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RESTRICTED

PHARMACEUTICAL ADVISERS
SM/NRP/76/005.
NEPAL.

Terminal report

Prepared for the Government of Nepal by the
United Nations Industrial Development Organisation,
executive agency for the United Nations Development Programme

Based on the work of Joel D. Amiran, pharmaceutical adviser

United Nations Industrial Development Organisation
Vienna

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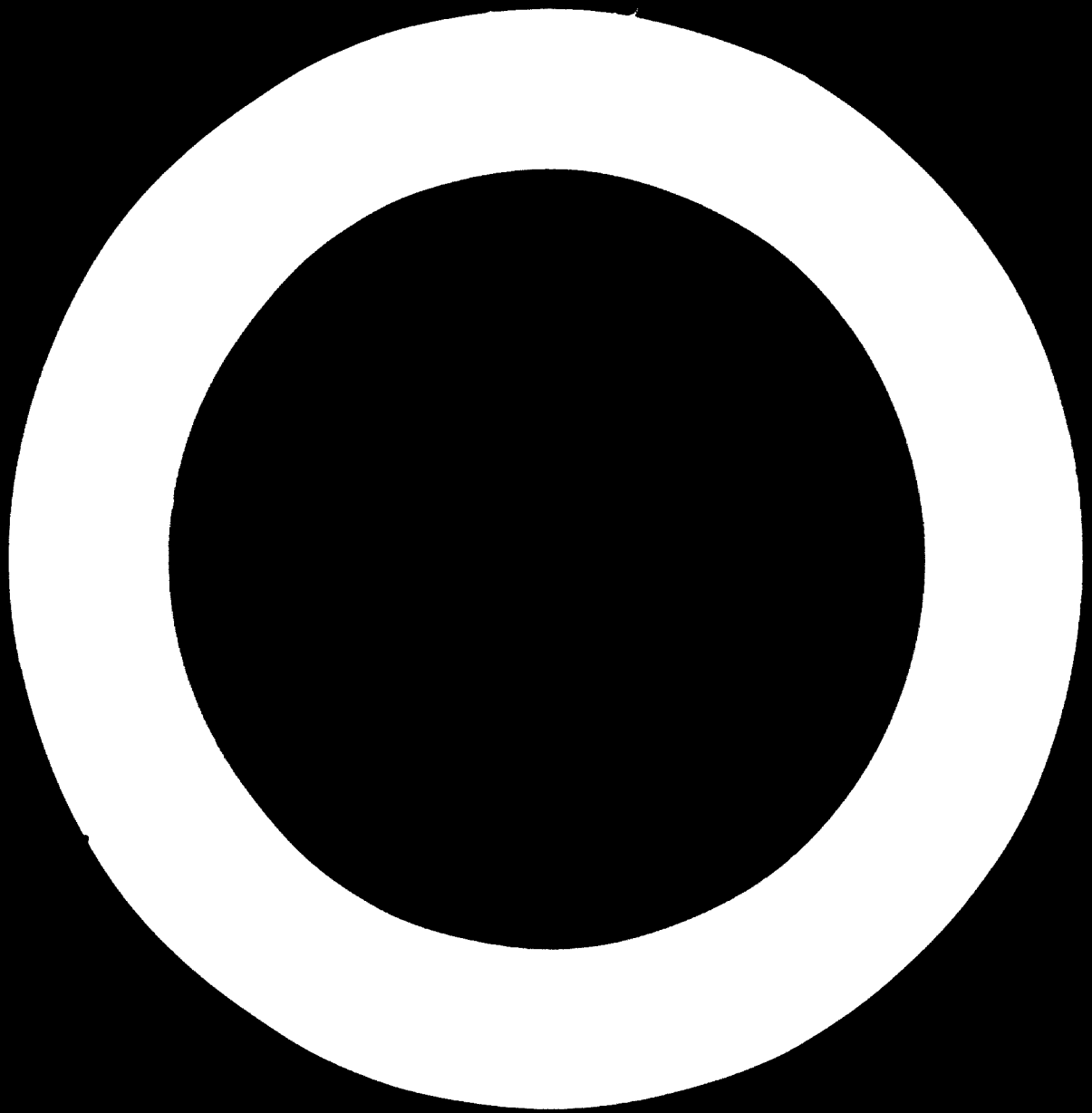
SUMMARY

The following report presents findings and recommendations made following a two-year assignment in assisting Royal Drugs Ltd. in its Five Year Expansion Programme. The growth of the company is reviewed, from a small unit attached to the Medicinal Plants Research Department, to an independent and viable government corporation.

An itemised list of machines and equipment with a projection for 5- 10 years was drawn up for each department, and forwarded officially to UNDP and UNIDO for possible financing. The total amount required is estimated at US\$ 1,200,000 of which US\$ 530,000 has been paid by the donor country, under the project NEP/78/009. UNIDO has been requested to look for possible financing of the balance. Negotiations between Royal Drugs Ltd and UNICEF were conducted, and an agreement signed for the financing by UNICEF of a complete production unit for the mass production of Rehydration salts in Nepal.

