technical and economic implications of establishing a pilot plant for fermentation based pharmaceuticals in preparation for a future investment decision.

**C. Background and Justification**

The 20 Year Long Term Plan accords great importance to the health of the population. Under the consecutive four year plans country-wide grassroot level public health programmes are being implemented. They are accompanied by efforts to expand the supply of both traditional and modern medicines. The Government's Third People's Health Plan, prepared with WHO assistance, calls for an increase and an expansion of the range of pharmaceutical products.

## Fermentation Pilot Plant Study

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Modern medicines are in part imported and in part delivered by the Burma Pharmaceuticals Industry (BPI) under the Pharmaceutical Industry Corporation of the Ministry of No. 1 Industry. However, local production is confined to dosage form formulation and the bulk pharmaceuticals have to be almost entirely imported. In addition most of the machines are old and obsolete and require replacement and renovation.

Faced with these needs the Government has taken concrete measures to upgrade the national pharmaceutical industry. The intention of the Government is to advance, as far as possible, from pure formulation to production in order to save foreign exchange. In the years 1980 - 1982 a Development Centre for Pharmaceutical Technology was established with assistance from the Government of Japan. It is supporting the industry with expertise in technology and quality and with training. Further plans comprise a major rehabilitation and modernization of BPI's existing facilities. The rehabilitation is planned for 1987 - 1989 at a cost of US\$ 87.9 million (FE component - US\$ 35.3 million). The latter plan is now being reviewed by the World Bank under a UNDP supported project - DP/BUR/84/004 Pharmaceutical Industries Rehabilitation Study. As background for the necessary investment decisions the WB study will contain, inter alia, a 10 year demand forecast and an economic evaluation of domestic production versus imports. The study is planned to be completed in November 1986.

One of the Government's long term objectives is to undertake production of antibiotics currently imported at a rate of 38 tons per year. The following table shows the main imports.

Benzyl Penicillin	1.5 t
Procaine Penicillin Fortified	8.0 t
Streptomycin	15.0 t
Tetracycline Hydrochloride	5.5 t
Ampicillin	2.0 t
Penicillin V	6.0 t
<u>Total</u>	<u>38.0 t</u>

Two factors are critical in the consideration of this plan - the economic scale of production and the sophisticated technology together with the required special skills. Given the current demand situation as well as the results of earlier studies already conducted by the Government the building of a commercial plant appears at present not to be justified. It is expected that the WB study will help to determine reasonable future timing for such a project.

Fermentation Pilot Plant Study

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It is the intention of the Government to utilise the time before an investment decision is made for further absorption of technology and for training of personnel as well as for testing of locally available materials (agricultural: maize, soyabeans, sucrose, groundnuts and vegetable oil; chemicals: urea, sulphuric acid, sodium chloride and hydrochloric acid). For this purpose experimenting and training on a laboratory scale is not adequate especially in the case of fermentation. The production trials made by the DCPT were entirely inconclusive, inter alia, as regards assessment of the adequacy of local raw materials.

In view of the above the Government is considering as an interim stage the establishment of a fermentation pilot plant for antibiotics and other fermentation based pharmaceuticals. However, before taking a final decision the Government wishes to evaluate the technical and economic implications of this plan. In this connexion UNDP support has been requested to carry out a study in accordance with the terms of reference of this project.

D. Output

A report containing but not necessarily limited to the following:

- (i) demand for fermentation based pharmaceuticals (antibiotics etc.) based on the WB study
- (ii) description of the development work already carried out by the DCPT; assessment and conclusions
- (iii) specification (qualitative and quantitative) of further necessary development work (including training)
  - a) within the capabilities of DCPT
  - b) outside of their capabilities
- (iv) assessment of technical and economic feasibility of small scale production in view of (i) and the findings of the WB study
- (v) preliminary design of a fermentation pilot plant based on (i) to (iv) and including but not necessarily limited to:
  - a) functions (experiments, training, services etc.)
  - b) capacity (production)
  - c) manning (core staff and training requirements)
  - d) technology

## Fermentation Pilot Plant Study

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- e) equipment (including cost estimate, based preferably on information from suppliers)
- f) premises and layout (including cost estimate of construction work)
- g) supplies (raw and ancillary materials, cost)
- h) utilities (demand, sources, cost)
- i) market (destination and distribution of services and products)
- (vi) Implementation schedule
- (vii) total cost of investment and distribution of financing
- (viii) estimate of the operating cost and financing
- (ix) preliminary cost/benefit analysis
- (x) conclusions and recommendations

### E. Activities

Activity	Proposed starting date	completion date
Assessment of needs of services, training and production (parts i. to iv. of the report/output/)	Beginning January 1988	Mid-February 1988
Preliminary design (parts v. and vi. of the report)	Mid-February 1988	Mid-March 1988
Economic analysis (parts vii. to ix.)	Beginning March 1988	End March 1988
Draft report and review of conclusions and recommendations with Government	April 1988	April 1988

**Fermentation Pilot Plant Study**

- e) equipment (including cost estimate, based preferably on information from suppliers)
- f) premises and layout (including cost estimate of construction work)
- g) supplies (raw and ancillary materials, cost)
- h) utilities (demand, sources, cost)
- i) market (destination and distribution of services and products)
- (vi) Implementation schedule
- (vii) total cost of investment and distribution of financing
- (viii) estimate of the operating cost and financing
- (ix) preliminary cost/benefit analysis
- (x) conclusions and recommendations

**E. Activities**

Activity	Proposed starting date	completion date
Assessment of needs of services, training and production (parts i. to iv. of the report/output/)	Beginning January 1988	Mid-February 1988
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Economic analysis (parts vii. to ix.)	Beginning March 1988	End March 1988
Draft report and review of conclusions and recommendations with Government	April 1988	April 1988

ANNEX III-1: LEADING GROUPED CAUSES OF MORBIDITY TREATED IN (533) HOSPITALS  
FOR THE YEAR 1984.

GROUPED BASIC LIST	CAUSE GROUP	CASES			PERCENT
		Male	Female	Total	
010-079	Infectious and parasitic diseases	182254	124956	307210	33.0
380-410	Complications of pregnancy child-birth and the puerperium	-	131271	131271	14.1
470-560	Injury and poisoning	74035	33922	107957	11.6
460-469	Symptoms signs and ill-defined c conditions	45301	43958	89259	9.6
310-328	Diseases of the REspiratory system	41935	37411	79346	8.5
330-349	Diseases of the digestive system	32022	21292	53314	5.7
350-378	Diseases of the genito-urinary system	17169	21261	38430	4.1
220-296	Diseases of nervous system and sense organs	15903	21307	37210	4.0
420-422	Diseases of the skin and subcutaneous tissue	12723	8662	21385	2.3
200-207	Diseases of blood and blood forms organs	4755	7164	11919	1.3
080-170	Neoplasms	4864	6639	11503	1.2
180-193	Endocrine Nutritional and metabolic diseases and immunity disorders	5697	5419	11116	1.2
430-438	Diseases of the musculoskeletal system and connective tissue	4184	3567	7751	0.8
210-219	Mental disorders	4725	1698	6423	0.8
V00-V08	Supplementary classification of factors influencing health status and contact with health services	448	5419	5867	0.6
450-456	Certain conditions originating in the perinal period	2440	2964	5404	0.6
300-307	Diseases of the circulatory system	1899	1421	3320	0.4
440-448	Congenital anomalies	988	1127	2115	0.2
	GRAND TOTAL	451342	479458	930800	100.0

SOURCE: MINISTRY OF HEALTH

ANNEX III-2: LEADING GROUPED CAUSES OF MORTALITY TREATED IN (533) HOSPITALS FOR THE YEAR 1984

GROUPED BASIC LIST	CAUSE GROUP	DEATHS			PERCENT
		MALE	FEMALE	TOTAL	
010-079	Infectious and parasitic diseases	6316	4478	10794	35.7
310-328	Diseases of the respiratory system	2358	1946	4304	14.2
460-469	Symptoms signs and ill-defined conditions	1817	1471	3288	10.9
470-560	Injury and poisoning	2250	865	3115	10.3
220-296	Diseases of nervous system and sense organs	1319	1579	2898	9.6
330-349	Diseases of the digestive system	973	411	1384	4.6
450-456	Certain conditions originating in the perinatal period	584	562	1146	3.8
380-410	Complication of pregnancy child-birth and the puerperium	-	887	887	2.9
180-195	Endocrine Nutritional and metabolic diseases and immunity disorders	562	260	822	2.7
080-170	Neoplasms	303	173	476	1.5
200-207	Diseases of the blood and blood forming organs	108	303	411	1.4
350-378	Diseases of the genito-urinary system	173	216	389	1.3
210-219	Mental disorders	87	-	87	0.3
440-448	Congenital anomalies	43	43	86	0.3
300-307	Diseases of the circulatory system	22	43	65	0.2
420-422	Diseases of the skin and subcutaneous tissue	43	-	43	0.1
V01-V08	Supplementary classifications of factors influencing health states and contact with health services	-	43	43	0.1
430-438	Diseases of the musculoskeletal system and connective tissue	-	22	22	0.1
	GRAND TOTAL	16958	13302	30260	100.0

SOURCE: MINISTRY OF HEALTH

ANNEX III-3: SINGLE LEADING CAUSES OF OUT-PATIENT MORBIDITY STATISTICS FROM  
ALL OUT-PATIENT DEPARTMENTS (1984)  
(WINTER SEASON)

BASIC LIST	CAUSE GROUP	SEX	CASES			PERCENT
			URBAN	RURAL	TOTAL	
203	Other and unspecified anaemias	M	54	10	64	5.5
		F	191	23	214	
		T	245	33	278	
016	III-defined intestinal infection	M	107	16	123	5.3
		F	136	9	145	
		T	243	25	268	
020	Pulmonary tuberculosis	M	144	20	164	5.3
		F	97	6	103	
		T	241	26	267	
V01	Supervision of pregnancy and puer perium	M	-	-	-	5.1
		F	223	31	254	
		T	223	31	254	
052	Malaria	M	116	15	131	5.0
		F	106	16	122	
		T	222	31	253	
323	Bronchitis, chronic and unspecified, emphysema and Asthma	M	100	10	110	4.9
		F	117	17	134	
		T	217	27	244	
468	Debility unspecified	M	52	4	56	3.2
		F	100	6	106	
		T	152	10	162	
312	Other acute upper respiratory infections	M	74	5	79	2.9
		F	56	12	68	
		T	130	17	147	
420	Infection of skin and subcutaneous tissue	M	68	10	78	2.9
		F	61	5	66	
		T	129	15	144	
328	Other diseases of respiratory system	M	45	3	48	2.0
		F	42	8	50	
		T	87	11	98	
422	Other diseases of skin and subcutaneous tissue	M	40	8	48	2.0
		F	42	6	48	
		T	82	14	96	
435	Rheumatism excluding the back	M	27	2	29	1.8
		F	58	3	61	
		T	85	5	90	
551	Certain traumatic complication and unspecified injuries	M	48	6	54	1.7
		F	31	2	33	
		T	79	8	87	
322	Influenza	M	28	3	31	1.5
		F	38	5	43	
		T	66	8	74	
349	Other diseases of the digestive system	M	24	1	25	1.4
		F	44	3	47	
		T	68	4	72	
	All other causes	M	1006	144	1150	49.5
		F	1161	166	1327	
		T	2167	310	2477	
TOTAL		M	1933	257	2190	100.0
		F	2503	318	2821	
		T	4436	575	5011	



ANNEX III-4: SINGLE LEADING CAUSES OF OUT-PATIENT MORBIDITY STATISTICS FROM  
ALL OUT-PATIENT DEPARTMENTS (1984)  
(RAINY SEASON)

BASIC LIST	CAUSE GROUP	SEX	CASES			PERCENT
			URBAN	RURAL	TOTAL	
203	Other and unspecified anaemias	M	53	9	62	6.0
		F	241	28	269	
		T	294	37	331	
016	III-defined intestinal infections	M	136	11	147	5.4
		F	132	15	147	
		T	268	26	294	
323	Bronchitis, chronic and unspecified, emphysema and Asthma	M	116	9	125	5.1
		F	147	8	155	
		T	263	17	280	
052	Malaria	M	147	11	158	4.9
		F	101	9	110	
		T	248	20	263	
V01	Super vision of pregnancy and puerperium	M	-	-	-	4.9
		F	233	34	267	
		T	233	34	267	
020	Pulmonary tuberculosis	M	135	23	158	4.4
		F	78	8	86	
		T	213	31	244	
468	Debility unspecified	M	67	11	78	3.6
		F	112	9	121	
		T	179	20	199	
420	Infections of skin and subcutaneous tissue	M	70	9	79	2.9
		F	74	9	83	
		T	144	18	162	
322	Influenza	M	81	6	87	2.7
		F	61	2	63	
		T	142	8	150	
076	Other helminthiasis	M	72	7	79	2.7
		F	61	6	67	
		T	133	13	146	
312	Other acute upper respiratory infections	M	48	5	53	2.4
		F	75	3	78	
		T	123	8	131	
422	Other diseases of skin and subcutaneous tissue	M	55	5	60	1.9
		F	38	4	42	
		T	93	9	102	
330	Diseases of teeth and supporting structures	M	27	6	33	1.7
		F	51	10	61	
		T	78	16	94	
349	Other diseases of the digestive system	M	33	4	37	1.7
		F	44	11	55	
		T	77	5	82	
233	Conjunctivitis	M	29	5	34	1.5
		F	45	5	50	
		T	74	10	84	
	All other causes	M	1067	174	1241	48.2
		F	1250	157	1407	
		T	2317	331	2648	
TOTAL		M	2136	295	2431	100.0
		F	2743	318	3061	
		T	4879	613	5492	

SOURCE: MINISTRY OF HEALTH

ANNEX III-5: SINGLE LEADING CAUSES OF OUT-PATIENT MORBIDITY STATISTICS  
FROM ALL-PATIENT DEPARTMENT (1984)

(SUMMER SEASON)

BASIC LIST	CAUSE GROUP	SEX	CAUSES			PERCENT
			URBAN	RURAL	TOTAL	
016	III-defined intestinal infections	M	186	13	199	7.0
		F	185	19	204	
		T	371	32	403	
203	Other and unspecified anaemias	M	73	5	78	5.8
		F	239	16	255	
		T	312	21	333	
323	Bronchitis, chronic and unspecified emphysema and Asthma	M	113	11	124	4.8
		F	142	12	154	
		T	255	23	278	
V01	Supervision of pregnancy and puer perium	M	-	-	-	4.8
		F	253	23	276	
		T	253	23	276	
020	Pulmonary tuberculosis	M	123	12	135	4.0
		F	87	11	98	
		T	210	23	233	
052	Malaria	M	117	6	123	4.0
		F	98	8	106	
		T	215	14	229	
468	Debility unspecified	M	69	7	76	3.5
		F	114	11	125	
		T	183	18	201	
076	Other helminthiasis	M	73	8	81	3.4
		F	111	6	117	
		T	184	14	198	
420	Infection of skin and subcutaneous tissue	M	97	7	104	3.4
		F	82	11	93	
		T	179	18	197	
422	Other diseases of skin and subcutaneous tissue	M	61	9	70	2.3
		F	56	6	62	
		T	117	15	132	
349	Other diseases of the digestive system	M	53	8	61	2.1
		F	57	3	60	
		T	110	11	121	
312	Other acute upper respiratory infections	M	51	3	54	2.0
		F	58	4	62	
		T	109	7	116	
330	Diseases of teeth and supporting structures	M	27	9	36	1.8
		F	58	12	70	
		T	85	21	106	
435	Rheumatism, excluding the back	M	34	4	38	1.8
		F	61	6	67	
		T	95	10	105	
322	Influenza	M	42	4	46	1.7
		F	43	7	50	
		T	85	11	96	
	All other causes	M	1077	172	1249	47.6
		F	1319	164	1483	
		T	2396	336	2732	
TOTAL		M	2196	278	2472	100.0
		F	2963	319	3282	
		T	5159	597	5756	

SOURCE: MINISTRY OF HEALTH

ANNEX III-6: Government Health Expenditure (K in million)

Fiscal Year	Current	Capital	Total	% of GDE
1984-85	334.5	289.1	623.6	1.19
1985-86	382.7	308.9	691.6	1.23
1986-87	382.6	233.4	616.0	1.05

SOURCE : MINISTRY OF HEALTH

ANNEX III. 7. Health Manpower in Rwanda.

Sr. No.	Categories of Health Workers	Year		
		1977-78 No.	1982-83 No.	1987-88 No.
1.	Medical Doctor (inservice)	3176	3823	5105
2.	Medical Doctor (Nonservice)	2611	4558	5971
3.	Dental Surgeon (inservice)	190	317	380
4.	Dental Surgeon (Nonservice)		154	370
5.	Nurse (inservice)	4063	4526	5756
6.	Nurse (Nonservice)			2482
7.	Health Assistance	994	1306	1546
8.	Community Health Visitor	1283	1401	1567
9.	Midwife	6426	7831	9187
10.	Public Health Supervisor I	160	461	481
11.	Public Health Supervisor II	180	363	673
12.	Medical Technician	90	96	105
13.	Pharmacist	73	73	77
14.	Radiographer	90	90	101
15.	Physiotherapist	100	109	112
16.	Laboratory Technician I	254	302	317
17.	Laboratory Technician II	396	462	463
18.	X-Ray Technician I	42	42	54
19.	X-Ray Technician II	63	63	74
20.	Vaccinator	867	867	867
Total (inservice)		18447	21917	23665

SOURCE : MINISTRY OF HEALTH

**ANNEX III.8.**

Existing Strength and Distribution of HA, PHS I, PHS II in Department of Health (1989).