An Essential Drugs List for Nepal was drawn up, consisting of some 150 different drugs. The further sub-division and implementation of this list is considered necessary, in order to conform to National needs. The importance of a Drug Act for Nepal and its impact on a National Drug Policy is explained.

A two-week official visit to Burma with a senior Nepalese delegation highlighted the excellent potential for future technical co-operation (TCDC) between the two countries in Pharmaceutical Industry and Allied fields.



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INTRODUCTION

Royal Drugs Ltd. was established in 1972 in the public sector with the following aims:

- (a) To enable the country to gradually achieve self sufficiency in the field of Essential Drugs.
- (b) To modernize the manufacturing facility set up in 1968, as part of the Royal Drugs Research Laboratories, and thereby convert a small experimental unit into an economical enterprise.

In 1975 Royal Drugs Ltd. launched a 5 year Expansion Programme, and, through appropriate government channels, requested a short term Pharmaceutical Adviser for Special Industrial Services (SIS)^{1/}. Three 6 months extensions of the adviser's services were however requested by His Majesty's Government of Nepal, so that the total period of the contract amounted to 2 years: 8th August 1976 to 7th August 1978.

ACKNOWLEDGEMENTS

I wish to tender my heartfelt thanks to HMG of Nepal: the Ministry of Forests, the Department of Health Services - Ministry of Health, and the Foreign Aid and Programme Division -- Ministry of Finance.

I am particularly indebted to Mr. A.B. Rajbhandari, Secretary Ministry of Forests, and to Dr. P.N. Suwal, General Manager Royal Drugs Ltd. for their constant support, co-operation and encouragement.

I should also like to express my gratitude to the UNDP Office for the valuable assistance given to me; in particular the close support and assistance provided by Mr. M. Kulessa, former Resident Representative, Mr. J. Raheem, ^{former} Deputy Resident Representative and Mr. K. Malik, Junior Professional Officer.

I would like to thank Mr. H.K. Kuloy UNICEF Representative and Mr. Steward McNab FAO/UNICEF Nutrition Officer for fruitful discussions held at Royal Drugs Limited.

And last, but not least, I would like to show my appreciation to the staff of Royal Drugs Ltd. for a very fruitful and enjoyable collaboration.

^{1/} See Annex I for job description.

CONCLUSIONS AND RECOMMENDATIONS

The principal conclusions and recommendations on the findings of this assignment are presented below.

1.1 THE DRUG ADMINISTRATION ACT (PHARMACY LAW AND ORDINANCES)

The Drug Administration Act should be integrated within the Public Health Laws. For some years a final draft has been prepared which is awaiting ratification by the Bastriya Panchayat. An ad hoc Committee, composed of members from the Ministry of Health and the Ministry of Forests with at its head an experienced senior officer, could be appointed at high ministerial level, to facilitate the process of legislation, and to plan short and long term implementation of the Drug Administration Act.

The Act will have to deal mainly with:

- (a) The quality of drugs, imported or manufactured locally,
- (b) The licensing of establishments for the sale of drugs and poisons,
- (c) Power of inspection,
- (d) Pharmacies and Pharmacists.
 - Licensing of pharmacists
 - Proprietorship
 - Responsibility
 - Dispensing hours
 - Employment in public institutions
 - Practice of pharmacy in hospitals and dispensaries.
- (e) Sale of drugs by unqualified persons,
- (f) Labelling of containers,
- (g) Trade control of Poisons and poisonous substances.

It seems unrealistic to require that a comprehensive Drug Act be implemented rapidly, a period of 15-20 years appearing to be a conservative estimate. The ad hoc Committee for the implementation of the Drug Act should submit a report listing the work to be done, the budgets required, and the schedules for the implementation of each chapter of the Drug Act.

1.2 COMMERCIAL UNIT FOR MEDICINAL PLANTS

- An officially recognised Commercial Unit for Medicinal Plants and Plant Products should be created as a separate unit, at the Royal Drugs Research Laboratories, Department of Medicinal Plants.

- The unit should be headed, on a full-time basis, by a senior officer who will co-ordinate with the other sections of the Department of Medicinal Plants.

- The Unit's main functions will be to select a number of medicinal plants and develop processes for their commercial exploitation, either as plant materials or as active constituents extracted from plants.

- Musk

The above unit mentioned should, with the financial help of international organizations, set up an experimental Musk deer farm for the official trade and exploitation of Musk.

1.3 TRADITIONAL (AYURVEDIC) MEDICINES

- Selected Ayurvedic Medicines should be included, through Royal Drugs Ltd. in the Essential Drugs List of Nepal.

- Controlled clinical trials should be started on established Ayurvedic medicines at the Ayurvedic Hospital with the collaboration of senior allopathic and Ayurvedic doctors.

1.4 THE ESSENTIAL DRUGS LIST FOR NEPAL

- Nepal, as yet, cannot afford luxury medicinal products. The products that can satisfy the basic health necessities should therefore receive primary consideration.

- The Essential Drugs List for Nepal (see Annex VIII) that was lately compiled and circulated through Royal Drugs Ltd. should be subdivided in three chapters, so as to conform to national needs.

(a) A Primary list for use by paramedical personnel in integrated rural development projects, and in remote areas. This list should consist of a limited number of preparations, including such products as analgesics, antidiarrhoeals and rehydration salts, antianemics in the form of vitamins and iron tablets, specific over-the-counter drugs for Mother and Child Health, etc... Selected Ayurvedic drugs could form part of the above Product Mix.

(b) The Basic Drug List should comprise about 100 drugs for the use of medical personnel in Health Posts, in the treatment and cure of the most abundant and serious diseases, viz., malaria, tuberculosis, diarrhoeal diseases, and specific parasitic diseases. Drugs for Mother and Child Health (MCH) should also be included in this list.

(c) The third list should include about 25 more drugs in addition to the above, available at District and Regional Hospitals. They will include the expensive drugs for special indications warranting their use.

The establishment and careful update of the above lists should greatly reduce the overall cost of drugs to the Department of Health Services, and help make Basic Drugs available to all.

1.5 ROYAL DRUGS LTD PRODUCTION PROGRAMME

Local production of drugs should be gradually increased, from the 62 different drugs presently being manufactured, to approximately 150 different drugs by 1981/82 - see Annex VIII A to C for detailed lists. This increase will make a considerable impact on the country's self-reliance in drugs and achieve about 65% of the country's total needs for essential drugs. To that effect a detailed analysis of additional machines required to achieve the above target was drawn up - see Annex V for detailed list of existing and additional machines required.

1.6 HUMAN VACCINES

Royal Drugs Ltd. should start planning now if the production of Human Vaccines is to be effective by 1984-1985. Vaccines under consideration: Tetanus, Tetanus toxoid, Diphtheria and Tetanus, etc...

A separate building as well as a suitable house for small animals, and facilities for horses will have to be foreseen. Qualified manpower will have to be recruited, and training courses arranged abroad with the help of international organizations.

The Biological Department of the Burma Pharmaceutical Industry should be chosen as one of the training centres for the Industrial production of Human Vaccines and Sera, and the production of lyophilised vaccines.

1.7 THE MEDICAL COMMITTEE AND THE MEDICAL DIVISION

(a) A Medical Committee consisting of members selected from the Department of Health Services, the Armed Forces Services, Senior Physicians, and Royal Drugs Ltd. should be expanded. The Medical Committee should advise on a Drug Policy.

(b) The Medical Division of Royal Drugs Ltd. should be headed by a Senior Physician, who will supervise the distribution to the medical profession of information on new and currently available drugs in Nepal, including costs, efficacy, and side effects. For this task major medical publications and up to date medical books should be available to him. The Medical Director should act as Secretary to the Medical Committee.

1.8 RESEARCH AND DEVELOPMENT

(a) Research and Development should be restricted to the specific health needs of the country. The search for local medicinal plants for the development of drugs should be encouraged.

(b) Products Development, such as the application of new technologies for the formulation of new drug forms, should be given high priority.

The Products development unit should experiment on tablet excipients, disintegrating agents, special coating procedures, suspending and emulsifying agents for liquid forms etc...

The unit could also experiment on certain products, like suppositories and cosmetics, whose immediate need may not be felt. Musk, if made available through official sources, could be incorporated into Ayurvedic drugs for local use, or used in high quality perfumes and cosmetics for export purposes.

1.9 TECHNICAL CO-OPERATION BETWEEN NEPAL AND BURMA (TDC) IN THE PHARMACEUTICAL AND ALLIED FIELDS

Within the limits of financial support that Royal Drugs Ltd. obtains from UNDP and UNIDO for its Expansion Programme, fellowships for training in Burma should be requested for specific fields.

Both on technical and ethical grounds, training programmes for Nepalese senior staff of Royal Drugs Ltd. should prove fruitful in Burma Pharmaceutical Industries.

The following fields should be considered first:

- (a) Planning This includes production and materials planning,
- (b) Sterile Products For the mass production of large volume Intravenous Fluids, small volume injectibles, and sterile antibiotic powder vials.
- (c) Industrial Quality Control of Pharmaceuticals
- (d) Integrated study and production of Ayurvedic Drugs at the Ayurvedic Institute at Mandalay.