Div/S	Health Assitant			PHS I			PHS II		
	Sanct	Fill	Vancnt	Sanct	Fill	Vancnt	Sanct	Fill	Vancnt
Kac	39	36	3	25	23	2	26	20	0
Kay	14	9	5	12	10	2	11	11	0
Kar	28	28	0	17	13	4	24	19	5
Chi	47	39	8	16	14	4	9	9	0
Sag	145	136	9	72	59	13	119	117	2
Tan	32	32	0	21	17	4	19	18	1
Baq	125	121	4	62	52	10	96	90	6
Mag	122	121	1	59	56	3	64	59	5
Han	129	129	0	72	53	19	106	103	3
Hoo	46	46	0	22	19	3	21	20	1
Rak	76	74	4	39	32	7	35	27	8
Yan	78	74	4	37	35	2	32	30	2
Sha	89	85	4	59	50	9	37	34	3
Aye	161	157	4	72	54	18	72	72	0
<b>Total</b>	<b>1133</b>	<b>1067</b>	<b>46</b>	<b>587</b>	<b>467</b>	<b>100</b>	<b>665</b>	<b>629</b>	<b>36</b>

SOURCE : MINISTRY OF HEALTH

ANNEX III Existing Strength and Distribution of Traditional Medicine Practitioner (1985).

Dist/Stat	Clinic incharge			Deputy Clinic Incharge			Assistant Clinic incharge			Total		
	Sanct	Fill	Vacant	Sanct	Fill	Vacant	Sanct	Fill	Vacant	Sanct	Fill	Vacant
Kac	5	4	1	6	3	3	6	5	1	17	12	5
Kay	4	3	1	5	2	3	5	3	2	14	8	6
Kar	5	3	2	6	1	5	6	3	3	17	7	10
Chi	5	2	3	6	1	5	6	3	3	17	6	11
Sag	6	6	0	7	5	2	7	6	1	20	17	3
Tan	4	3	1	5	1	4	5	4	1	14	8	6
Baq	8	8	0	9	7	2	9	8	1	26	23	3
Mag	8	7	1	6	5	3	8	6	2	24	18	6
Nan	13	12	1	13	12	1	13	12	1	39	36	3
Non	5	5	0	5	1	4	5	3	2	15	9	6
Rak	6	4	2	7	2	5	7	4	3	20	16	10
Yan	14	12	2	14	7	7	16	14	2	44	33	11
Sha	7	5	2	8	5	3	8	7	1	23	17	6
Aye	10	9	1	10	6	2	10	7	3	30	24	6
Total	160	83	17	109	60	49	111	85	26	320	228	92

SOURCE : MINISTRY OF HEALTH

**Annex III-10: HEALTH INSTITUTIONS AND HEALTH PERSONNEL**

Sr. No.	Particulars	1981/82	1982/83	1983/84	1984/85 (Provi- sional acutal)	1985/86 (Provi- sional)
1	2	3	4	5	6	7
1	Hospitals	620	620	620	620	620
2	Beds	25,379	25,379	25,379	25,379	25,019
1	Per 10000 Population	7.40	7.26	7.11	6.97	7.01
3	Dispensaries	47	47	47	47	47
4	Rural Health Centres	1,267	1,267	1,267	1,267	1,337
5	Maternal and Child Health Centres	336	336	336	336	348
6	Primary and Secondary Health Centres	52	62	62	62	64
7	School Health Teams	72	72	72	72	80
8	Indigenous Medicine Dispensaries Centres	89	89	89	89	89
9	Doctors	7,831	8,381	8,931	9,481	10,031
1	Public	4,728	4,898	4,902	4,905	5,223
2	Co-operative and Private	3,103	3,483	4,029	4,576	4,808
3	Per 10000 Population	2.28	2.39	2.50	2.61	2.70
10	Dental Surgeons	411	471	531	591	630
1	Public	349	376	376	376	401
2	Co-operative and Private	62	95	155	215	229
11	Health Assistants	1,300	1,300	1,300	1,300	1,346
12	Health Supervisor I	461	461	461	461	481
13	Dental Nurses	36	36	36	36	86
14	Lady Health Visitors	1,401	1,401	1,401	1,401	1,567
15	Nurses*	5,315	5,326	5,335	5,332	5,560
1	Per 10000 Population	1.55	1.52	1.50	1.47	1.50
16	Midwives	7,831	7,831	7,831	7,831	8,187
17	Indigenous Medical Practitioners	359	369	369	369	369
18	Health Supervisors II	363	363	363	363	673

\* Nurses from other State Organizations were included.

Source: Ministry of Planning and Finance

Annex III-11 No. of Health Facilities in Myanmar.

g. States/Divisions No.	Spec: Hosp	Cent: Hosp	200 Bedded	150 Bedded	100 Bedded	50 Bedded	25 Bedded	16 Bedded	Station R.H.C. Bedded	Sub Centres	Urban Health	School Health	M.C.H	
1. Kachin	2	1		1		5	2	9	15	47	201	1	12	19
2. Kayah		1						4	2	8	24	1	1	6
3. Kayin		1			1			5		10	40	1	1	8
4. Chin		1				5	2	3	9	55	236		2	9
5. Sagaing		1			3	3	5	27	40	175	725	1	5	41
6. Tanintharyi		1			1			11	8	39	162	1	2	12
7. Bago		1		2	1	4	6	14	33	142	594	3	5	35
8. Magway		2			3	3	4	16	28	145	592	2	6	35
9. Mandalay	3	1			5	5	3	14	36	155	620	13	12	36
10. Mon		1			1			8	10	55	212	1	4	15
11. Rakhine		1			2			13	19	95	385	1	4	18
12. Yangon	9	8		1	1	7	5	5	17	70	273	35	21	21
13. Shan	2	2	1	1	5	1	8	35	32	114	420	2	6	52
14. Ayeyarwady		1			4	5	5	10	40	185	760	2	9	43
<b>Total</b>	<b>16</b>	<b>23</b>	<b>1</b>	<b>5</b>	<b>27</b>	<b>36</b>	<b>51</b>	<b>167</b>	<b>305</b>	<b>1337</b>	<b>5443</b>	<b>64</b>	<b>90</b>	<b>348</b>

Source : Health Ministry of Myanmar



ANNEX III, 12: EXPORTS OF PHARMACEUTICALS DURING 1990-91

( Demand Submitted by Social Security Board )

( ANTIBIOTICS )

Sr. No.	Description	Packing	Quantity	
			No.	Kg.
1.	Injection Amoxycillin 250 mg/vial in packs of 10's	Box	200	0.5
2.	Capsule " 250 mg in foil pack of 100's	"	200	2.5
3.	Syrup " 125 mg/5ml x 60 ml	Bot.	200	0.3
4.	Injection Ampicillin 125 mg + cloxacillin 125 mg x 10 vials	Box	30	0.975
5.	Injection " 250 mg + cloxacillin 250 mg x 10 vials	"	50	0.2
6.	Capsule " 250 mg + cloxacillin 250 mg x 100's in foil pack	"	80	4.0
7.	Capsule Cloxacillin 250 mg x 100's cap in foil pack	"	200	5.0
8.	Injection " 250 mg x 10's vial	"	50	0.125
9.	Benzathine Penicillin Inj: 2.4 mega Unit	Vial	600	
10.	Griseofulvin 125 mg Tab. x 100's	Bot.	200	
11.	Lincomycin 600 mg/2ml Injection	Vial	100	
12.	Clindamycin HCl hydrate Injection 500 mg/ml	"	100	
13.	Erythromycin Injection 250 mg	"	100	0.025
14.	Erythromycin Tablet 250 mg x 100's	"	100	2.5
15.	Cephalexin 250 mg Injection x 10's	Box	100	
16.	Dibecacin Injection 50 mg	Vial	1000	
17.	Nystatin Oral Tablet 500,000 IU/tab x 100's	Bot.	16	
18.	Nystatin Vaginal Tablet in foil pack	Lo.	500	
19.	Nystatin Ointment	Tube	400	
20.	Nystatin Jelly	"	200	
21.	Hydrocortisone 5 mg + Cinecaine HCl 5 mg + Framycetin Sulphate 6 mg Neulin 10 mg per gm/ointment in 30 gm tube for haemorrhoidal use	"	500	
22.	Betamethasone 0.1% + Neomycin Sulphate 0.5% in Ointment in 15 gm Tube	"	500	
23.	Framycetin 0.5% Eye Drop x 8 ml with dropper	Bot.	800	
24.	Framycetin 0.5%, gramicidin 0.005%, dexamethasone 0.05% Eye/Ear Drop x 8 ml with dropper	"	1500	
25.	Betamethasone disodium phosphate 0.1% neomycin Eye/Ear/Nose Drop x 5 ml with dropper	"	600	

(  A N T I B I O T I C S  )

Sr. No.	Description	Packing	Quantity	
			Nos.	Kg.
26.	Polymyxin B sulphate 7500 IU + Neomycin sulphate 5 mg + gramicidin in isotonic 20 mg per ml x 5 ml Eye Drop with dropper	Bot.	400	
27.	- do - + dexamethasone 1 mg - 0.1% in isotonic x 7.5 ml Eye Drop with dropper	"	300	
28.	Polymyxin B. sulphate 16250 U + Neomycin sulphate 3.5 mg + Benzalkonium Chloride 0.004% + Hydroxypropyl Methylcellulose 0.5% Eye Drop x 5 ml bot.	"	200	
29.	Polymyxin B. sulphate 16250 U + Neomycin sulphate 3.5 mg + Benzalkonium Chloride 0.004% + Hydroxypropyl Methylcellulose 0.5% Eye Drop x 5 ml bot. Eye Ointment	Tube	300	
30.	Tetracyclin 0.3% (3 mg/ml) + Benzalkonium Chloride 0.01% Eye Drop x 5 ml with dropper	Bot.	200	
31.	Tetracyclin 0.3% (5mg/ml) + Benzalkonium Chloride 0.01% Eye Ointment	Tube	500	
32.	Dexamethasone 0.1% + Neomycin 3.5 mg/ml + Polymyxin B sulphate 6000 U/ml Eye Drop x 5 ml with dropper	Bot.	250	
33.	Polymyxin B. sulphate 10,000 units Bacitracin Zinc 500 U x 4 gm tube	Tube	100	
34.	Oxytetracycline Hydrochloride 0.5% + hydrocortisone Acetate 1.5% + Polymyxin B. sulphate 10,000 units Eye/Ear drop x 3 ml	Tube	500	
35.	Chloramphenicol 1% hydrocortisone Carprylate 0.5% Eye/Ear drop x 3 ml	Bot.	500	
36.	- do - Eye Ointment x 3 gm	Tube	500	
37.	Framycetin 1% en lane - paraffin gauze 10 x 10 cm x 10 pieces	Pkt.	250	

( GENERAL MEDICAL STORES DEPARTMENT )

ANTIBIOTICS

Sr. No.	Description	Packing	Quantity	
			Nos.	Kg.
1.	Dalacin 'C' 150 mg x 100's	Bots.	265	
2.	Garamycin Eye drops 15 ml	"	155	
3.	Cortisone Kemicetin Eye drops 3 ml	"	1510	
4.	Cortisone Kemicetin Eye Oint 3 mg	Tubes	405	
5.	Lincocin 500 mg x 100's	Bots.	553	
6.	Lincocin Syrup 250 mg/60 ml	"	530	
7.	Sefradex Eye/Ear Drops 8 ml	"	15906	
8.	Sefracycin Eye Drops 8 ml	"	7755	
9.	Sefracycin Skin Oint 15 mg	Tubes	60	
10.	Sefracycin Nebuliser 15 ml	Bots.	500	
11.	Vibracycin 100 mg x 100's	Boxes.	12	
12.	Amoxycillin 100's	Bots.	10	
13.	Ampipenix caps. 250 mg x 100's	"	10	0.25
14.	Vibracycin Tabs. T.7	Boxes.	60	
15.	Ampiclox 75mg x 10's	"	310	0.23
16.	Ampiclox 500 mg x 10's	"	90	0.45
17.	Floxapen 250 mg x 10's	"	520	
18.	Kemicetin succinate 1 gm	Vials	40	
19.	Netremycin 100mg/2ml	"	840	
20.	Orbenin 500 mg x 10's	"	3540	
21.	Penbritin 500 mg x 10's	"	30	
22.	P.A.M 300,000 unit/ml	"	49951	
23.	Vibracycin 100 mg	"	50	
24.	Cidomycin 5 x 1ml	"		
25.	Sefracycin sterile powder 500 mg	Boxes.	134	
26.	Dalacin 300 mg x 2 ml	Vials	150	
27.	Amoxil 500 mg x 10's	"	3050	
28.	Garamycin 80 mg x 20's	Boxes.	3000	15.0
29.	Lincocin 300 mg	"	5000	
30.	Kadacillin 15 ml	Vials	2750	
31.	Ampipenix 250 mg x 10's	"	5260	
32.	Ampipenix 1 gm (ampicillin) 10's	Boxes	275	0.69
33.	Cidomycin 20 mg/2ml 5x2 ml	"	35	0.35
34.	Cidomycin 20mg/2ml 5x2 ml (Paediatric)	"	700	
		"	700	

15.	Amoxicillin Caps (Ibiamox Caps)	250 mg 5 x 20 blister	2,200 Box
16.	Gentamycin Sulphate Injs (Gentotal Injs)	80 mg/200 , 100 Amps	4,571 Box
17.	Rifampicin Caps	300 mg 100 x 10 's	1589 Boxes
18.	Tetracycline HCl Caps	250 mg 100 x 10's	4739 Boxes
19.	Chloramphenicol Caps	250 mg 100 x 10's	2790 "
20.	Benzathine Benzyl Penicillin (Retarpen Injs)	12,00,000 1.u, 100 vls	1544 "
21.	Cloxacillin caps	250 mg, 100's (blister of 5 x 20's)	12,500 "
22.	Netromycin Injs	100 mg 2 ml	4,000 Vials
23.	Bneamycin Injs	50 mg 1 ml	1,000 "
24.	Garamycin Eye Drops	5 ml	2,350 Bot
25.	Dalacin - C Injs	150 mg/ml 2 ml	3,000 Vials
26.	Syntophytone Eye Drops Contains per ml :	3 CC	10,000 Bots
	-Prednisolone acetate	5 mg	
	-Chloramphenicol	2 mg	
27.	Rifadin syrup (Rifampicin)	100 mg/5ml, 60 ml	5,706 Bots
28.	Fulcin tab (Griseofulvin)	100's, 125 mg	2,512 Bot
29.	Cortisone- Kemicetine Eye/Ear Drops Contains: Chloramphenicol Hydrocortisone	3 CC 1% 0.5%	14,265 "
30.	Nystatin lactose tab	10,000 units, 15's	1703
31.	Clindamycin HCl cap (Dalacin - o)	150 mg 10's	999 Boxes
32.	Spectinomycin Injs (Trohicin)	2 mg	2000 Vials
33.	Netilmycin sulphate Inj (Netromycin Injs)	100 mg 2 ml	1446 "

ANNEX III.14.i IMPORTS OF <sup>199</sup> PHARMACEUTICALS DURING 1986-87

MEDICINES & MEDICAL EQUIPMENT TRADING )

S. NO	PRODUCT	SPECIFICATION	QUANTITY	REMARKS
1.	Kanamycin sulphate Inj :	1 Gm/VI	8762 Vials	
2.	Lincomycin HCl monohydrate	300 mg/ml 2 ml	4381 "	
3.	(Lincomycin Injs)			
3.	Spectinomycin dihydrochloride powder for injection (Trohicin inj )	2 mg	3464 "	
4.	Clindamycin HCl (Dalacin - C caps)	150 mg, 100's	876 Box	
5.	Griseofulvin tabs (Grisovin F tabs	125 mg, 100's	1859 Bot	
6.	Ampicillin Syrup (Ampicyn Syrup )	125 mg/5CC, 60 CC	17,511 Bot	
7.	Doxycycline tablets (Vibramycin PCT )	100 mg, 7's	1,528 Box	
8.	Adriamycin Inj:	10 mg, 10 ml	713 Vial	
9.	Fransyotin Sulphate Eye Drop (Sofransyotin Eye Drops)	0.5% 8 ml	14,673 Bots	
10.	Sofradex Eye/Ear Drops	8 ml	26,250 Bot	
	<u>Per ml Contains:</u>			
	-Sofransyotin	5 mg		
	-Gramicidin	0.05 mg		
	-Dexamethasone	0.5 mg 10		
11.	Amoxycillin Inj: (Amoxil Inj)	500 mg 10 Vials	876 Packs	
12.	Ampicillin + Cloxacillin Injection (Ampiolor 75 mg Inj:)	50/25 mg, 10 vials	876 "	
13.	Ampicillin + Cloxacillin Caps ( Ampiolor 500 mg Caps)	250/250 mg, 100's	560 Packs	
14.	Ampicillin Caps (Ampicin Caps)	250 mg 5 x 20 blister	17,560 Box	

ANNEX III.14. II REPORTS OF PHARMACEUTICALS DURING 1967-68

( MEDICINES & MEDICAL EQUIPMENT EXPORTS )

Sr. No.	Product	Specification	Quantity	Kg.
1.	Ensamycin inj:	50mg 1ml	1100 Amps	
2.	Metromycin inj:	100mg 2ml	2594 Vls 1875 "	
3.	Chloramphenicol Succ inj:	100's	310 Boxes	
4.	Chloramphenicol Ear Drops	10cc	3256 bots	
5.	Adriamycin inj:	10mg 10ml	646 Vls 500 "	
6.	Kanacnyin sulphate inj:	1gm / vl	3308 Vial	
7.	Dibekacin Meizi inj:	50mg/vl 10 vls	389 Boxes	
8.	Delacin C caps	150mg 100's	1950 Boxes 1250 "	
9.	" " inj:	150mg/ml S.S. 2ml	4160 Vials	
10.	Trobicin inj:	2mg	4167 Vials 2500 "	
11.	Ampicillin syrup	250mg/5cc 60ml	3666 bot 6250 "	26.0
12.	Soframycin Cream (Framycetin)	15gm 0.5%	4270 Bot	
13.	Sofradex Eye/Ear drops	8ml	31651 bots	
	per ml contains:		12918 "	
	-Framycetin	5mg		
	-Gramicidin	0.05mg		
	-Dexamethasone	0.5mg		
14.	Soframycin eye drops (Framycetin)	8ml	23540 Bot	
15.	Cidomycin eye drops	8ml	12244 bots 12415 "	
16.	Amoxicillin syrup	125mg/5cc 60ml	62459 bots	95.2
17.	Rifampicin caps	300mg 100x10	2005 boxes 359 boxes	601.0 107.7
18.	Amoxicillin caps	250mg 10x10	12503 boxes	312.6
19.	Tetracycline caps	250mg 100x10	2776 boxes	694.0
20.	Gentamycin sulphate inj:	80mg/2cc 100 vls	6689 boxes	48.7
21.	Amoxicillin inj:	500mg 10's	2986 boxes	14.9
22.	Ampiclox inj:	75mg 10's	775 boxes	0.6
23.	Fulcin (Griseorulvin tabs)	125mg 100's	5060 bots	63.3
24.	Erythromycin caps	250mg 12x8's	8754 boxes	210.1
25.	Cloxacillin syrup	125mg/5cc 60cc	66964 bots	100.4
26.	" caps	250mg 5x20	23373 boxes	584.3
27.	Amoxicillin caps	250mg 100x10	1360 boxes	340.0

Sr. No.	Name of Product	Specification	Quantity	Kg.
28.	Penicillin G Benzathine G inj:	1.2 M.U. 100 vials	2177 ctns	261.2 H
29.	Chloramphenicol caps	250mg 100x10	3402 Boxes	
30.	Cloxacillin inj:	250mg 100 vials	2863 boxes	
31.	Ampicillin inj:	250mg 100 vials	2666 boxes	
32.	Amoxicillin caps	250mg 20x5's	4600 boxes	
33.	Cloxacillin caps	250mg 20x5's	2645 boxes	
34.	Ampicillin Mixture	125mg/5ml 60ml	22140 bots 29997 "	
35.	Ampicillin caps	250mg 100x10's	686 boxes 1000 "	
36.	Gentamycin sulphate inj:	80mg/2ml 100 vials	1391 Boxes 1000 "	
37.	Chloramphenicol cap	250mg 100x10's	453 boxes	
38.	Tetracycline caps	250mg 100x10's	1371 boxes 1000 "	
39.	Ampicillin inj:	250mg 100 vls	1251 packs 938 boxes	
40.	Streptomycin sulphate inj: 1g with 5ml solvent		792880 vials	
41.	Amoxicillin caps	250mg 20x5's	4000 boxes	
42.	Cloxacillin caps	250mg 20x5's	2000 "	
43.	Nystatin Lactose tabs	100000 I.U. 15's	2500 boxes	
44.	Gentamycin sulphate inj:	80mg/2cc 100's	375 "	
<u>CHEMOTHERAPEUTICS</u>				
45.	Septtrin tabs	500's	1275 boxes	
46.	Co-trimoxazole tabs	480mg 1000's	2572 cont:	
47.	Isoniazid tab	100mg 1000's	1000 bots	
48.	D-Ethambutol tabs	500mg 100x10's	878 boxes	
<u>VETERINARY MEDICINES</u>				
1.	Lincomix	4gm/Lb 1 lb	4738 pkts	
2.	Dihydrostreptomycin sulphate inj:	10gm 30ml	4889 vls	
3.	Oxytetracycline inj:	10% 100ml	4488 bots	
4.	Trimethosulf conc:W/S	25gm sachet	2586 sachet	

Sr. No.	Name of Product	Specification	Quantity	Kg.
5.	Norocillin inj:Procaine penicillin	3,00,000 IU/ml	5880 vial	
6.	Sulohaquinoxaline W/S powder	25% 500G pack	1223 pack	
7.	25% Amprolum + 1.6% Ethopabate 25kg drum with plastic opaque bags at FOC for 1 kg packs	25 kg drum	44 drums	
8.	Amproluin W/S powder	20% 10x30gm box	1240 boxes	



ANNEX III.14. iii IMPORTS OF PHARMACEUTICALS DURING 1988-89

( MEDICINES & MEDICAL EQUIPMENT TRADING )

Sr. No.	Product	Specification	Quantity	Kg.
1	2	3	4	5
<u>ANTIBIOTICS</u>				
1.	Ampicillin capsules	250mg 100x10's	607 boxes	151.75
2.	" syrup	125mg/5cc 60cc	30360 bts	45.54
3.	Adriamycin inj	10mg 10ml	980 Vials	0.01
4.	Rifampicin caps 300mg	300mg 100x10's	535 Boxes	160.50
5.	Tetracycline capsules	250mg 100x10's	1080 Boxes	270.00
6.	Chloramphenicol sodium Succinate inj	1gm 100 vls	270 Boxes	27.00
7.	Glaferan inj	500mg	1000 Vials	
8.	Dalacin C capsules	150mg 10x10's	550 Boxes	
9.	" C syrup	75mg/5cc 80ml	1100 Bets	
10.	Trebicin inj	2gm	1100 Vials	
11.	Mycostatin cream	15gm	1100 tubes	116.5
12.	Seframycin cream	15gm	2000 tubes	
13.	Sefratulle	10 x 10cm 50's	550 Boxes	
14.	Chloramphenicol Ear drops	20cc	8720 Bets	
15.	Cortisone chloramphenicol Eye Ear drop	3cc	8810 Bets	
16.	Cortisone chloramphenicol Eye eint:	3gm	1830 Tubes	
<u>CHEMOTHERAPEUTICS</u>				
1.	Methambutol tablets	500gm 50x10's	8810 Bets	
2.	Co-trimoxazole tablets	480mg 1000's	1145 tins	
3.	Co-trimoxazole syrup	200mg/5cc 100ml	11050 Bets	

## ANNEX III-15: IMPORTS OF PHARMACEUTICALS DURING 1988-89

( ARMY MEDICAL STORES )

<u>Sr.No.</u>	<u>PRODUCT</u>	<u>UNIT</u>	<u>QUANTITY</u>	<u>SIZE</u>	<u>QUANTITY (Kg.)</u>
1.	<u>ANTIBIOTICS</u>				
1.	Tetracycline Syrup 125mgm	Bots	25000	Bn	
2.	Tetracycline HCL 100mg/Ped Drops	"	40000	10 mL	
3.	Ampiclox Oral Drops (Ampicillin 60mg cloxacillin 30mg per drops 8ml)	"	1200	0 mL	
4.	Ampicillin Inj 500mgm IV/IM.	Box	200	5's	
5.	Amoxil Caps 250mgm(Amoxycillin 60mgm)	"	200	100's	
6.	Amoxil 500mgm inj.	"	150	5's	
7.	Ceporan inj 250mg(Cephaloridine)	"	240	5's	
8.	Ceporan inj 500mg (Cephaloridine)	"	440	5's	
9.	Cephalexin Caps 250mgm	Bots.	450	100's	
10.	Claforen injo 0.250	Vials	1100	Bn	
11.	Amoxil (Amoxicillin) 125mgm/5ml Syrup	Bots.	1200	Bn	
12.	Dalacin C Caps HCL hydrate 150mgm Caps 100's	Box	350	100's	
13.	Dalacin-C inj 300mgm inj (Clindamycin Phosphate 150mgm/mL inj)	Amps	500	Bn	
14.	Dalacin Syrup (Clindamycin Hcl hydrate 75mg/5ml Syrup)	Bots	500	Bn	
15.	Dibekacin Sulphate inj (MEIJI) 50mg IM	Vials	500	1PK	
16.	Erythromycin 250mgm tabs.	Box	10	500's	
17.	Cephalexin Caps 500mgm.	Box	600	100's	
18.	Fungisone Inj 50mgm IV (Amphotericin-B 50mgm inj IV)	Amps	300	50 mgm	
19.	Gentamin Inj 80mgm 2ml	Box	100	100's	
20.	Carbenicillin inj 1G	Vial	2200	Bn	
21.	Griseofulvin 125mgm tabs.	Box	600	100's	
22.	Kanamycin 250mgm Caps.	Bots.	100	100's	

<u>Sr. No.</u>	<u>Nomenclature</u>	<u>AMU</u>	<u>QTY</u>	<u>SIZE</u>
23.	Kano inj 0.5G (Kanamycin 500mg inj)	Vial	2000	1a
24.	Kano inj 1G (Kanamycin)	"	1200	1a
25.	Mycostatin Oral Susp (Mycostatin 100000Unit/ml Susp 12 doses)	Bots.	750	1a
26.	Mycostatin Oral tabs (Nystatin 500000 Unit tabs 100's)	"	50	100's
27.	Prostaphlin-A Syrup 125mg (Cloxacillin 125/5ML Syrup)	"	2000	60ML
28.	Prostaphlin-A Caps 250mg (Cloxacillin 250mg Caps)	Box	200	100's
29.	Orbenin 250mg IM/IV Cloxacillin 250mg inj.	Vials	1200	1a
30.	Rimaotan Caps 300mg (Rifampicin)	Bots.	900	100's
31.	Erythromycin Lactobionate 250mg Inj/IV	Bots.	300	1a
31.	Rimaotan Caps 150mg (Rifampicin)	Bots	150	100's
32.	Linocin Syrup 250mg (Lincomycin 250mg/5ml Syrup 60ML)	Bots.	500	60ML
33.	Rifocin 250mg inj 3ml (Rifampicin 250mg IV inj)	Box	50	10's
34.	Synthomyetine Succinate inj 1G (Chloramphenicol Sod Succinate 1 G)	Box	500	10's
35.	Terramycin inj 250mg IV (Oxytetracycline HCL inj IV)	Box	100	100's
36.	Vibramycin 100mg Caps (Doxycycline hydrate 100mg Caps)	Bots.	20	100's
37.	<u>SULPHONAMIDES</u>			
1.	Septin inj 5ml IM (Trimethoprim 80mg Sulphamethoxazole 400mg inj)	Box	60	5's
2.	Septin Tabs (Co-trimoxazole tabs)	Bots	80	1000's
3.	Sulfepim Oral Suspension ( Trimethoprim 40mg, sulphamethoxazole 200mg5ml	Bots.	800	1a

ANNEX III.16. IMPORTS OF DIFFERENT ANTIBIOTICS BY M.P.I

DURING 1986-87 / 1987-88 / 1988-89

1986-87

Sr. No.	I t e m s	Unit	Quantity	Value	Remarks
				U.S.\$	
1.	Ampicillin Trihydrate B.P.Powder	Kg	1400	112910	
2.	Chloramphenicol B.P 50/60 Mesh Powder	"	2000	73240	
3.	Procaine Penicillin G Fertilized B.P	BU	2500	114187	
4.	Streptomycin Sulphate B.P	Kg.	2500	113225	
5.	Tetracycline Hydrochloride B.P 50/60 Mesh Powder	"	3200	96160	
			Total :-	<u>509722</u>	

1987/88

1.	Ampicillin Trihydrate B.P.Powder	Kg.	1000	80650	
2.	Chloramphenicol B.P.50/60 Mesh Powder	"	2000	73240	
3.	Streptomycin Sulphate B.P.	"	1020	46195	
4.	Tetracycline Hydrochloride B.P. 50/60 Mesh Powder	"	800	24040	
			Total :-	<u>224125</u>	

1988/89

1.	Ampicillin Trihydrate B.P.Powder	Kg.	3500	282275	
2.	Chloramphenicol B.P.50/60 Mesh Powder	"	1000	36620	
3.	Penicillin G B.P. Crystalline ( Sodium Salt )	BU.	800	36540	
4.	Procaine Penicillin G Fertilized B.P.	"	1890	86325	
5.	Phenoxymethyl Penicillin O Potassium B.P.	Kg.	990	22007	
6.	Streptomycin Sulphate B.P.	"	3500	158515	
7.	Tetracycline Hydrochloride B.P.50/60 Mesh Powder	"	2500	75125	
8.	Tetracycline Hydrochloride ( Micronized )	"	30	1369	
			Total :-	<u>698776</u>	

SOURCE : MPI

**ANNEX III-17 BUILDINGS AND PLANT LAYOUT**

On the page overleaf in Figure III-2 is a layout plan of BPI's plant facilities in Gyogone. The site covers an area of 42 acres and the buildings have a total floor space of 45,000 m<sup>2</sup>.

The main areas are as follows:

<u>Name of Facility</u>	<u>Area (m<sup>2</sup>)</u>
Main Production Building	12,709
Antibiotics Building	1,068
Transfusion Plant	772
Codein Plant	495
Biological Laboratories	2,892
Alcohol and Yeast Production and Storage Facilities	3,136
Alcohol Administration Building	1,534
Power & Maintenance Buildings	1,544
Main Storage Building	8,595
Other Godowns	1,440
Canteens	1,195
Administration Building	1,987
Others	<u>7,633</u>
Total	45,000

Further drawings of layouts are enclosed in Annex III-9.

Source : IBRD Study, 1987

**ANNEX III-18** Burma - Production capacity and production of  
Burma Pharmaceutical Industry (BPI), 1980/81

Sr. No.	Type of product	Unit	Production capacity 1980/81	Production 1980/81			
				quantity 1)	% of capacity	value mill.K	%
1	Biological products (vaccines, sera; 11 items)	mill.doses	6.25	5.05	81	3.7	3
2	Tablets and capsules (63 items)	mill.	1,800	1,200	67	51.0	43
3	Ointments & similar preparations (21 items)	1,000 kg	242	174	72	9.4	7
4	Liquids (24 items)	1,000 kg	766	660	89	10.3	8
5	Powders and solids (4 items)	1,000 kg	825	403	49	2.7	2
6	Sterile products (59 items)	mill.smp./ vials/bottles	74	55	74	27.6	21
7	Alcohol & allied products (95 I and 90 I ethyl and other blended alcohol)	gallons	300,000	376	125	23.6	18
8	Baker's yeast	n.a.	n.a.	126	n.a.	0.9	1
<b>Total</b>						<b>129.2</b>	<b>100</b>
1) rounded							
Source: Burma Pharmaceutical Industry (BPI), Rangoon, 1981							

Source : GTZ Study, 1982

**ANNEX III-19**

**Burma - Production of Burma Pharmaceutical Industry (BPI) by quantity of main items, 1977/78 to 1980/81**

Sr. No.	Type of product	Unit of quantity	1977/78	1978/79	1979/80	1980/81
1	Biological products (vaccines, sera; 11 items)	million ampoules/vials	5.73	6.29	7.69	5.68
2	Tablets, capsules (63 items)	million tablets/caps.	1,187.97	1,121.54	1,139.35	1,200.22
3	Ointments & similar preparations (21 items)	1,000 kg	183.53	159.52	150.01	173.58
4	Liquids (24 items)	1,000 kg	530.35	602.43	596.55	680.11
5	Powders, solids (4 items)	1,000 kg	630.53	480.00	320.23	402.64
6	Sterile products (59 items)	million amp./vials/bottles	58.12	62.62	60.98	54.58
7	Alcohol & allied products (90 and 95 I-ethyl alcohol and other blended alcohol)	gallons	n.a.	n.a.	n.a.	375.75
8	Baker's yeast	lbs	n.a.	n.a.	n.a.	125.57

Source: Burma Pharmaceutical Industry (BPI), Rangoon, 1981

**ANNEX III-20**

**Burma - Production of Burma Pharmaceutical Industry (BPI), by value of main items, 1977/78 to 1980/81**

Sr. No.	Type of products	1977/78 million K	1978/79 million K	1979/80 million K	1980/81 million K
1	Biological products	3.11	3.12	3.67	3.68
2	Tablets	49.06	45.40	41.51	51.03
3	Ointments & similar preparations	11.30	9.67	7.26	9.42
4	Liquids	10.02	9.80	9.71	10.31
5	Solids	4.37	3.23	2.25	2.68
6	Sterile products	29.73	31.01	28.69	27.55
	Sub-total	107.59	102.23	93.09	104.67
7	Alcohol & allied products	n.a.	n.a.	n.a.	23.63
8	Baker's yeast	n.a.	n.a.	n.a.	0.89
	Sub-total	n.a.	n.a.	n.a.	24.52
	Total	107.59	102.23	93.09	129.19

Source: Burma Pharmaceutical Industry (BPI), Rangoon 1981

Source : GTZ Study, 1982

**ANNEX III-21 BPI SALES OF MAJOR PRODUCT GROUPS  
ACCORDING TO DOSAGE FORM IN 1985/86**

Product Groups	Unit for Quantities	Quantity <sup>a/</sup>	Value in Kyats Million <sup>a/</sup>	Share of Total (%)
Solids	kg thousand	246	1.9	1.4
Ointments	kg thousand	123	5.3	3.9
Liquids	litre, thousand	518	8.5	6.3
Tablets	No. in million	1,181	55.9	41.4
Capsules	No. in million	38	10.0	7.4
Vials	No. in million	22	18.3	13.6
Ampoules	No. in million	30	11.3	8.4
Eye Ointments	Tubes, thousand	1,425	0.5	0.4
Infusion Solutions	No. in thousand	952	8.6	6.4
Biologicals <sup>b/</sup>	No. of Doses		3.2	2.4
Alcohol	Thous. of Litre		7.7	5.7
Yeast	kg		0.9	0.7
Others			2.7	2.0
<b>Total</b>			<b>134.8</b>	<b>100.0</b>

<sup>a/</sup> Quantities and values are provisional actual which may differ marginally from actual figures.