For long-term application:

- (a) Industrial production of Human Vaccines and Sera, and the production of lyophilised vaccines, at the Biological Department of the Burma Pharmaceutical Industries.
- (b) The organization and methods of Medicinal Plants extraction and distillation, at pilot and semi-industrial scales, at the Burma Pharmaceutical Industry.

2 FINDINGS

2.1 HMG STAFF

2.1.1 The Counterpart

The General Manager, who is a graduate of the London School of Pharmacy is a very able Administrator and technical man. Moreover, many years as Director-General of the Department of Medicinal Plants have given him an extremely precious experience in the field.

2.1.2 The senior staff

The Chief Production Officer, as well as the managers of the different production sections and the Quality Control department are all qualified pharmacists with M.Sc. or B.Sc. degrees from Indian Universities.

Towards the end of 1978, there may however be a manpower shortage due to the fact that both junior and senior officers will be following training schedules abroad. In particular, the manager of the tablets department will be leaving at the end of 1978 for two years tuition leading to a higher degree in Pharmacy. The problem is being given serious consideration by the General Manager, as it might cause considerable delay to the project. Three new science graduates have been recruited in 1977 and 1978, and they are being trained in the factory. Rotation of production managers in the different sections has also been successfully implemented.

2.1.3 Skilled and unskilled labour

These workers are recruited in the surrounding areas and are trained in the factory. Being a government organization, Royal Drugs Ltd. follows the accepted pattern of recruitment through the Public Service Commission, advertisement of vacant posts, salary scales, permanency and advancement.

Permanent workers are encouraged to complete their secondary school educations and every facility is afforded to them for this purpose.

2.2 ROYAL DRUGS EXPANSION PROGRAMME

2.2.1 Present facilities

The factory started operations in 1968 with a floor area of 780 sq. m. It produced a range of drugs^{2/} in tablet, capsule, and liquid forms, ointments, and large volume intravenous fluids as well as rehydration salts.

At that time the equipment^{3/} and the facilities were adequate, considering the quantities required. Since its conversion, in 1972, into a commercial

^{2/} See Annex VIII for list of drugs.

^{3/} See Annex IV for list of existing equipment.

organization of the public sector, the company steadily and appreciably increased its production and sales. By the end of 1974 the commercial success of the company had created an acute space problem in the existing hired facilities. Moreover, because of the limited capacity of the machines, a further increase in production, that would lead to the 1980 targets ^{4/} as they were then evaluated, was not possible.

Table 1 a/
Sales target and Achievements

(a) US Dollars

<u>Year</u>	<u>Targets</u>	<u>Achievement</u>	<u>Profit</u>
1972-73	120,000	114,080	18,193.68
1973-74	203,200	202,560	33,301.04
1974-75	260,000	271,630	42,893.87
1975-76	433,400	454,400	93,513.76
1976-77	480,000	539,254	98,390.13
1977-78	600,000	-	
1978-79	800,000	-	
1979-80	200,000	-	
1980-81	260,000		

(b) Nepal Rupees (till 1977 - US\$ 1 = NRs.12.45)

<u>Year</u>	<u>Targets</u>	<u>Achievement</u>	<u>Profit</u>
1972-73	15,00,000	14,26,000	2,27,421.17
1973-74	25,40,000	25,32,000	4,22,513.26
1974-75	33,50,000	33,96,000	5,36,173.47
1975-76	54,80,000	56,80,000	11,68,922.00
1976-77	60,00,000	67,40,680	12,37,376.71
1977-78	75,00,000	-	
1978-79	1,00,00,000	-	
1979-80	2,50,00,000	-	
1980-81	3,25,00,000	-	

^{3/} See Annex III for detailed Production Charts.

^{4/} See Annex V for breakdown of production according to individual departments and also projected targets.

The country's demand for drugs for 1975-1976, as per the WHO Regional Office, was US\$ 3 million. Royal Drugs Ltd. contribution for that year was 15% of that sum.

The country demand for drugs for 1979-80 was estimated by the WHO Regional Office as US\$ 4 million. Royal Drugs Ltd. contribution for 1980-81 is expected to be 65% of that sum.

The organization supplies its products to various hospitals and health posts, at about production cost price, to help the Basic Health Services Programme of the Department of Health Services. But keeping in view the financial aspects of a public corporation, the company has been able to show marginal profits every year.

2.2.2 The new building complex

Royal Drugs Ltd. acquired 2.6 hectares of land (26,000 sq.m.) at Babar Mahal in 1975.

The main factory building, with a total floor area of 6,500 sq.m. will house the tablets, liquids and ointment sections, the sterile products unit, the quality control department, and the products development section. The main factory building will be air-conditioned, with proper humidity control, where required.

The raw materials store as well as the finished-goods store have already been moved to their respective buildings^{5/}, while the tablets packaging section has started to operate on a temporary basis in a closed part of the raw materials store.

It is hoped that the construction work will be completed by 1979-80 and that the new machines will be installed by that time.