<sup>b/</sup> Viz. vaccines and sera.

Source: IBRD Study, 1987



**ANNEX III-22** BPI SALES 1985/86 ACCORDING TO MAJOR THERAPEUTIC CLASSES AND COMPARATIVE FIGURES FROM SELECTED OTHER COUNTRIES (Percentages)

Therapeutic Class	BPI	Indo-nesia <sup>a/</sup>	Malay-sia <sup>b/</sup>	Five African Countries <sup>c/</sup>
Analgesics and antipyretics	3.5	10.0	8.1	8.2
Chemotherapeutics	9.9			
Antibiotics	25.2	36.2	25.0	31.8
Antimalarials	11.4	2.6		15.6
Infusion solutions	7.1		5.3	6.0
Vitamins	12.9	9.2	2.3	3.6
Others	30.0			
Total	100.0			

a/ Consumption in district hospitals and health centers in 25 provinces, 1978, as quoted in "The Pharmaceutical Industry in ASEAN Countries", UN Asian and Pacific Development Institute, C.Sepulveda et.al. 1980.

b/ Institutional consumption 1978; *ibid.*

c/ Congo, Togo, Benin, Cameroon and Central African Republic, 1977. Study carried out by CTU for the African Development Bank, 1980.

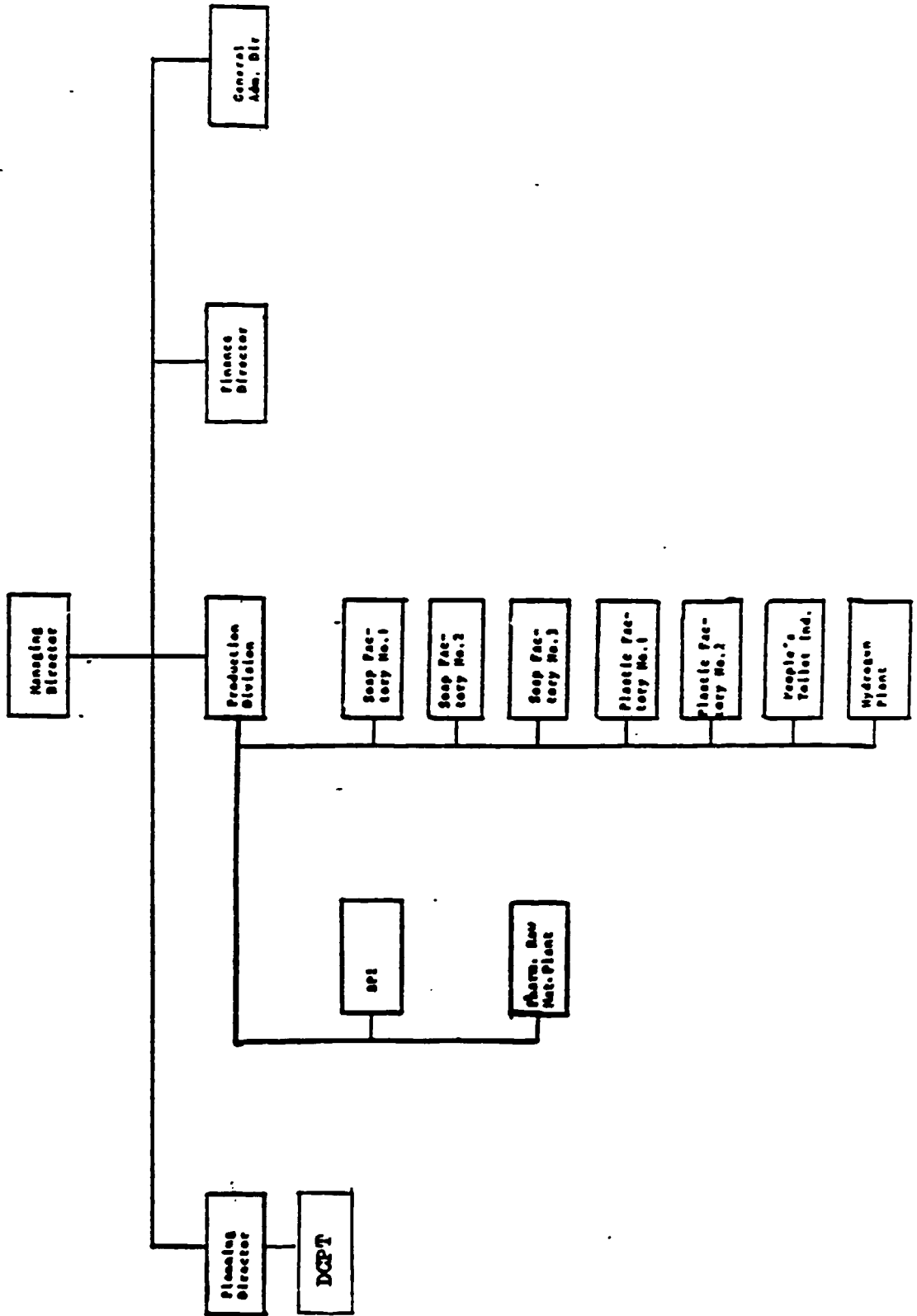
ANNEX III-23 Details Production of Antibiotic (Quantity)

During 1986-87 / 1987-88 / 1988-89

Sr. No.	Items	Size	Productions			Remarks
			1986/87	1987/88	1988/89	
<u>OINTMENTS</u>						
1.	Chloramphenicol Ointment	15gm	27827	12146	-	
<u>LIQUIDS</u>						
1.	Chloramphenicol Ear Drops.	15cc	21803	-	-	
2.	Chloramphenicol Syrup	60cc	202192	-	-	
<u>TABLETS</u>						
1.	T. 157. Penicillin V Tab.	20's	125011	-	24005	
2.	T. 157. " "	100's	2479	-	13892	
3.	C. 2. Tetracycline Cap.	16's	670033	-	298817	
4.	C. 2. " "	100's	23101	14951	30911	
5.	C. 2. " "	500's	5548	-	3900	
6.	C. 3. Chloramphenicol	16's	306337	483068	89015	
7.	C. 3. " Cap.	100's	19759	33940	8998	
8.	C. 3. " "	500's	4961	6647	2999	
9.	C. 10. Ampicillin Cap.	16's	239008	93833	36677	
10.	C. 10. " "	100's	15070	8000	8497	
11.	C. 10. " "	500's	4669	2201	599	
<u>INJECTIONS</u>						
1.	S.P. 91. Streptomycin Sulphate Injection	10ml. Vial.	7704800	960000	3257300	
2.	S.P. 94. Crystalline Penicillin 5 Lakhs	" "	929620	-	1435550	
3.	S.P. 95. Fortified Procaine Penicillin 4 Lakhs	" "	12655950	3803350	4181350	
4.	S.P. 117. Tetracycline Eye Ointment.	Tube	1210032	345600	933408	

Source: MPI.

**MYANMA**  
**APPENDIX III-24: ORGANIZATION CHART/PHARMACEUTICAL INDUSTRIES (MPI)**



Factorywise Production Value for the Previous five fiscal years.

(Kyats in millions)

Factories	84-85	85-86	86-87	87-88	88-89	Remarks.
Burma Pharmaceutical Industry	130.30	138.22	120.43	77.47	121.53	
Pharmaceutical Rawmaterial Factory	2.45	2.26	1.02	1.03	1.69	
Toilet Industry	29.59	26.47	17.72	5.19	15.08	
Plastic Factory No. (1)	15.31	19.65	5.77	6.00	5.22	
Plastic Factory No. (2)	12.87	11.34	7.24	2.73	1.42	
Plastic Factory No. (3)	2.51	5.35	5.75	3.72	3.84	
Soap Factory No. (1)	144.60	129.55	97.28	63.66	46.77	
Soap Factory No. (2)	115.33	127.59	109.63	73.27	39.79	
Soap Factory No. (3)	12.62	14.65	12.04	5.31	3.34	
Industrial Oil Factory	24.75	25.74	36.54	30.33	19.74	
Refined Oil Factory	—	8.05	6.95	8.39	11.01	
Coconut Industry	2.04	10.75	6.38	2.79	2.51	
Total —	492.37	519.65	426.75	279.89	272.01	

Source: MPI

## Basic data sheet of the factories under Myanmar Pharmaceutical Industries

ANNEX III-26

Sr. No.	Factories	Year of commencing operation	Investment Kyats in millions			Annual requirement of major raw materials			Annual production capacity			Capacity Utilization				
			Local	F.E	Total	Item	A/U	Quantity	Item	A/U	Quantity	84-85	85-86	86-87	87-88	88-89
1.	Burma Pharmaceutical Industry	1957	70.21	36.50	106.71	Oil and waxes	MT	190	Pharmaceutical Products (Powder)	kilos	520,000	66	69	56	32	29
						Sugar	"	950	• do (Liquid)	Liters	718,830					
						Antibiotics	"	40	• do (Ointment)	kilos	205,000					
						Vitamins	"	45	•• do (Tablet & Capsules)	(ooo) Nos.	1839,392					
						Industrial raw material	"	150	•• Injection (ampoules)	"	65,700					
						Hormones	"	0.2	• Biological Products	(ooo) Doses	9,360					
						Chemicals	"	1325	••• Alcohol Products	gallons	297,000					
						Broken rice	"	1200	••• Yeast	pounds	120,000					
						Molasses	"	4450	• Contact Lens	Nos.	3,750					
						Component Bottles	mill-ion	27	• Dehusked tamarind seeds.	MT	300	22	21	14	23	95
						Ampoules with accessories	"	150	• Castor Oil	"	100					
2.	Pharmaceutical Raw Material Factory	1971-72	26.79	1.57	28.36	Tamarind Seeds	MT	600	• Citronella Oil	Ky	500					
						Crude Castor Oil	"	200	• Menthol Oil	"	500					
						Lemongrass Leaves	"	400	• Pyrethrum extract	MT	11					
						Industrial Raw Materials	"	90	• Dried ferrous Sulphate	Kg	700					
						Pyrethrum flowers	"	9	Liquid glucose	Kg	2,500					
						Sulfuric Acid & Other Chemicals	"	13								
						Tapioca Powder	"	5								

Source: MPI

ANNEX IV. 1. EQUIPMENT IN THE FERMENTATION DEPARTMENT  
( INCLUDING LABORATORIES )

SR. No.	ARTICLE	SPECIFICATION	QUANTITY ( SET )
1.	Centrifuge Max. Refrigerated Max.	: Revolution 18000 r.p.m : Centrifugal forces 43000 x G	1
	Refrigerator	: hermetically sealed	
	Timer	: 0 to 60 min.	
	Exterior	: Steel finished with damp-proof melamine plastic.	
	Chamber	: Stainless steel	
2.	Centrifuge, Low - speed	Max. : Revolution : 3500 r.p.m Max. : Centrifugal force : 2750 x G Capacity : 50 ml x 12 tubes 15 ml x 60 tubes Type of rotar : Swing type	1
3.	Temperature Gradient Incubator	On low - temp side temp range : 0°C to Room temp temp control accuracy : $\pm 0.2^\circ\text{C}$ Refrigerator : hermetically type 300W Pump : 15W, 15 l/min On high temp side temp range : Room temp to 75°C temp control accuracy : $\pm 0.2^\circ\text{C}$ Heater : 150 W x 2 Shaker : 20 to 70 r.p.m no variable range	1
4.	Microscope, Phasecontrast	Observation tube : trinocular, inclined 45° Stage : mechanical stage, traversing area 50 x 76 mm Condenser : Phase turret (N.A. 1.25) Total magnification : 100x - 1000 x 50x - 500 x (Photograph) Eyepieces : GFW 10x (2) Objectives : GF Plan DL, 10x, 20x, 40x, 100x Illuminator : halogen lamp 12V, 50W Power source : A.C., 100V, 50Hz, single Phase	1

SR. No.	ARTICLE	SPECIFICATION	QUANTITY (SET)
5.	Microscope, Microflex type	Photoapparatus consisting of microflex HFM mains body, power cord type AE, ocular finder, focusing magnifier 4 x, motorised dark box H-35 FA and Camera adaptor	1
6.	Zoom scope	<p>Parallel optic zoom system</p> <p>Stereo micro-magnification : From 3.3 to 150 x depending on eye pieces and auxillary objective lens used.</p> <p>Eye pieces : wide field 10x, Ultra - wide field 15 x and 20 x.</p> <p>Objective lens : 0.66 x to 4 x with 6 : 1 zoom ratio</p> <p>Interpupillary distance   Adjustable from 50 to 74 mm.</p> <p>Focusing : Fine focusing with rack and pinion control, coarse focusing with pillar clamp, fine focusing range approx. 40m.</p> <p>Optical Head : Rotatable 360°</p>	1
7.	Drying Oven	<p>Temp range : 50°C to 300°C</p> <p>Time to reach maximum temp : 30 to 45 min.</p> <p>Temp control accuracy : <math>\pm 2^\circ\text{C}</math> at 300°C</p> <p>Inner wall : Stainless steel, SUS - 304</p> <p>Capacity : 72 litre</p>	1
8.	Rotary Evaporator	<p>Number of revolution : Approx. 30 to 180 r.p.m</p> <p>Motor : Condenser type torque motor, 4 - pole 30W</p>	3
9.	Freeze dryer	<p>Temp in cold trap : - 54°C</p> <p>Cap of cold trap : 5 litre</p>	1
10.	Fraction Collector	<p>Sample Collecting method : weight method</p> <p>Sample Collecting range : 1 - 20 gm</p> <p>Test tube Capacity : 200 pcs</p>	3

SR. No.	ARTICLE	SPECIFICATION	QUANTITY (SEE)
11.	PH - meter	measuring range: PH 0 - 14 mV - $\pm$ 700  Accuracy : 0.03 PH $\pm$ 5 mv  Min graduation : 0.1 PH 10 mv  Temp Compensation : 0 - 100°C	1
12.	Ultrasonic vibrator	Frequency : 20 kHz  output : 200 W  Capacity : 2 ml - 500 ml (max)  Timer : 70 min	1
13.	NEOCOOL ASPIRATOR	Temp range : 5°C to + 40°C  Free air capacity : 6 to 7 l/min = 2  Refrigerator : Air - cooled closed type, 300 W  Thermometer : -10°C to + 50°C remote reading type  Over cooling prevention device } : gas - type compact } thermostat	1
14.	Direct reading balance	For semi-micro analysis  capacity : 200 gm  Readability : 0.01 mg  Projection scale : -12 + 112  One div; of projection scale; 1 mg  Pan dia : 75 mm	1
15.	Spectro- photometer	Built - in micro computer  Optics : grating (Littrow mounting type)  Light sources: D <sub>2</sub> lamp and W lamp, atically switchable  Detector : photomultiplier  Sample compartment : beam spacing 100 mm, 120 (W) x 300 (D) x 140 (H)  Wave length range : 190 - 900 m u  Wave length indicator : 4 - digit, 0.1 m u  Wave length accuracy : $\pm$ 0.3 m u  Wave length reproducibility : 0.1 m u	1



SR. No.	ARTICLE	SPECIFICATION	QUANTITY (SET)
16.	Infrared-Spectro photometer	<p>Stray light: below 0.0% at 220 <math>\mu</math>m</p> <p>Bandwidth : 0.1, 0.2, 0.5, 1,2 and 4 <math>\mu</math>m</p> <p>Photometric accuracy; <math>\pm 0.02</math> ABS (0-0.5ABS) <math>\pm 0.3\%</math> T</p> <p>Photometric reproducibility: <math>\pm 0.001</math> ABS (0-0.5 ABS) <math>\pm 0.1\%</math> T</p> <p>Scan speeds: 15,30,60,120,240 and 480 <math>\mu</math>m.</p> <p>Wavenumber ranges: 4000-650 <math>\text{cm}^{-1}</math>.</p> <p>Resolutions: Standard 1.5 <math>\text{cm}^{-1}/1000 \text{cm}^{-1}</math> (more. 0.4 <math>\text{cm}^{-1}/1000 \text{cm}^{-1}</math>)</p> <p>Photometric system: double beam, optical null, Littrow type filter-grating single monochromator.</p> <p>Light source: Special coil type, 1100°C, 45W</p> <p>Sample compartment: OPL 150 mm, beam spacing 110 mm, optical axis height 78 mm.</p> <p>Gratings: high energy type (H type) single element, 1<sup>st</sup> order.</p> <p>Detector: double sealed window, high sensitivity, vacuum thermocouple.</p> <p>Wave number accuracy: <math>\pm 6 \text{cm}^{-1}</math> for 400-2000 <math>\text{cm}^{-1}</math> <math>\pm 3 \text{cm}^{-1}</math> (for 2000-650<math>\text{cm}^{-1}</math>)</p> <p>Scan times: 2.5 min. - 58 hrs. Standard 5 min (for qualitative analysis)</p> <p>Wave number scale expansion } : 1/2 x, 1 x, (note back size) 2 x, 4 x, 5 x, 8 x, 10 x, 20 x, 40 x, 80 x</p>	1

Sl. No.	ARTICLE	SPECIFICATION	QUANTITY (Set)
17.	Prism-Scope melting point determinator	2 eye-pieces revolver: x 75, x 150 Thermometers: -20 to 120°C, 220-360°C $\frac{1}{2}^{\circ}$ Temp and v controller : 10A, with V meter Camera holder: lens dia. up to 60 mm	1
18.	Agarwell-cutter	Standard processing caps: 12 petri dishes/min Hole punching: number of holes: 4 hole diameter: 8 mm hole pitch : $\square$ 34 mm Petridish to be used : 90 (Dia) x 15 (H) mm Thickness of agar layer: 3 to 4 mm	1
19.	Micro-planter	Collecting cap : approx. 0.005 ml Collecting bar : $\phi$ 3 mm number of bars : 27	1
20.	Incubator	Effective inside caps: 400 litre Temp range : 10°C to 35°C Temp control : high-precision electronic system for automatic operation (graduations of 1°C), variable from - 10°C to 50°C Temp sensor : platinum thermometric resistor	2
21.	Autoclave	Cabinet interior: Stainless steel Max. pressure: 1.3 Kg f/cm <sup>2</sup> Max. temperature: 123°C Heater : pipe heater 1.5 KW Chamber Capacity: 20 litre Chamber material: Stainless steel Timer : 60 min.	1
22.	Hot air sterilizer	Automatic type Operating temp range: max. 220°C Temp. accuracy : $\pm$ 2.5°C Thermoregulator: liquid expansion type Timer: electric timer, 72 min Door: Single wall Capacity: approx. 356 litre	1

Sr. No.	ARTICLES	SPECIFICATION	QUANTITY (SET)
23.	Dispenser	Fluid flow range : 5 ml - 100 ml speed control range: approx. 18 - 30 times/ min (10 ml) , approx. 12 - 20 times/ min (100 ml)	1
24.	Fermenter	(1) Fermenter 1. Fermenter Vessel. Capacity of Vessel : 30 litres Diameter of Vessel : 284 mm Depth of Vessel : 479 mm	2
25.	Fermenter	150 litre (Local) Capacity of vessel : 150 lit Diameter of vessel : 460 mm Depth of vessel : 900 mm Impeller diameter : 180 mm BEING TESTED (UNDER COMMISSIONING )	1 No.
26.	Compressor unit for Fermenter	Max. pressure : 7 Kg/cm <sup>2</sup> Air outflow rate : 1601/min No of revolution : 1240 rpm Air tank : 85 l	1
27.	Shaker	Refrigerated Shaker with panel for erlenmeyer 1,000 ml flask for erlenmeyer flask 200 ml	2
28.	Centrifuge, basket type	Number of revolution : 2000 rpm effective capacity : 121 litre Size of basket : 400 $\phi$ x 200 (D) mm	1
29.	FRACTIONAL DISTILLATION APPARATUS	Distilling vessel capacity : 20 litre steam heating : Up to 1 Kg/cm <sup>2</sup> Initial distillation : 5 litre/hr Time of initial distillation : approx. 30-40 min	1
30.	Thermo-Shaker	Temp range : room temp + 5°C to 70°C Temp controller : thermister Heater : 1.3 KW	1

SR. No.	ARTICLE	SPECIFICATION	QUANTITY (SET)
		Circulating system : pump circulation type 12l/min  Shaking : horizontal  Shaking width } : 40 mm  number of shakings: 20 to 150 times/min Sample capacity: 17.5% test tubes 99 x 2 Optical system: double-beam type Wavelength range : 195 nm - 380 nm Spectrum width: approx. 7.5 nm Wavelength accuracy: $\pm 2$ nm Photometric Scale : 0.005 - 2.56 (10-steps)  Light source : heavy hydrogen lamp. Detector : photoelectric tube	1
32.	Liquid - Chromatograph	Main Unit UV - VIS spectrophotometric Detector Data Processor.	1
33.	Gas-generator	Used for 10 sets of burner gas generating cap : 3 m <sup>3</sup> /h Dimensions (mm): 750(W) x 550(D) x 290(H) weight (Kg) : approx 43	2
34.	Autoclave	Internal dimension 650W : 760H; 800D mm Max. Pressure 2.0 Kg/cm <sup>2</sup> Heating Source : Saturated Steam Sterilization : Two position control 100°C ~ 132°C	1

ANNEX IV-2-EQUIPMENT IN THE UTILITIES DEPARTMENT

.1. Boiler House

Specifications

Model	KMH - 02A
Kind of Boiler	Fire Tube - Smoke Tube Boiler ( Horizontal Type )
Boiler Unit	Fully Packaged - Indoor Service
No. of Heat Passage	Two (2) Passages
Construction	All - welded
Design Pressure	10 Kg/cm <sup>2</sup> g ( 142.2 psig )
Working Pressure	Up to 9 Kg/cm <sup>2</sup> g ( 128.0 psig )
Steam Temperature	Saturated Steam 179.1°C ( 354.4°F )
Evaporation Equivalent ( K.C.R )	1,200 Kg/h ( 2,646 lbs/h )
Actual	1,000 Kg/hr ( 2,205 lbs/h )
Boiler Horse Power	77 B.H.P
Heat Output	642x10 <sup>3</sup> Kcal/h ( 2,548x10 <sup>3</sup> Btu/h )
Boiler Efficiency	87%
Burning System	Oil-Fired
Draft System	Forced Draft
Kind of Fuel	Heavy Oil (A)
Ignition	Electric Spark
Net Calorific Value of Fuel	Heavy Oil (A) 10,140 Kcal/Kg (18,250 Btu/lb)
Fuel Consumption	Heavy Oil (A) 72.8 Kg/h (160-5 lbs/h)
Feed water Temp.	20°C (68°F)
Heating Surface	12.15 m <sup>2</sup> (130.8 ft <sup>2</sup> )
Power Requirements	6.4 KW
Hydro. Test Pressure	16 Kg/cm <sup>2</sup> g (227.6 psig)
Normal water Capacity	1,600 Kg (3,527 lbs)
Boiler Weight (Dry)	4,900 Kg (10,803 lbs)

.2. Air Compressor

Specifications of Compressor

Type - Form	VE-4
Cylinder Diameter	200 mm
Stroke	125 mm
Speed	562 rpm
Piston Displacement	8.7 m <sup>3</sup> /min
Delivery Pressure	7 Kg/cm <sup>2</sup> g

Specifications of Motor

Type- Form	EFOUP - KK
Output	37 KW
Frequency	50/60 Hz
Voltage	400 V
Speed (SS)	1500/1800 rpm
Poles	4 P
Frame No.	EFOU- 200 M

.3. Toshiba Air Cooled Chilling Unit

Specifications

Model	EUA - 302 E	
Cooling Capacity	67,600 Kcal/h	
Painting	(Munsell 1.08 G 5.1/2.2)	
Height	2,000 mm	
Width	Dimensions	
Depth		3,330 mm
		1,200 mm
Net weight	1,580 Kg	
Operation weight	1,640 Kg	
Main Circuit	3 Phase 200 V 50 Hz	
Power Supply Control Circuit	1 Phase 200 V 50 Hz	
Current	97.8 A	
Output	26.3 KW	
Power Factor	77.6%	
Starting Current	283 A	
Compressor Motor	10.7 x 2 KW	
Condenser	Finned Tube	
Condenser Fan	Propeller	
Fan Motor Output	0.4 x 3 KW	
Evaporator	Shell & Tube	
	Outlet Temp	
Chilled water	7°C	
	Volume	
	225 l/min	
	Loss Head	
	1.5 m/q	

Scope of Chilled water Outlet	5 - 15°C
Refrigerant Control	Expansion Valve
Refrigerant (Volume)	R - 22 ( 24 Kg )
	Inlet 65 A Frange
Pipe Chilled (Diameter) water	
	Outlet 65 A Frange
	Drain 15 A Female

**.4. Toshiba Hermetic Centrifugal Water Chiller**  
**(120 RT)**

**Main Specification**

Model	RS - 12 CS
Refrigerating Capacity	362,880 Kcal/h
Refrigerant	R - 11
Chilled water Inlet Temp	12°C
Chilled water Outlet Temp	7°C
Chilled water Quantity	72.6 m <sup>3</sup> /h
Cooler	2. path Pressure drop; 8 m Aq
Water pressure	10 Kg/cm <sup>2</sup> or less
Cooling water Inlet Temp	38°C
Cooling water Outlet Temp	42°C
Cooling water Quantity	118 m <sup>3</sup> /h
Condenser	1 - path Pressure drop; 4 m Aq
Water pressure	10 Kg/cm <sup>2</sup> g or less
Main Electric Motor	125 KW 6600 V 50 Hz 3φ
Starting System	Reactor Start
Compressor	1 stage gear accelerating system
Capacity control Range	100 ~ 20%
Weight in operating	4500 Kg

.5. Cooling Water Pump

Specifications

<u>Pump</u>		<u>Motor</u>	
Type	JOV - GH	Type	TFO - KK
Bore	125 x 100 mm	Output	18.5 KW
Capacity	2.3 m <sup>3</sup> /min	Voltage	400 V
Total Head	24 m	Hertz	50 Hz
Speed	1500 rpm	Poles	4 P

.6. Chilled Water Pump

Specifications

<u>Pump</u>		<u>Motor</u>	
Type	JOV - GH	Type	TFO - KK
Bore	100 x 80 mm	Output	15 KW
Capacity	1.21 m <sup>3</sup> /min	Voltage	400 V
Total Head	23.0m	Hertz	50 Hz
Speed	1500 rpm	Poles	4 P

.7. Well Water Pump

Specifications

<u>Pump</u>		<u>Motor</u>	
Type	PMU & MV	Type	VCTO - KK
Bore	80 mm	Output	11 KW
Capacity	0.4 m <sup>3</sup> /min	Amperes	23 A
Total Head	60 m	Voltage	400 V
Speed	2900 rpm	Hertz	50 Hz
		Poles	2 P

Weight 173 Kg

.8. Iron Removing Pump

Specifications

<u>Pump</u>		<u>Motor</u>	
Type	JOV - GH	Type	TFO - K
Bore	65 x 50 mm	Output	3.7 KW
Capacity	0.4 m <sup>3</sup> /min	Voltage	400 V
Total Head	20 m	Hertz	50 Hz
Speed	1500 rpm	Poles	4 P



.9. Lift Pump

Specifications

<u>Pump</u>		<u>Motor</u>	
Type	JOV - GH	Type	TFO - KK
Bore	80 x 65 mm	Output	7.5 KW
Capacity	0.75 m <sup>3</sup> /min	Voltage	400 V
Total Head	35 m	Hertz	50 Hz
Speed	3000 rpm	Poles	2 P

.10. Cooling Tower

Specifications

Cooling Capacity	690,000 Kcal/h
Entering Temp	43°C
Leaving Temp	38°C
Air Temp	32°CWB
Cooling water	2,300 l/min
Fan Motor	3.7 KW
Power Source	AC 3φ 400 V
Pressure Drop	2.2 m Aq
Operating weight	1.870 Kg
Type	MT - 15012

ANNEX IV.3. RESUME OF JAPANESE EXPERTISE PROVIDED AND  
TRAINING GIVEN TO LOCAL STAFF IN JAPAN

No. of Japanese Experts attached to the DCPT during the year 1981-83

	Time period of teaching	
1. Team leader	1 person	21 months
2. Mechanic, operators & fitters	3 "	5.1 months
3. Pharmaceutical research	4 "	16 months
4. Fermentation research	2 "	2 months
5. Medicinal plants	2 "	3 months

No. of trainees sent to Japan during the year 1981-83

1. Tableting Technology	1 person	6 months
2. Injection "	1 "	6 months
3. Fermentation Technology	1 "	6 months
4. Pharmaceutical Quality Control	2 "	7 months

No. of Japanese Experts attached to the DCPT during the year 1983-85

1. Team Leader	2 persons	24 months
2. Engineering and Mechanic	3 "	1.7 months
3. Pharmaceutical Research	2 "	2 months
4. Medicinal Plants	1 "	3 months
5. Fermentation Research	2 "	1.3 months
6. Pharmaceutical Quality Control	3 "	4 months

No. of trainees sent to Japan during the year 1983-85

1. Tableting technology	1 person	6 months
2. Injection Producing technology	1 "	6 months
3. Fermentation Technology	1 "	6 months
4. Medicinal Plants Technology	2 "	12 months
5. Pharmaceutical Quality Control	1 "	6 months

Project Director of Matsuda Hirata, Sakamoto, Architects, Planners &  
Engineer

Mr. M. Takahashi and Resident Engineer Mr. Matsuda

Date of Arrival 19-1-81

departure 22-1-81

ANNEX IV.4. Details of the Training of local staff abroad

No. No.	Name	Department	Particulars of training	Country	Duration	Remarks
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1.	U Myint Hla	Tablet Dept.	Tablet Formulation and Preparation	Japan	7-1-82 8-7-82	
2.	U Tin Shwe	Injection Dept.	Injection Formulation and Preparation	Japan	7-1-82 8-7-82	
3.	U Kyaw Sein (3)	Method Research	Quality Control	Japan	9-1-82 9-4-82	
4.	U See Thein	Utilities Dept.	Maintenance Engineering	Japan	5-1-82 4-12-82	
5.	U Kyaw Sein (2)	Quality Control	Quality Control Dept.	Japan	24-1-83 8-6-83	
6.	U Myint Swe	Injection Dept.	Pharmaceutical Preparation	Japan	11-1-84 20-6-84	
7.	Daw Saw Yu Men	Fermentation Dept.	Fermentation Technology	Japan	24-1-83 10-8-83	
8.	Daw Khin Than Myint	Quality Control Dept.	Quality Control	Japan	11-1-84 19-6-84	
9.	Daw Mi Mi Khine	Medicinal Plant Dept.	Pharmacognosy	Japan	11-1-84 19-6-84	
10.	U Maung Maung	Fermentation Dept.	Doctorate Microbiology	France	8-9-83 28-7-87	Doctorate degree, Diploma
11.	U Myint Sein	Quality Control	Process Biochemistry	France	8-9-83 9-12-88	Doctorate degree
12.	U Tin Oe	Fermentation Dept.	Fermentation	Japan	26-9-84 20-3-85	Training

Sr. No.	Name	Department	Particulars of training	Country	Duration	Remarks
13.	Daw Kyi Kyi Win	Medicinal Plant Dept.	Pharmacognosy	Japan	26-9-84 20-3-85	Training
14.	U Aung Myint (1)	Tablet Dept.	Pharmaceutical Product Development	Japan	26-9-84 20-3-85	
15.	U Myo Myint	Fermentation	Microbiology	France	20-9-84 7-11-89	Doctorate degree
16.	U Kan Thoin	Tablet Dept.	Practical Training in Pharmacy	Singapore	9-11-85 12-1-86	
17.	Daw Saw Yu Non	Fermentation	International Microbiology	Japan	5-10-87 20-11-88	Diploma (Industrial Post graduate University Course)

ANNEX IV.5 RESUME OF QUALIFICATIONS AND TRAINING/

EXPERIENCE OF KEY PERSONNEL OF DCPT

.1. U TIN Oo

(i) ACADEMIC QUALIFICATIONS

Electrical engg. (COM) 1963

Govt. Technical Institute

M. Sc. (Chemical Process Engg.)

Leningrad Chemico-Pharmaceutical

Institute, U.S.S.R 1972

(ii) Experience/Training

Dy. Research officer, DCPT 1984

(Head of Fermentation Dept.)

Asst. Research officer, DCPT 1979-84

Asst. Manager, MPI 1973-79

(Vaccine Production fermentation)

Basic Engg. Course 1965-69

Leningrad University

Research Work on Fermentation

of Yeast Polysaccharide

Chemico Pharmaceutical 1969-72

Institute, Leningrad

Training at Ascorbic acid

plant, Leningrad; Leningrad

Antibiotic Research Institute

Minsk Antibiotics Plant ,

(Tetracycline fermentation)

Training at Meiji College of

Pharmacy, Tokyo, Japan

(Fermentation of Kanamycin)

Training at Osaka University

(Steroid fermentation)

.2. DAH SAN YU MON

ACADEMIC QUALIFICATIONS

B. Sc. (Industrial Chemistry) 1978

Yangon Arts and Science University

B.E. (Chemical) 1980

Yangon Inst. of Technology

Diploma in Microbiology 1988  
Osaka University  
(Production of Naridomycin)

Experience/Training

Biology Dept., MPI 1981-82  
Fermentation Dept, DCPT 1982  
Hoshi College of Pharmacy, Tokyo 1983  
(Instrumentation analysis) (6 months)

Takeda Chemical Industry, Osaka  
(Fermentation and Purification of  
Dihydrostreptomycin and Naridomycin  
Meiji College of Pharmacy, Tokyo  
(Purification of enzymes)

DCPT 1983-87  
(Dihydrostreptomycin Purification,  
Import Substitution of raw materials)

Osaka University 1987-88  
Production of Naridomycin  
Studies on dissolved oxygen  
Factory visits to Ajinomoto Co.  
(MonoSodium Glutamate Production)  
Gifu Factory  
(Medomycin, cloxacillin, Penicillin,  
Cellulase, Protease)  
Present Position, Assistant Research officer, DCPT  
(Fermentation Dept.)