2.2.3 Machines and other equipment

A long-term evaluation of the machines and other equipment necessary for a 5-10 years period was made on the basis of the production projections to 1980-1981^{6/}

^{5/} Please refer to Annex II for excerpts of Progress Reports 1976-1978.

^{6/} Please refer to Annex V for existing and additional machines required.

Keeping in mind the company's policy to lower its production costs as much as possible, the machines were individually selected with the following criteria:

- (a) High output, corresponding to actual needs,
- (b) Modern technology,
- (c) Reasonable cost,
- (d) Ease of handling, low maintenance.

As an example: much thought was given as whether to buy a rotary tablet compressor having 35 stations (similar in build and operation to the existing two tablet compressors of 16 stations each), or from the same manufacturer, a newer model giving the same output with only 25 stations. Though slower, but because it cost appreciably less and was thoroughly field proven, the 35 stations compressor was preferred.

The list of machines was modified several times in order to simplify and reduce production operations.

Table 2

List of equipment that was included for higher efficiency

<u>Equipment</u>	<u>Department</u>	<u>Characteristics</u>
<u>Mixer-granulator</u>	Tablets	Considerable reduction of wet mixing and granulation periods.
<u>Machine for Sugar Coating or film coating of tablets</u>	Tablets	Simplification of the coating process. Time saving. More uniform product obtained.
<u>Thermocompression Still</u>	Sterile Products	Very low energy consumption cost, high yield of distilled water of very high purity.
<u>Rotary bottle washing machine, heavy duty type</u>	Sterile Products	Considerable reduction of rejects in large volume intravenous fluids bottles.

In the tablets and liquids packaging sections, Labour Intensive Method were retained: (a) all labelling will be manual, (b) Hand-counters or suitable balances will be used to count or weigh tablets into bottles.

2.2.4 The Quality Control Department

Up to 1977 the Royal Drugs Research Laboratory handled all the quality control for Royal Drugs Ltd., while the latter provided the manpower (2 qualified pharmacists) to do the actual work. In 1977, the decision was taken by Royal Drugs Ltd. to operate its own Quality Control Department in order to have direct control over the operations. The staff was strengthened and rules made more stringent. While additional equipment and glassware were immediately purchased from India, plans were drawn up for a well equipped Quality Control Laboratory in the new building.

2.3 THE ESSENTIAL DRUGS LIST FOR NEPAL

Two separate lists of Drugs were drawn up.

The first includes all the drugs presently manufactured by Royal Drugs Ltd. as well as 80 new preparations that the company considers manufacturing within a period of 3 years at the new factory.^{7/}

The Medical Committee approved 8 new preparations from this list, and their production will start soon.^{8/}

The second list, which is to serve as a guide for an Essential Drugs List for Nepal ^{9/}, contains about 150 different preparations and has been given very wide diffusion.

2.4 DEVELOPMENT OF NEW PRODUCTS

Leading physicians, and specialists in the Kathmandu Valley, and in the Western and Central Regions were interviewed, and major hospitals and drugstores were visited, so as to gather on-site needs and requests.

There was a general consensus among the physicians visited that Royal Drugs Ltd. should increase its range of products. Since that was impossible with the existing facilities, efforts were made to experiment on new product formulations for the new factory ^{10/}.

^{7/} See Annex VIIIB for list of existing drugs and new drugs proposed for future production.

^{8/} See Excerpts of progress reports page 7.

^{9/} See Annex VIIIC for Essential Drugs List.

^{10/} See excerpts of progress reports page 3.

2.5 RAW MATERIALS

All synthetic raw materials for the formulation of finished products are imported. Quotations are requested from qualified manufacturers in Eastern and Western Europe, Japan and India. Royal Drugs Ltd. usually accepts the lowest quotation. Raw Materials are not ordered simultaneously on a yearly basis, but according to needs.

2.6 THE DRUG ADMINISTRATION ACT (DRUG LAWS AND ORDINANCES)

The Drug Administration Act is at the stage where it has to be ratified at the Rastriya Panchayat (National Assembly) level.

There are about 25 qualified pharmacists in Nepal, most of whom are employed by Royal Drugs Ltd. or Royal Drugs Research Laboratories.

In Hospital pharmacies, compounders are in charge. The same situation prevails in Drugstores.

In the absence of a Drug Administration Act, both reliable drugs, from Multinational and National firms operating in India, and substandard "spurious" drugs enter into Nepal.

2.7 DISTRIBUTION OF DRUGS

2.7.1 Distribution of Royal Drugs Ltd. Products

Up to 1977, Royal Drugs Ltd. distributed its drugs to the Department of Health Services, Hospitals, etc. through a semi-government co-operative: Sajha Swasthya Sewa. This co-operative handles the Annual requirements for local and imported drugs and chemicals to be supplied to the Department of Health Services, the major hospitals in the Kathmandu Valley etc.