.3.

DR. MYINT SKIN

ACADEMIC QUALIFICATIONS

B. Sc. (Chemistry) 1969  
University of Yangon  
Diploma (Medical Technology)  
University of Yangon  
D.E.A. (Food Sc.) 1985  
INSAIA - INPL, Nancy, France  
(Physiological and Kinetic Studies  
Corynebacterium Glutamicum - lysine Production)

Ph. D. (Biotechnology) 1988  
INP, Lorraine, Nancy, France  
(Kinetics and Modelling of the  
Lysine fermentation by *C. glutamicum*)

Experience / Training

Biochemistry Dept., Yangon Hospital 1970-82  
(Production of blood grouping Sera,  
blood Components, Immuno Chemical  
investigations at Central Blood Bank)

WHO fellowship to study plasma 1972  
fractionation technology in Hungary and U.K.

Research Chemist, DGPT 1982  
(Methods Research and Quality Control)

Short term Practical training at  
Rhône - Poulenc's fermentation plant  
at St. Aubin - les - Elbeuf, Normandy and  
Vitry - Sur - Seine, Paris, France.

Present - Asst. Research Scientist, DGPT 1988  
(Microbial nutrition and medium design)

4. DR MAUNG MAUNG

ACADEMIC QUALIFICATIONS

B.Sc. (Botany) 1967-68  
University of Yangon

M. Sc. (Botany) 1979-82  
University of Yangon

Ph. D. (Biotechnology - Microbiology) 1983-87  
Institute National des  
Sciences Appliquées, Toulouse, France  
Acetic acid fermentation, Pristinamycin  
production fermentation

Experience / Training

Training-Dept. of Pharmaceutical  
Chemistry, Sector Biochimique, Rhône -  
Poulenc Industries

Manufacturing plant at St. Aubin - les -  
Elbeuf (Streptomycin, Penicillin, Vitamin B<sub>12</sub>,  
Spiramycin)

Manufacturing plant Usine de Vitry - Sur - Seine  
(Pristinamycin, Spiramycin)

Research Assistant, DCPT 1982-86  
(Fermentation Dept.)  
Present - Asst. Research officer, DCPT 1986  
(Microbial fermentation and  
strain improvement on Streptomyces)

.5. DR. KYO MYINT

ACADEMIC QUALIFICATIONS

B. Sc. (Botany) 1969

University of Yangon

M. Sc. (Botany) 1978

University of Yangon

(Production of Citric acid by *A. niger*)

D.E.A. 1986

Institut National des Sciences

Appliquees, Toulouse, France

(Degradation of Pristinycine

by Proteolytic activity)

Ph. D. INSA, Toulouse, France Fermentation 1989

(Production of antibiotics by non technology

conventional techniques)

Research Assistant, DCPT 1983-87

Present - Asst. Research officer, DCPT 1987

(Fermentation Dept.)



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ANNEX IV-6 LIST OF EQUIPMENT REQUIRED  
FOR PILOT PLANT (DCPT)

<u>Sr.No.</u>	<u>EQUIPMENT</u>	<u>NO.</u>
1.	Counter current liquid - liquid extractor, A.I.S.I.316 stainless steel, laboratory model, through put 200 litres in one hour, with explosion proof motor (Westfalia, Podbielniak types)	1
2.	A.I.S.I.304 stainless steel holding tank with cover, 150 litre capacity	1
3.	A.I.S.I.316 stainless steel tank, jacketed with conical bottom and agitator, explosion proof motor, 50 litre capacity	1
4.	A.I.S.I.304 stainless steel crystalliser, jacketed capacity 50 litres, with agitator	1
5.	A.I.S.I.304 stainless steel centrifugal pump laboratory model	1

**ANNEX IV-7**

**Statement Showing Acreages Production and Acre Percentage  
under Various Groups of Crops**

Serial No.	Crops	1985-86 (in thousand)		Percentage (Sown Area)
		Acreage	Production (tons)	
1	2	3	4	5
I	Cereals	13759	14828	53.62
a	Paddy	12114	14091	47.21
b	Wheat	296	187	1.15
c	Maize	677	313	2.64
d	Other Cereals	672	237	2.62
2	Oil Crops	5732	1017	22.34
a	Groundnut	1470	551	5.73
b	Sesamum	3489	244	13.60
c	Sunflower	575	212	2.24
d	Others	198	10	0.77
3	Peas and Beans	2249	611	8.76
a	Black Mung	251	93	0.98
b	Burma White Bean (Butter Beans)	187	91	0.73
c	Burma Red Bean (Sultani/ pya)	112	29	0.44
d	Gram	539	168	2.10
e	Pigeon Pea	204	51	0.79
f	Others			
4	Industrial Crops	1201	3962	4.68
a	Cotton	532	98	2.07
b	Jute	151	49	0.59
c	Sugarcane	308	3792	1.20
d	Rubber	190	15	0.74
e	Virginia Tobacco	20	8	0.08
5	Food Crops	676	512	2.63
a	Potato	44	180	0.17
b	Onions and Garlic	83	267	0.32
c	Chillies	178	43	0.69
d	Vegetables	351	-	1.37
e	Spices	20	22	0.08

Source: UNDP, Selected Sectoral Reviews, Burma, 1988

ANNEX IV-8. Production and exports of major crops, 1988/89  
(in thousand tons)

Crops	1988/89 <sup>a/</sup>	
	Production	Exports
Paddy	13,552.8	198.0
Wheat	229.8	-
Maize <sup>b/-</sup>	259.3	6.0
Pulses	581.9	18.7
Groundnuts	564.5	-
Sesamum	177.8	0.02
Chillies	37.9	-
Onion	161.2	-
Garlic	40.9	-
Potatoes	116.3	-
Balad jute	25.4	-
Ginned cotton	20.7	0.9
Sugar cane	2,321.7	-
Rubber	14.7	2.1
Burmese tobacco	56.1	-
Virginia tobacco	1.0	-

Source: UNIDO Industry Sector Review Mission to Myanmar, 1989.

a/ Provisional.

b/ Maize cob and maize sheet.

**ANNEXURE I LIST OF MAJOR EQUIPMENT FOR THE PILOT PLANT**

**Note:** Equipment number consists of four digits

1st. digit indicates unit of operation, i.e., Fermentation (1), Recovery/purification (2), Sodium penicillin (sterile) (3), Ampicillin bulk (4) and Solvent recovery (5)

2nd digit indicates type of equipment Tank (1), Pump (2), Filter/centrifugal extractor (3), Continuous sterilizer/Still for product concentration (4), drier (5), Solvent recovery distillation column (6), mill (7)

3rd and 4th digits indicate serial number of type of equipment for the specific production unit.

- A. The equipment have been designed keeping in view the actual need based requirement of the fermentation pilot plant.
- B. Many equipment have been standardized to reduce *CRITICALITY* of the process equipment and hence reduce down time to increase availability and productivity on equipment.
- C. Inventory on capital investment reduced to minimum keeping in view the high costs of equipment.
- D. The process equipment designed, has the desired flexibility to produce any product as the plant equipment is adequate for any standard process unit operations and can cater to the needs of most of the fermentation based products.

ANNEX VIII-1: List of Major Equipment for the Pilot Plant

Sr. No.	Equipment No.	Equipment Specifications	Floor of Installation and Operation	Cost (F.O.B) US \$
(1)	(2)	(3)	(4)	(5)
<u>FERMENTATION</u>				
1.	T-1101	Fermentor, capacity 30 lits SS-316 (AISI), Jacketted with 0.2 KW agitator motor propeller type impeller	2 nd	1500/-
2.	T-1102	Fermentor, capacity 300 lits SS-316 (AISI), Jacketted with 0.5 KW agitator motor propeller type agitator two 1/8 dia baffles	2 nd	3500/-
3.	T-1103	Fermentor capacity 1000 lits SS-316 (AISI), Jacketted with 4.0 KW agitator motor straight blade turbine impeller 1/3 D, Three 1/8D baffles	2 nd	7500/-
4.	T-1104	Fermentor capacity 2000 lits SS-316 (AISI) Jacketted with 8.0 KW agitator motor two impellers (straight blade turbines 1/3D) Four 1/10D baffles	2 nd	9700/-
5.	T-1105	-do-	2 nd	9700/-

(1)	(2)	(3)	(4)	(5)
6.	T-1106	<p>Fermentor capacity 20,000 lits SS-316 (AISI)  internal vertical cooling tube banks four numbers  of 10 tubes each (50 mm Dia-4.0 m length) connected  to 10 cm in-coming, out-going cooling water  headers. Hight 6.3 m Dia -2.1 m wall thickness 8mm,  Agitator motor - 90 KW with two speed reduction gear  for 60 and 100 RPM with three impellers (two straight blade  turbines and one axial flow type). Air sparger  all instruments (TRC, P.I, PSV, PHRC, DOA, Foam control device)  connected.</p>	2 nd	75000/-
7.	T-1107	-do-	2 nd	75000/-
8.	F-1301	<p>Cartridge type sterilisable air filter 20 M retention as primary  air filter for T-1101 and T-1102</p>	2 nd	300/-
9.	F-1301 B	<p>Cartridge type sterilisable air filter 0.3 M retention as sterile  air filter for T-1101</p>	2 nd	400/-
10.	F-1302 B	<p>Cartridge type air filter 0.3 M retention as sterile air filter  for T-1102</p>	2 nd	400/-
11.	F-1303 A	<p>Cartridge air filter 20 M retention (Three elements) for T-1103</p>	2 nd	300/-
12.	F-1303 B	<p>Cartridge air filter 0.3 M retention (one element) sterile filter  for T-1103</p>	2 nd	400/-

(1)	(2)	(3)	(4)	(5)
13.	F-1304 A	Cartridge air filter 20 M retention three elements for T-1104	2 nd	700/-
14.	F-1305 A	-do- for T-1105	2 nd	700/-
15.	F-1304 B	Cartridge air filter 0.3 M retention one elements for T-1104	2 nd	400/-
16.	F-1305 B	-do- for T-1105	2 nd	400/-
17.	F-1306 A	Cartridge air filter 20 M retention six elements for T-1106	2 nd	1300/-
18.	F-1307 A	-do- for T-1107	2 nd	1300/-
19.	F-1306 B	Cartridge air filter 0.3 M retention six elements for T-1106	2 nd	2600/-
20.	F-1307 B	-do- for T-1107	2 nd	2600/-
21.	T-1108	Media mixing tank 7500 lits capacity, S S-304 (AISI) Agitator motor 7.5 KW two impellers, propeller/axial flow type	1st	19500/-
22.	T-1109	Media mixing tank 2000 lits capacity SS-304 Agitator motor 2.0 KW with one impeller (propeller)	1st	8000/-
23.	T-1110	Oil storage tank 500 lits capacity M.S	1st	400/-
24.	T-1111	Extra medium number-1 preparation tank capacity 1500 lits SS-316 with Jacket for T-1106	2 nd	1000/-
25.	T-1115	-do- for T-1107	2 nd	1000/-
26.	T-1112	Extra medium no.2 preparation tank capacity 1000 lits SS-316 for T-1106	2 nd	1000/-
27.	T-1116	-do- for T-1107	2 nd	1000/-

(1)	(2)	(3)	(4)	(5)
28.	T-1113	Extra medium No 3 preparation tank capacity 750 lits SS-316 for TA 1106	2nd	1100/
29.	T-1117	Extra medium No 3 preparation tank capacity 750 lits SS-316 for TA 1107	2nd	1100/
30.	T-1114	Extra medium No 4 holding tank SS-316 Cap. 500 lits for TA-1106.	2nd	900/
31.	T-1118	Extra medium No 4 holding tank SS-316 Cap. 500 lits for TA-1107.	2nd	900/
32.	T-1119	Concentrated sulphuric acid dosing tank M.S 200 lits	2nd	50/
33.	S-1401	Heater holder, steriliser, cooler for Extra medium No.1 for TA-1106 SS-316 with M.S Jackets	2nd	1050/
34.	S-1402	Heater holder, steriliser, cooler for Extra medium No.2 for TA-1106 SS-316 with M.S Jackets	2nd	800/
35.	S-1403	Heater holder, steriliser, cooler for Extra medium No.3 for TA-1106 SS-316 with M.S Jackets	2nd	650/
36.	S-1404	Heater holder, steriliser, for Extra medium No.4 for TA-1106	2nd	1100/
37.	S-1405	Heater holder, steriliser, cooler for Extra medium No.1, for TA-1107 SS-316 with M.S Jackets	2nd	1050/
38.	S-1406	Heater holder, steriliser, cooler for Extra medium No.2 for TA-1107 SS-316 with M.S Jackets	2nd	800/
39.	S-1407	Heater holder, steriliser, cooler for Extra medium No.3 for TA-1107 SS-316 with M.S Jackets	2nd	650/
40.	S-1408	Heater holder, steriliser, for Extra medium No.4 for TA-1107	2nd	1100/



(1)	(2)	(3)	(4)	(5)
41.	TA-1120	Concentrated acid tank M.S 800 lits	2nd.	200/
42.	F-1308	Oliver Rotary vacuum filter with all accessories, S.S plated M.S Drum dia 2.0 MTS, Drum width 2.0 MTS, Knief discharge. RPM 3 to 8 for through put 5000 to 8000 lits fermenter broth per hour, with conveyor belt discharge for mycelia cake.	GF	38000/
43.	P -1201	Media pump 7.5 KW, 30M head, 12 M <sup>3</sup> /hr, SS-316, centrifugal type with mechanical seal.	GF	1500/
44.	P -1202	-do-	GF	1500/
45.	P -1203	RVF filtered broth pump 5.0 KW, 30M head, 9M <sup>3</sup> /hr. SS-316, centrifugal type with mechanical seal.	GF	1300/
46.	P -1204	Water-ring vacuum pump for Oliver rotary vacuum filter C.S body	GF	1000/
47.	P -1205	Four head metering pump for Extra medium No.1, No.2, No.3, No.4 SS-316, 3.0KW, 1500RPM	2 nd	1800/
48.	P -1206	-do-	2 nd	1800/
49.	T-2101	Filtered broth holding tank SS-316, Cap-22000 lits, Jacketted	GF	13,800/
50.	T-2102	Ethyl acetate holding tank, Jacketted, SS-304 Cap-7500lits.	1 St	5,500/
	T-2103	Concentrated Sulphuric acid tank, MS. Cap-2000 lits.	GF	1,170/
	T-2104	Dilute acid holding tank, M.S.R.L with Jacket, Cap-3500 lits.	GF	3,800/
	T-2105	Detergent holding tank, SS-304 Cap-750 lits 1.0 KW FLP motor	1 St	1600/
54.	E-2301	Counter Current liquid - liquid extractor and phase Separator podbiel Niak type for a throughput. of 4,000 LPH to 5,000 LPH with explosion proof motor and fittings.	GF	150,000/

1)	(2)	(3)	(4)	(5)
55.	T-2106	Product layer holding tank capacity 3000 lits SS-316 with agitator Jacket.	1 St	6000/
56.	T-2107	-Do-	1 St	6000/
57.	T-2108	Potassium Carbonate Solution holding Tank SS-316 Cap-1000 lits explosion proof motor for agitator.	1 St	1,600/
58.	F-2302	Filter for product layer. Horizontal pressure filter 400 mm Dia SS- plates, Cake holding capacity - 66 lits.	1 St	4000/
59.	T-2109	Chilled filtered product solution holding tank SS-316, 3000 lits capacity with jacket.	1 St	4000/
50.	T-2110	Product solution and potassium carbonate solutions continuous mixing tank with PHRC to control carbonate solution addition SS-316 200 lits capacity with explosion proof agitator motor.	1 St	450/
61.	E-2303	Liquid - liquid phase Separator Centrifugal (Alfalaval type) with disc Separator Set.	G.F	42,000/
62.	T-2111	Product extract collection tank SS-316 Capacity - 2000 lits with jacket and agitator with explosion proof motor.	1 St	8000/
63.	F-2304	Horizontal pressure filter SS-316, 400 mm dia SS plates, holding capacity - 60 lits	1 St	4000/
64.	S-2401	Distillation still for penicillin extract to displace water with solvent and to precipitate product. The still operate under high vacuum. SS-316, Cap - 2000 lits with jacket agitator condenser, distillate — receiver tank.	1 St	22000/

(1)	(2)	(3)	(4)	(5)
65	F-2305	<p>Penicillin filter with proper screen to filter clear solution and retain penicillin crystals.</p> <p>The super filter will operate under vacuum and pressure. Thorough washing, and discharge of washed, partially dried crystals is ensured with paddle (45) agitator with FLP motor HP 37 KW. Capacity 250 Kg, with two wash tanks SS-316, Cap - 200 lits</p>	1 St	27000/
66	DR-2501	<p>Dryer for penicillin crystals.</p> <p>Cylindrical vacuum dryer with central shaft with vertically rotating agitator blades, limpet Coils on body for hot water circulation. Explosion proof motor and fittings.</p>	GF.	27,000/
67	P-2201	<p><u>PUMP</u></p> <p>Note : All pumps are of SS-316 Centrifugal type with mechanical seal and explosion proof motor, unless otherwise specified.</p> <p>Filtered broth pump 10.0 KW motor</p>	GF	1500/
68	P-2202	<p>rating 15 m<sup>3</sup>/hour delivery pressure 9 Kg/cm<sup>2</sup></p> <p>Solvent pump 7.5 KW motor, 5m<sup>3</sup>/hour</p>	GF	800/
69	P-2203	<p>delivery pressure 10 kg/cm<sup>2</sup></p> <p>Detergent pump 5.0 KW motor.</p>	GF	700/
70	P-2204	<p>1 m<sup>3</sup>/hr delivery pressure 12 Kg/cm<sup>2</sup></p> <p>Acid pump, metering pump piston type, positive displacement pump, 3.0 KW motor 1500 lits/hour delivery pressure 9.0 Kg/cm<sup>2</sup>.</p>	GF	1000/

(1)	(2)	(3)	(4)	(5)
71.	P-2205	Product layer filtration pump 3.0 KW 30 m head 5 m <sup>3</sup> /hour.	GF	600/
72.	P-2206	Potassium Carbonate extract pump 2.5 KW 25 MTS head 6 m <sup>3</sup> /hour.	GF	600/
73.	P-2207	Chilled product layer pump 2.5 KW 25 MTS head 6 m <sup>3</sup> /hr .	1 St	600/
74.	P-2208	Feed pump to phase Separator 2.5KW 25MTS head 6 m <sup>3</sup> /hr.	GF	600/
75.	P-2209	Extract pump to still 2.5 KW 25 MTS head 6 m <sup>3</sup> /hr	1 St	600/
76.	P-2210	Wash Solvents pump 1.5 KW 20 MTS head 4 m <sup>3</sup> /hour.	1 St	500/
77.	G-2600	Nitrogen manifold for the plant with 6 Nos pigtails Connecting for 6 cylinders, and necessary 12 mm and 6 mm liner (SS-304) to different units.	GF	300/
<u>Sodium penicillin production unit</u>				
78.	T-3101	Penicillin solution preparation tank SS-316 Capacity-300 lits	1 St	3000/
79.	F-3301	Horizontal plate pressure filter, SS-316 8 plates Cake holding Capacity - 30 lits.	GF	2,500/
80.	T-3102	Filtered penicillin solution holding tank 1000 lit SS-316	1 St	1200/
81.	P-3201	Pump for penicillin solution filtration and feeding to column 3.0 KW, 30 MTS head, 6 m <sup>3</sup> /hr.	GF	1,200/
82.	S-3601	M.S.R.L column for resin (Cationic) Dia 0.5 m Hight 4.5 m	1 St	2000/
83.	F-3302	Pressure filter, vertical plate and frame SS-316 40 mm x 40 mm plates and frames.	1 St	2500/
84.	F-3303	Clarity grade cartridge filter (Sterilisable)	1 St	400/
85.	F-3304	Sterility grade cartridge filter (Sterilisable)	1 St	400/
86.	S-3401	Still for azetropic distillation of sodium penicillin solution with condenser condenser, distillation receiver Capacity 1000 lits.	1 St	15000/

1)	(2)	(3)	(4)	(5)
87.	P-3202	Vacuum pump for distillation systems	2 nd floor	1,200/
88.	P-3203	Three stage ejector with inter condensers	2 nd floor	500/
89.	F-3305	Centrifuge SS-316 720 mm Dia basket with explosion proof motor and required fittings to handle sterile product with pump and wash tanks.	1 St	15,000/
90. A	D-3501	Double cone rotary vacuum dryer SS-316 with M.S Jacket for hot water circulation, capacity 100 Kg	GF	15,000/
B	M-3702	Mill for sodium penicillin (Sterile tank)	GF	2,200/
		<u>(4) Ampicillin Production Unit</u>		
91.	T-4101	Penicillin dissolution tank SS-316, 500 lits Cap, with explosion proof 2.0 KW motor, propeller type impeller	1 St	3,000/
92.	F-4301	Filter for penicillin solution. Horizontal pressure filter plate dia' 400 mm, cake holding capacity 30 lits.	1 St	3,500/
93.	F-4302	Fine filter; cartridge type for retaining 1 micron and above with SS-316 Casing.	1 St	500/
94.	T-4102	Filtered alkali holding tank SS-316 300 lits cap.	1 St	700/
95.	T-4103	6 APA Reactor SS-316 Jacketted 2000 lits cap; 5.0 KW variable Speed drive FLP motor, four baffles of 1/10 tank dia, with retention screen at bottom and axial flow impeller for mixing. The Reactor to have provisions for TRC, PHRC, PSV, PI and alkali addition.	1 St	12,000/
96.	T-4104	Acid holding tank PVC tank 200 lits cap.	2 nd	50/
97.	T-4105	Solvent holding tank SS-304 with JKT 200 lits cap, with line filter.	2 nd	2,000/

(1)	(2)	(3)	(4)	(5)
98	F-4303	Filter for 6APA reaction mixture SS-316 Horizontal plate type 400 mm dia Cake holding capacity 30 liters	1 St	2,000/
99	T-4106	Crystalliser SS-316 Jacketted cap-3000 liters two peddle agitator with 5.0 Kw motor	2nd (suspend to 1st floor)	12,000/
100	F-4304	Centrifuge SS-316 900 mm basket bottom discharge type with mechanical scraper and other standard fittings	1 St	16,000/
101	T-4107	Wash solvent tank cap - 200 lits SS-316	1 St	700/
102	D-4501	Double cone vac dryer with hot water circulation in jacket SS-316 Capacity 150 kg dry material with standard fittings	GF	4,000/
103	P-4201	Pump for penicillin solution 2.0 Kw 30 m head 5 m <sup>3</sup> /hr Flpmotor	1 St	1,100/
104	P-4202	Pump for 6APA reaction mixture 2.0 Kw motor, 30 m head, 5m <sup>3</sup> /hr	1 St	1,100/
105	P-4203	Pump for Wash solvent 1.5 Kw motor 20 m head - 5 m <sup>3</sup> /hr	1 ST	1,000/
106	T-4108	Ampicillin reactor SS-316 - L, Cap 2000 lits, with jacket agitator with variable speed drive, 5.0 Kw motor with provisions for TRC. P.I., PSV	2nd (suspend to 1st floor)	12,000/
107	T-4109	Extraction tank SS-316, with jacket cap - 3000 lits, agitator with 5.0 Kw motor	1 St	12,000/
108	F-4305	Pressure filter horizontal type SS-316 40 mm dia plates, cake holding capacity - 80 lits	1 St	2,500/
109	F-4306	Cartridge type clarity grade filter, SS-316 housing	1 St	400/
110	T-4110	Crystalliser SS-316 Capacity 2500 lits with jacket agitator 5.0 Kw explosion proof motor two speed drive	2nd floor (suspended to 1st floor)	12,000/

(1)	(2)	(3)	(4)	(5)
111.	P-4202	Pump for extract solution filtration, SS-316 3.0 KW motor 6 m <sup>3</sup> /hr. Head 30 MTS	1 St	1,200/
112.	M-4701	<p>Granulator for granulating the crystals to 20 and 25 meshsize as per requirement. SS-316 with set of mesh screens.</p> <p>Note : 6 APA and Ampicillin production can be planned to utilise the same wash solvent Tanks, pump, centrifuge, and dryer for both the products. The equipment must be cleaned and checked before product change.</p> <p>(5) <u>Solvent Recovery Unit</u></p> <p>Note : All solvent tanks are underground tanks and all pumps are submerged type centrifugal pumps unless Specified. All tanks pumps, stills should be earthed, to avoid hazards due to static current.</p>	GF	2,200/
113.	T-5101	Spent solvent tank M.S Capacity - 25000 lits	underground	15,000/
114.	T-5105	Recovered/ fresh solvent tank M.S capacity - 25000 lits	"	15,000/
115.	T-5102 T-5106	<p>Single tank with two compartments for spent and recovered/fresh Solvent capacity of each compartment - 15,000 lits M.S</p>	"	17,000/
116.	T-5103 T-5107	<p>Single tank with two compartments for Spent, and recovered/fresh solvent capacity of each compartment 15,000 lits, M.S</p>	"	17,000/

(1)	(2)	(3)	(4)	(5)
117.	T-5104	Single tank with two compartments for spent and recovered/fresh solvent. M.S tank compartments coated with acid resistant resin to prevent corrosion due to hydrochloric acid fumes. capacity of each compartment 15000 lits	underground	19,000/
118.	P-5201	pump for TA 5101 3.5 KW, head 30 MTS, 12 m <sup>3</sup> /hr	Above tank	1700/
119.	P-5202	Pump for TA 5102 "	Submerged ) " type )	1700/
120.	P-5203	Pump for TA 5103 "	"	1700/
121.	P-5204	Pump for TA 5104 "	"	1700/
122.	P-5205	Pump for T-5105 "	"	1700/
123.	P-5206	" T-5106 "	"	1700/
124.	P-5207	" T-5107 "	"	1700/
125.	P-5208	" T-5108 "	"	1700/
126.	S-5601	Distillation still for Spent broth SS-316 (AISI) Seive plate trays 19 Nos, column height 8 MTS diameter 1.2 MTS, with all standard accessories and fithings	GF	65,000/
127.	S-5602	Distillation still with bubble cap trays SS-316 (AISI) Hight 14 MTS Dia 1.2 m 33 bubble cap trays.	"	70,000/
128.	S-5603	Batch still with bubble cap trays SS-316 (AISI)	"	60,000/
Note : S-5603 still can be used for distillation of treated methylene chloride mother liquor.				



UTILITIES - EQUIPMENT COSTS

Sr. No.	Utility Equipment	COST		
		US	\$	FCB
<b>A. TUBE WELL WATER</b>				
i.	Two numbers tube wells with deep well submerged pumps. Depth of tube well pipe under ground - 46 MTS, with piping, valves, and fittings. Pump-Cast iron, capacity 0.4 m <sup>3</sup> /min Total head - 60 MTS. Speed 2900 RPM Power - 11.0 KW Cost of each set \$ 3770/	7,540/		
ii.	Chemical treatment tank for iron removal with pump and accessories Supplier - Japan organo company Ltd.	20,000/		
<b>B. DEMINERALISE WATER</b>				
i.	Two resin columns MSRL hight 2.0 M Diameter - 0.68 M M.S shell thickness - 6 MM Rubber lining thickness - 4 MM	4,100/		
ii.	Feed pump for columns, C.S. body Cap. - 0.3 m <sup>3</sup> /min head - 30 MTS Motor power - 3.7 KW	1,600/		
iii.	D.M. water storage tank, capacity - 20 m <sup>3</sup>	1,300/		
iv.	D.M. water supply pump. C.S. body, 0.3 m <sup>3</sup> /min, head - 30 MTS, Motor power - 3.7 KW	1,600/		
<b>C. PYROGEN FREE DISTILLED WATER</b>				
	Distilled water generation capacity 600 lits/hour, 4-effects, SS-316 Still with,	27,000/		
i.	Feed water Storage tank, Cap - 1000 lits			
ii.	Distilled water storage tank capacity - 1000 lits with jacket for steams to hold temp of dist' water at 80°C.			
iii.	SS-316 Centrifugal feed pump capacity 100 lits/min, head → 30MTS, motor power → 2.0 KW			
iv.	Complete instrumentation with solenoid Controls, and autovalves to maintain required flow and pressure on all effects (stages) of evaporator.			

D. TOWER WATER

Two number, induced draft towers similar to the one in DCPT.

22,430/

Cooling capacity 6,90,000 KCal/hr

entering temp. -43°C, leaving temp - 38°C

wet bulb temp -32°C

Rate of supply of cool water - 2300 lits/min

fan motor - 3.7 KW

Supplier - Japan cooling tower institute

E. CHILLED WATER

Two centrifugal water chillers similar to the one in DCPT

167,500/

Refrigerating capacity 3,62,880 KCal/hr

Refrigerent - R-11

Chilled water inlet temperature :- 12°C

Chilled water outlet temperature:- 7°C

Rate of chilled water supply :- 72.6m<sup>3</sup>/hr

F. BRINE at - 15°C

150,000/

Heat load - 2,76,700 KCal/hr

Brine - Calcium chloride 21% solution

Specific gravity - 1.21, PH - 7.5

Brine inlet temperature - -10°C

Brine outlet temperature -15°C

Refrigeration capacity -90 TR

Compressor motor -95 KW

Hot brine/Gold brine tank with compartments.

M.S. resin coated tank with 150 mm THK cold insulation all sides, capacity + 25,000 lits

Hot brine feed pump to chilling unit

Capacity 50 m<sup>3</sup>/hr

motor power + 20 KW

Cold brine supply pump to process units

capacity + 60 m<sup>3</sup>/hr

motor power + 25 KW

G. STEAM

Fire tube boiler. Oil fired, forced draft. 130,000/  
Design rating ÷ 8000 Kg steam generation  
per hour  
Actual supply (at 85% effi<sup>n</sup>) ÷ 6300 Kg/hr.  
Design pressure ÷ 10.0 Kg/cm<sup>2</sup>  
Operating pressure ÷ 9.0 Kg/cm<sup>2</sup>  
BHP (Boiler horse power) ÷ 511

H. COMPRESSED AIR

(a) COMPRESSOR -1

Rated capacity ÷ 60 m<sup>3</sup>/min 150,000/  
Delivery pressure 7.0 Kg/cm<sup>2</sup>  
motor power 240.0 KW

(b) COMPRESSOR -2

Rated capacity ÷ 10m<sup>3</sup>/min 27,000/  
Delivery pressure 7.0 Kg/cm<sup>2</sup>  
motor power 40.0 KW

I. DIRECT POWER

Existing feeder main line is of 6.600 KV capacity 153,000/  
Two transformers of 1050 KVA rating at 440 Volts,  
are in commission.  
Existing DCPT plant consumes about 400 KW power  
on average.  
Another feeder line of capacity 6.600 KV to be  
drawn with proper selection of transformer ratings,  
to get the maximum power rating.  
Total cost of High power cable, transformers and  
installaction

J. DISEL GENERATOR ÷ For emergency power requirements

Power generating capacity 150 KW 35,000/

ANNEX VIII-2 Calculation of the Production Capacity  
of the Pilot plant for Penicillin and  
Ampicillin

Nominal Volume of the fermentor :	20,000 litres
Actual total Volume of the fermentor :	19,575 litres
Volume at harvest at 80 percent :	15,660 litres
Fermentation Cycle :	192 hours
Penicillin Productivity at harvest time	20,000 Units/ml
	(Average)

Turn over time including transfer,  
cleaning, checking, routine maintenance  
and restarting 12 hours

Fermentation working days

Alternative I, allowing  
115 days for maintenance,  
equipment changes etc. 250 days

Alternative II, allowing  
30 days for annual  
maintenance and 30 days  
for routine maintenance  
and untoward stoppages 305 days

Number of fermentation batches  
harvested in one year

Alternative I : 29.5 batches  
Alternative III : 36.0 batches

Number of batches harvested in  
one year for 2 fermenters :

Alternative I : 59 batches  
Alternative II : 72 batches

Annual Production of Potassium Penicillin G  
at 65 percent recovery

$$\text{Alternative I : } 59 \times 20,000 \times \frac{65}{100} \times 15,660 \times 10^3$$

= 12,011 BU Per year  
or 7.53 tons Per year

$$\text{Alternative II : } 72 \times 20,000 \times \frac{65}{100} \times 15,660 \times 10^3$$

= 14,658 BU Per year  
or 9.19 tons Per year

Production of Ampicillin at the conversion  
rate of 1.47 kg of Potassium Penicillin G  
for 1 kg of Ampicillin

for Alternative I :	5.12 tons
for Alternative II:	6.25 tons

The calculation for arriving at the respective production capacities is similar for Penicillin productivities of 35,000 and 55,000 Units/ml.

ANNEX VIII-3 Calculation of Production capacities  
of the Pilot Plant for Tetracycline

Nominal Volume of the fermenter :	20,000 litres
Actual Total Volume of the fermenter :	19,575 litres
Volume at harvest at 60 percent :	15,660 litres
Fermentation Cycle	192 hours
Tetracycline productivity at harvest times	10 g./litre (average )

Turn over time, Fermentation working days,  
number of fermentation batches harvested  
in one year, number of batches harvested  
in one year for 2 fermentors for  
Alternatives I and II are identical  
as in the case of Penicillin (cf. Annex VIII-2)

Annual Production of Tetracycline at 65 percent of recovery

$$\text{Alternative I : } 59 \times 10 \times \frac{65}{100} \times 15,660 \\ = 7.03 \text{ tons per year}$$

$$\text{Alternative II : } 72 \times 10 \times \frac{65}{100} \times 15,660 \\ = 7.33 \text{ tons per year}$$

The calculation for arriving at the respective production capacities is similar for Tetracycline Productivities of 15,20 and 25 g /litre.