Starting 1977, Royal Drugs Ltd. decided to deliver its products directly to the above government institutions because of delays in deliveries of Royal Drugs products. The company's products are distributed outside of the Kathmandu Valley through private carriers (trucks) or by Parcel Post. Since the direct delivery system has been implemented, the company has direct control over the supply of its products and the efficiency in supply and delivery has greatly improved.

2.7.2 The 'Hill Drug Scheme' Pilot distribution project

The above organization is part of the Britain - Nepal Medical Trust and operates Pilot projects in 2 Far Eastern Zones. Its goal is to ensure that drugs are supplied cheaply to the remote areas and high hills by controlling sales and preventing peddling. The organization has 22 shops in operation in the Kosi and Mechi Zones. It buys most of its drugs from Royal Drugs Ltd. at Hospital rates.

2.8 MEDICINAL PLANTS

At present Royal Drugs Ltd. is using only local liquid Belladonna extract for its tablet formulations, and local liquid Vasaka extract for its expectorant cough syrups. Both extracts are produced by Royal Drugs Research Laboratories.

A meeting was held with the ESCAP Consultative Mission on the Essential Oil Industry ^{11/} as well as with the Romanian exploratory mission sent by the UNIDO - Romanian Centre to Nepal and Afghanistan in 1977 ^{12/} Phase II of the UNIDO - Romanian Centre will consist in sending a mobile unit towards the autumn of 1978, for the collection and extraction of active principles from medicinal plants in different parts of Nepal, and possibly a short-term (7 months) Romanian expert, through UNIDO, for the economic mapping of spontaneous flora.

2.9 AYURVEDIC DRUGS

The policy ^{13/} of the Department of Health Services is to provide certain amounts of inexpensive and effective Ayurvedic Drugs to the health posts. In accordance with this policy, Royal Drugs Ltd. will gradually take up the manufacture of these drugs in a separate unit at the factory.

^{11/} ESCAP: Report of the ESCAP Consultative Mission on the Essential Oil Industry, United Nations 1977.

^{12/} The Mission's Report Phase I RP/RMS/76/009 gives a descriptive information on the activities of the Department of Medicinal Plants.

^{13/} Basic Health Services - long-term country programme 1975-1990. Department of Health Services.

2.10 REHYDRATION SALTS

A document^{14/} signed on the 30th July 1976 by HMG of Nepal stated, under the heading of "Maternal and Child Health"; "Oral Rehydration will be encouraged throughout the Health Service System to the maximum possible extent. This will include provision for Oral Rehydration Solutions. UNICEF Assistance will primarily be used for improving the capacity of Royal Drugs Ltd. for producing and packing oral rehydration mixtures in Nepal".

Diarrhoeal Diseases (dysenteries and cholera) are regarded as the biggest killer of infants and children in Nepal^{15/}.

Co-ordination between the UNICEF Representative at Kathmandu and Royal Drugs Ltd. has been an important task during the period of UNICEF's planned assistance in setting up a modern Rehydration Unit. This shall enable Royal Drugs Ltd. to produce Rehydration Salts on a countrywide basis^{16/}.

2.11 FINANCIAL SUPPORT OF ROYAL DRUGS LIMITED, EXPANSION PROGRAMME

2.11.1 Possibility of UNIDO's support for equipment and machines for a Quality Control Unit and Research and Development (Pilot units), Technical Assistance, and Fellowships

After UNIDO notified UNDP at Kathmandu of its willingness to look into the possibility of funding US \$400,000 (US\$200,000 in 1978-79, and the balance in 1980) for financial and technical assistance, Royal Drugs Ltd. presented its request for the first stage through the appropriate government channels to Foreign Aid and Programme Division - Ministry of Finance, for submission to UNIDO.^{17/}

^{14/} "Development of Services benefiting children in Nepal" Plan of Operations 1975-1980 of His Majesty's Government of Nepal in co-operation with UNICEF, WHO, UNESCO.

^{15/} Dr. M.R. Baral: Guidelines for Rehydration Therapy in Diarrhoeal Diseases, Kathmandu, December 1976.

^{16/} "Diarrhoea is really the headache of the developing world, and if the people there have access to the Electrotone - glucose mixture, which costs only two pennies, then they have something that is very effective. How to develop the felt need for that is the real problem". John Eliot Rohde in "Taking Science where the Diarrhoea is" page 364 in: "Acute Diarrhoea in childhood". Ciba Symposium Foundation, Elsevier 1976.

^{17/} See Annex VI for itemised list of equipment.

2.11.2 Support by a Donor Country, through UNDP, of Production Units

Under project NEP/73/009 - Primary Health Support Services Programme, UNDP notified Royal Drugs Ltd. of discussions being held with the Department of Health Services on the above project, whereby Royal Drugs Ltd. would receive an allocation of US \$100,000 for production equipment for basic drugs, for the Department of Health Services. ^{18/}

2.12 TECHNICAL CO-OPERATION BETWEEN DEVELOPING COUNTRIES (TCDC)

2.12.1 Official travel to the Union of Burma

Together with 3 Senior Officers of Royal Drugs Ltd., a two-weeks visit to the Union of Burma was made in the autumn of 1977. Specific recommendations on future technical co-operation between Royal Drugs Ltd. and the Burma Pharmaceutical Industry were made in a report submitted to UNIDO ^{19/}

2.13 SUPPORTING INDUSTRIES

2.13.1 Balaju Yantra Shala (Private) Ltd. - Balaju Industrial Estate.

It comprises the following divisions:

- (a) Electrical Division
- (b) Mechanical Division
- (c) Sanitary Engineering Division (Plumbing)

Royal Drugs Ltd. has contracted all three divisions for the different installations of the new factory.

2.13.2 Printing Presses, etc.

(a) Jore Ganes Press (Private) Ltd. at Balaju Industrial Estate

The above is the most modern printing press in Kathmandu, and Royal Drugs Ltd. orders some labels and secondary containers from it.

(b) Indian Printing Enterprises

Royal Drugs Ltd. orders all its requirements of printed laminate rolls, and pouches for rehydration salts, from two large companies in India,

^{18/}See Annex VII itemised list of equipment for Production Units, as requested from UNDP.

^{19/}See Annex X for full report on Mission to Burma.

one of which is a multinational. Royal Drugs Ltd. also orders a large quantity of labels and secondary containers from India.

2.13.3 Glass bottles

All glass bottles, including special neutral glass bottles for intravenous fluids, are ordered from India.

2.13.4 Plastic bottles for tablets

Polyethylene bottles and caps are obtained from a local supplier who manufactures them from imported granules.

Annex I

J O B D E S C R I P T I O N

Post Title : Pharmaceutical Advisor

Duration :

Date Required :

Duty Station : KATHMANDU, Nepal.

Duties : To develop and establish a Pharmaceutical Industry in
Nepal. The expert will be expected to :

1. investigate the local requirement of pharmaceuticals with projection for the next five years;
2. select a few specific basic pharmaceuticals which can feasibly be made by Royal Drugs Ltd., the National Industry;
3. introduce a range of pharmaceutical products, which as investigated, are appropriate for local needs;
4. suggest quality control of pharmaceuticals at Government and factory levels;
5. help the Royal Drugs Ltd. to finalize the lay-out of the new buildings including the internal layout of the machineries.
6. investigate the present export-market of drugs containing vegetable materials and examine the possibilities of their extraction for increased values;
7. draw up a development plan of the pharmaceutical industry on the basis of the above;
8. prepare a detailed list of equipment and machinery needed for production of drugs recommended by the expert.

Qualifications : Chemical engineer or Pharmacist with a great deal of experience in developing and establishing a Pharmaceutical industry.

Language : English.

Annex II

EXERPTS OF PROGRESS REPORTS 1976-1978

1.0 Royal Drugs Ltd. Expansion Programmes

1.1 The buildings of the new factory

The construction of the buildings was contracted to the National Construction Company of Nepal (NCCN). Royal Drugs Ltd. also enlisted the services of a local Architect and Consultant. The senior management was actively involved in decisions pertaining to the internal layout of the factory. For the outer architecture, the services of a Nepalese Architect was secured.

At present both the Raw Materials and the Finished Goods buildings have been completed and are operating normally. The tablets packing section was shifted temporarily in June 1978 to specially partitioned cubicles separated from the Raw Materials Stores. This urgent move was taken in order to relieve the congested tablets production section.

Several Indian firms were contacted to install the air conditioning system for the new factory. In addition, a Refrigeration Expert graciously volunteered his services to the company.

The site engineer of NCCN was sent by Royal Drugs Ltd. for 2 weeks to India, to investigate and recommend special flooring materials, water-proof paints, and ready-to-install aluminium window frames.

1.2 Machines and equipment

A systematic survey was made, with the co-operation of senior officers, of equipment and machines available at the factory, per department, together with the projected production. The new equipment that would be required was listed, together with per item:

- Capacity
- Cost of production
- Maintenance and serviceability
- Correspondance to actual needs.

The needs in machinery for a short-term projected production was also assessed, when it was estimated that the target of production of tablets for 1979 would correspond to the output of the two Rotary 16 stations compressors: 50 million tablets.

The following equipment was ordered from England and arrived in mid-1978:

- One large Horizontal Ribbon Mixer, 80-100 kg. capacity for wet granulation.
- Two Ovens, of 80 stainless steel trays each.
- One Rotary tablet compressor of 35 stations.