ANNEX VIII-4 Theoretical Potential Production capacity  
of Pilot plant to meet Projected demand of  
Tetracycline Per year

<u>S.No.</u>	Productivity of Tetracycline (average yield) <hr/> grams/litre	Annual Production capacity of Tetracycline <hr/> Tons		Projected annual demand for Tetre- Tetracycline in <hr/> 2,000 & <hr/> Tons
		Alternative I	Alternative II	
1.	10	6.03	7.33	
2.	15	9.02	11.01	11.47
3.	20	12.02	14.66	
4.	25	15.02	18.33	

ANNEX VIII-5 : EQUIPMENT FOR PHARMACEUTICAL  
FORMULATIONS IN DCPT

1. Fluidizing, Granulating and Drying Machine.  
Type : Automatic control type  
Granulating and Drying Capacity : 30 KG/batch
2. Kneading Machine.  
Type : High speed fluidizing system by propeller  
at bottom of vessel  
Kneading Capacity : 30-50 Kg/batch  
Model : 3MG - 200
3. Tableting Machine.  
Model : Clean Press Correct 36  
Capacity : 900 - 2,520 tablets/min.  
Minimum : 54,000 tab/hr  
Maximum : 151,000 tab/hr
4. Packer  
Capacity : 320 tabs/min  
Size of tablet : 8 mm  $\phi$   
Thickness of tablet : 3.5 mm - 4.0 mm
5. Coater  
Model : HCF - 100  
Coating Pan Type : Drying is executed by air flowing  
through tablets under negative pressure  
Capacity : 30 - 50 Kg/batch
6. Tablet Visual Inspection Machine  
Type : Belt conveyor type  
Object : For visual inspection of both faces of tablets  
Capacity : Max. 300,000 Tab/hr.
7. Tableting Machine (For Pessaries)  
Model : Clean Press Correct 17 K  
Capacity : 170 to 510 Tab/min



ANNEX VIII-5 (CONTD)

INJECTION DEPARTMENT

Japanese ampoules washing and drying machine	5000/hr
Strunk ampoules filling and sealing machine	6000/hr
Japanese ampoules outer surface washing machine	6000/hr
Japanese ampoules printing and corrugated packing	5000/hr

PENICILLIN V TABLETS

AI 250 mg/tabs. ----- 20's  
100's

17tons Pen V ----- Granulation  
----- Comp:

17000 kg AI PenV  
17000 Base Granulation  

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34000 Kg ----- 90 kg/day (8hrs) = 377 days

30kg x 3 batches ----- 90 kg/day

Compression ----- ( 90kg/day ) = 377 days

Annex VIII-6 FERMENTATION PILOT PLANT - MANNING TABLE

<u>S.No.</u>	<u>CATEGORY</u>	<u>PRODUCTION</u>	<u>UTILITIES</u>	<u>LABORATORIES</u>	<u>ADMINISTRATION</u>	<u>MISCELLANEOUS SOLVENT RECOVERY INCINERATOR STORES</u>
1.	Manager.				1	
2.	Supervisor Post Graduate Degree (Engineer, Technologist, Scientist)	1	1	1	1	
3.	Shift Supervisor (Graduate)	4	4	4	2	2
4.	Shift Technician (High School <u>OR</u> Trade Certificate)	16	8		4	3
5.	Skilled Worker (Middle School)	4		2		
6.	Semi Skilled Worker (Iterate)	4	4			4
	Total :	29	17	7	8	9
	Grand Total :	70				

NOTE : The above figures represent the maximum personnel required, when the pilot plant works continuously in three shifts of eight hours each and 305 days per year. In case the work is not continuous, the requirements will be correspondingly less. It is desirable to start with one half of the above strength and increase, as necessary.

ANNEX VIII-7 PACKAGING OF FINISHED PRODUCTS

<u>S.No.</u>	<u>PRODUCT</u>	<u>DOSAGE FORM</u>	<u>CONTAINER</u>	<u>STRENGTH</u>	<u>PACKAGING</u>
1.	Fortified Procaine Penicillin	Injection	Glass Vial	Penicillin G Procaine 300,000 Units +Penicillin G Sodium 100,000 Units	1 Vial  10 Vials
2.	Ampicillin trihydrate	Capsule	Hard gelatin Capsule	250 mg.	16 Capsules  100 Capsules
3.	Tetracycline hydrochloride	Capsule	Hard gelatin Capsule	250 mg.	16 Capsules  100 Capsules

ANNEX VIII-B: AMPICILLIN (BULK)

RAW MATERIALS AND UTILITIES (Based on 1984 P)

1. Process

In the first stage, 6 Amino Penicillanic Acid (6APA) is produced from Penicillin G through enzymatic hydrolysis using the enzyme Penicillin Amidase. The yield is approximately mole to mole.

In the second stage, 6APA is converted into ampicillin using pivaroyl chloride and phenyl glycine.

<u>2. Raw materials and Packaging</u>	<u>Requirement per 1 Kg of ampicillin</u>
Penicillin G Potassium	1.47 kg per kg
Cost of chemicals other than Penicillin	US\$ 22.143 per kg
Packaging	US\$ 1.429 per kg

3. Main Utilities

Electricity	2 kw per kg
Steam	0.3 tons per kg
Cooling water	7.5 m <sup>3</sup> per kg

NOTE: Alternative II (cf. Annex VIII-4)

ANNEX VIII-9 M.P.I. COST STATEMENTS (1989-90)

<u>S.No.</u>	<u>Particulars</u>	<u>Accounting Unit</u>	<u>Cost percent (K)</u>
1	Steam	Ton	60.48
2	Electricity	K.W.H.	0.45
3	Water (deminuatesed)	gal.	0.003
4	Fuel gas	1000 cu.ft.	7.50

SOURCE: BPI

ANNEX VIII-10: REALIZATION OF CAPACITIES OF  
PENICILLIN AND AMPICILLIN

<u>S.NO.</u>	<u>PRODUCTIVITY OF PENICILLIN (Units/ml)</u>	<u>PRODUCT</u>	<u>YEAR I Tons</u>	<u>YEAR II Tons</u>	<u>YEAR III Tons</u>
1	35,000	Penicillin G Potassium	8.04	12.06	16.08
2	- do -	Penicillin Potassium	8.04	12.06	16.08
3	- do -	Ampicillin	5.47	8.21	10.94
4	55,000	Penicillin G Potassium	12.64	18.95	27
5	- do -	Penicillin Potassium	12.64	18.95	27
6.	- do -	Ampicillin	8.60	12.89	17.19

ANNEX VIII-11: PENICILLIN POTASSIUM (BULK)  
(FOR CONVERSION TO AMPICILLIN)

COST OF RAW MATERIALS AND UTILITIES

<u>S.NO.</u>	<u>ITEM</u>	<u>Cost per kg (US\$)</u>	
		<u>Productivity</u> <u>35.000 U/ml</u>	<u>Productivity</u> <u>55.000 U/ml</u>
1	Raw materials	13.87	8.83
2	Utilities (includes fuel)	1.45	0.92

ANNEX VIII-12: PENICILLIN G POTASSIUM  
AND AMPICILLIN - PRICES

<u>S.NO.</u>	<u>YEAR</u>	<u>PRICE PER Kg.</u>	
		<u>Penicillin</u> US \$	<u>Ampicillin</u> US \$
1.	1978	23.00 (g)*	80.00
2.	1984	-	85.00 (C & F Karachi)
3.	9/1989	29.64 (v)**	81.20*** (Premix) F.O.B

\* Benzyl Penicillin Potassium

\*\* Phenoxy Methyl Penicillin Potassium B.P.  
(F.O.B., 22-9-89, BPI)

\*\*\* Compacted with 1 percent Magnesium stearate  
for direct capsule filling (BPI, Aug. Sept. 1989)



Annex VIII-13 Development Centre for Pharmaceutical Technology

Water Analysis (February 26, 1990)

<u>S.No.</u>	<u>Test</u>	<u>Well No.1</u>	<u>Well No.2</u>	<u>Canteen Supply</u> <u>(Drinking Water)</u>
1.	Permanent Hardness	24.590 ppm	25.093 ppm	27.602 ppm
2.	Temporary Hardness	15.206 ppm	6.082 ppm	1.014 ppm
3.	pH	6.0	5.7	5.7
4.	Iron Content	0.064 ppm	0.064 ppm	Nil
5.	Heavy Metals	S	S	S
6.	Free Chlorine	-	-	Nil
7.	Microbial Test	28300 colonies/10000 ml	colonies/ ml	18300 colonies/ml

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S = Satisfactory (Comply to B.P standard)

SOURCE : DCPT

Annex VIII-14 Development Centre for Pharmaceutical  
Technology Statement Showing Electrical  
Breakdowns

		<u>Total</u>	<u>Frequency</u>
89	July	13:56 hrs.	7 times
89	August	5:57 hrs.	8 times
89	September	2:40 hrs.	6 times
39	October	1:35 hrs.	3 times
89	November	2:22 hrs.	6 times
39	December	3:10 hrs.	2 times

ANNEX VIII -15

UTILITIES (I). REQUIREMENT

A. TAP OR TUBE WELL WATER

Sr. No.	PROCESS	WATER REQUIREMENT	
		(a) TREATED AFTER IRON REMOVAL (LTS)	(b) DEMINERALISE WATER (LTS)
1.	Fermentor, seed vessel, mixing tanks, dosing tank, rotary vacuum filter	-	45,000
2.	Broth acid dilution detergent and other solutions preparation	-	20,000
3.	Equipment wash	10,000	-
4.	Make up feed water to cooling towers to compensate losses due to evaporation (12.5%) + other losses (2.5%)	30,000	-
5.	Boiler feed water	-	150,000
6.	Make up water for generation of distilled pyrogen free water	-	15,000
7.	Solvent recovery column washing etc.	10,000	-
8.	Effluent treatment plant	10,000	-
9.	Miscellaneous use	10,000	10,000

Total- 130,000 240,000

Total water requirement (a)+(b) - 370,000 lits/day or 260 lits/min

B. DEMINERALISED WATER

Total requirement has been estimated in the table given for tap (tube well) water.

Total requirement of D.M. water 240,000 lits/day or 167 lits/min

C. PYROGEN FREE DISTILLED WATER

Sr. No.	Process	Distilled water Requirement (LTS)
1.	Sodium penicillin unit	3,000
2.	Washing area (for equipment wash before sterilisation)	3,000
3.	Ampicillin production unit	3,000
4.	Miscellaneous	3,000
Total-		12,000

**D. COOLED TOWER WATER**

Sr. No.	Equipment	Requirement (lit/min)
1.	Fermentors, seed vessels extra medium coolers	2000
2.	Brine unit condenser	600
3.	Other miscellaneous such as solvent distillation still condenser.	1000
	Total-	3600

**E. CHILLED WATER**

Sr. No.	Equipment	Consumption (lits/min)
1.	Fermentor, seed vessel, Ampicillin reactor, penicillin and sodium penicillin stills	1500
2.	Solvent recovery secondary condensers	600
3.	Miscellaneous	400
	Total-	2500

**F. BRINE AT - 15°C**

Sr. No.	Equipment	Consumption (lits/min)
1.	Ampicillin unit	500
2.	Miscellaneous (chilling) of Butyl acetate etc.)	500
	Total-	1000

**G. STEAM (PEAKLOAD REQUIREMENT)**

Sr. No.	Equipment	Consumption (Kg/hr. )
1.	Fermentor seed vessel	1500
2.	Solvent recovery (one column)	2700
3.	Miscellaneous (Distilled water still, fermentation vessels sterile sections, ejectors etc.)	1500
	Total-	5700

**H. COMPRESSED AIR**

Sr. No.	Equipment	Consumption (lits/min)
1.	Fermentors, seed vessels, air filters	25000
2.	Instruments air line for pneumatic controls etc.	1000
3.	Miscellaneous	4000
Total-		<u>30,000</u>

**I. DIRECT POWER (ELECTRICAL)**

Sr. No.	Equipment	Consumption (KW)
1.	Fermentation	266
2.	Recovery and purification	75
3.	Sodium Ampicillin (sterile area)	25
4.	Ampicillin	30
5.	Solvent recovery	50
6.	Utilities	615
7.	Buildings illumination	30
8.	Miscellaneous mycelia dryer, generator etc.)	50
Total-		<u>1141</u>
		Say 1150 KW

**J. DIESEL GENERATOR, CAPACITY REQUIRED**

Sr. No.	Description	Power requirement (KW)
1.	10H <sup>3</sup> /min air compressor	40
2.	CAPA reactor agitator	12
3.	Ampicillin reactor agitator	12
4.	Sterile air supply to sterile area	20
5.	Minimum illumination of operating equipment & floors	20
6.	Utilities block and miscellaneous	50
Total-		<u>154</u>
7.	Capacity of the existing generator	104
8.	Demand of emergency power for existing system	60
9.	Additional emergency power generation requirement	110 Say 150KW

ANNEX VIII-16: REQUIREMENT OF RAW MATERIAL

I. SUPPLIES

Requirement of 'A' Grade rawmaterials which contribute to more than 90% of total raw material cost

A. PENICILLIN 'G' or 'V' NONSTERILE BULK

Sr. No.	Name of Raw material	Consumption Kg/1kg of pen 'G' or 'V'
1.	Pharmamedia (cotton seed meal of special grade)	0.76
2.	Sugar	5.20
3.	Phenyl acetic acid or phenoxy acetic acid	0.570
4.	Cotton seed oil	1.41
5.	Butyl acetate	1.46
6.	Butanol	1.25
7.	Acetone	0.34

B. SODIUM PENICILLIN STERILE BULK

Sr. No.	Name of Raw material	Consumption kg/1kg of Sod 'Pen' (S)
1.	Potassium penicillin (non sterile)	1.30
2.	Butanol	1.63
3.	Acetone	2.30

C. AMPICILLIN NON STERILE BULK

Sr. No.	Name of Raw material	Consumption kg/1kg of Ampicillin
1.	Penicillin (non sterile)	1.27
2.	Disodium monohydrogen phosphate	0.50
3.	Dimethyl dichloro silane	0.14
4.	Methanol	3.00
5.	Methylene chloride	9.50
6.	Hydrochloric Acid	1.16
7.	D(-) alpha phenyl glycol chloride hydrochloride	0.64
8.	Caustic soda	0.24
9.	Acetone	0.35

ANNEX VIII-17

COST OF PRODUCTION

Production capacity of equipment designed for fermentation  
Pilot Plant and estimated cost of production per kg of Product.

A. PENICILLIN 'G' or 'V' BULK

- 1. Number of fermentors - 2
- 2. Number of batches per month - 6.8 (Say 6.0)
- 3. Yield of penicillin per one batch on the basis of litre 25,000 U/ml and recovery efficiency 70% 204.0 kg
- 4. Out put of penicillin product per month - 1,224.0 kg
- Out put of penicillin product per year - 14,688.0 kg

B. SODIUM PENICILLIN (STERILE BULK)

- 1. Out put per batch on the basis of 75% efficiency 35.0 kg.
- 2. Number of batches per day 2
- 3. Out put of sodium penicillin per month on the basis of 20 days production per month 1,400.0 kg
- 4. Total production per year 16,800.0 kg

C. AMPICILLIN BULK

Step	Process	Input per batch (kg)	efficiency %	output per batch kg	No. of batches per day	output per day
1st. Step	Penicillin to GAPA	72.0	85	35.5	3	106.5
2nd "	GAPA to Ampicillin	35.5	85	56.0	1	56.0

A. In a month

- 1. GAPA can be produced for 7 days  $7 \times 106.5 = 745.5$  kg out put
- 2. Ampicillin " 21 days  $21 \times 56.0 = 1176.0$  " "

B. Ampicillin production per year ——— = 14112.0 " "

Note- Fresh 6-APA gives the best quality and yield of product (Ampicillin). Hence 6APA manufacture has been restricted to 7 days per month to get just sufficient quantity for 21 days production of Ampicillin during the later part of the month. This will still leave two days in a month for cleaning and maintenance of equipment.

COST PER KG OF PRODUCT

If all the penicillin produced during the year (ie) 14,668 Kg is shared between production of sodium penicillin and Ampicillin at 1:2 proportion (ie) 4,896 Kg for sodium penicillin and 9,792 Kg for Ampicillin, respective product out puts will be

Sodium penicillin (Sterile bulk) per year - 3,667.0 Kg  
Ampicillin bulk " " - 7606.0 Kg

COST PER KG OF PRODUCT

Basis - I. (A) Penicillin production per month 1224 Kg  
(B) Sodium penicillin (sterile) month 306 Kg  
(C) Ampicillin bulk " " 634 Kg

II. Utilities - Refrigeration, compressed air, steam, tap (tube well) water, cooled water, chilled water are taken at standard local rates and converted

III. Raw material costs are calculated on the basis of actual consumption based on actual efficiency and output of each product.

IV. To meet the said rate of production 50 employees are needed. Their average wages are taken as K 1200/- per employee per month.

V. Fixed costs have been extrapolated at 15% of the variable costs for the designated production rates.

VI. Cost of utilities in Myanmar.

1. Electricity - K 00.45/ Unit (one KWH)
2. Water (treated) - K 0.00003/ gallon
3. H.S. Diesel oil - K 10.5 / gallon



Items	Cost per one kg of product in US \$					
	Penicillin 'G' or 'V'	Sodium penicillin (sterile)	Aspicillin Bulk			
<b>A. VARIABLE COSTS</b>						
1. Raw materials	14.94	46.0	64.14			
2. Utilities	11.75	5.0	11.70			
3. Direct Wages	5.26	3.1	2.90			
Sub total-	31.95	54.1	78.74			
<b>B. FIXED COSTS</b>						
1. Indirect utilities	}	}	}			
2. General expenses						
3. Depreciation				4.79	8.1	11.81
4. Stores over heads						
5. Intrest						
6. Selling over heads						
Total Costs-	36.74	62.2	90.55			