At the same time a modern automatic strip - packing machine arrived in 1978 and is slowly replacing the old semi-automatic machine purchased in 1968.

2.0 Ayurvedic (Traditional) medicines

Thorough visits were made of the Ayurvedic Medicines Production Centre - Vaidyakhana, and of the Ayurvedic Hospital. The production methods are somewhat primitive, and the Centre is running on a very restricted budget.

A Committee from the Department of Health Services selected in 1976 about 15 Ayurvedic Drugs that were to be manufactured by the Centre and distributed to 65 Integrated Health Posts - together with selected Allopathic medicines. ^{a/}

It seems that the acceptance of the above Ayurvedic medicines has not been very favourable at the Health Posts.

The Government Ayurvedic Hospital has 25 beds. Locally prepared Ayurvedic Drugs are used, but production methods are primitive. Cures are claimed for infections hepatitis, as well as for most other diseases.

^{a/}List attached at the end of this Annex.

A private Ayurvedic firm was also visited. Tablet presses with single punches are used, as well ^{as} tincture presses. Plant extracts are also produced.

Ayurvedic medicine is now being taught in a 3 years course at the Ayurvedic Campus of Tribhuvan University.

Dr. S. Matori, WHO Consultant on ayurvedic medicines to the Ministry of Health, visited Royal Drugs Ltd. in July 1977. He was told of the Company's policy to start producing selected Ayurvedic Drugs in a separate unit at the new factory.

3.0 Products Development

While a further increase in products was impossible in the present factory, efforts were made to experiment on new products, as well as to improve the quality of existing preparations.

The following development work was done:

- (a) Formulation and experimental production of a toothpaste.
- (b) Experimental production of Cold Tablets.
- (c) Experimental production of B Complex Vitamins.
- (d) Experimental production of a Chewable Calcium + Vitamins tablet.
- (e) Experimental production of an improved Chewable Antacid tablet.
- (f) Experimental production of an Antacid suspension.
- (g) Formulation and production of improved Film-coated tablets.
- (h) Improvement of existing preparations by the incorporation of selected disintegrating agents, and selected excipients.
- (i) Improvement of the "Gripo Mixture".
- (j) Experimental production of Film coated Metronidazole tablets for children.
- (k) Production of triple sulpha powders for reconstitution to Syrup, for children.

4.0 Essential Drugs List

In order to prepare the way for the gradual introduction, by Royal Drugs Ltd. of Essential Drugs in Nepal, exploratory meetings were held with a certain number of officials, senior physicians and pharmacists having diverse fields of expertise. As a result of these meetings a preliminary list of new drugs was drawn up, in different therapeutic categories. The list was modified several times, in consultation with senior physicians, and finally submitted by Royal Drugs Ltd. to different Ministries. This list should serve as a guide for the production and distribution of basic drugs in Nepal.

5.0 Financial support of Royal Drugs Ltd.

Expansion Programme by International Organizations.

5.1 Possible support by UNIDO/UNDP

UNIDO showed its willingness to consider financing part of the above programme, in the form of equipment and machines for the Pilot Plants, Quality Control Unit, Fellowships and Technical Assistance. Royal Drugs Ltd. prepared an itemised list of equipment for UNIDO's kind consideration. (list attached at the end of this Annex)

5.2 Contribution by a Donor Country through UNDP (Project NEP/78/009)

In June 1977 the UNDP Representative called a meeting attended by WHO and UNICEF country Representatives and the UNIDO expert, in order to discuss how best to use the funds of a Donor Country to improve the distribution of medical supplies by the Department of Health services throughout the country.

At this meeting it was pointed out that it was equally important to develop the production capacity within Nepal, of basic drugs which are at present imported from abroad. Later co-ordination with the Department of Health Services led to the recommendation (see Annex 7) that approximately one third of the donated funds be used by Royal Drugs Ltd., for its production units suggested by UNIDO.

6.0 UNICEF's Assistance to Royal Drugs Ltd.

6.1 Jeevan Jal (Life-giving water) - Oral Rehydration Salts.

Royal Drugs Ltd. started to manufacture oral Rehydration Salts under the name of RD-Sol. This was done some years back at the request of the United Mission Hospital at Shanta Bhawan, and the Teku Hospital. The salts were processed and packed manually into polythene lined paper bags and heat sealed.

The product had become very popular with physicians by 1976, and special high quality preferred Aluminium laminate pouches were imported from India, to better protect the product.

"RD-Sol" was mentioned at an International Symposium in London, in 1975. ^{b/}

UNICEF committed itself officially in 1976 to assist Royal Drugs Ltd. to produce and market RD-Sol on a country-wide basis. ^{c/}

For the next 1½ years discussions were held regularly between Royal Drugs Ltd. and UNICEF for the supply to Royal Drugs Ltd. of a Complete Unit for the mass production of Rehydration Salts, including a 3-years nation-wide publicity drive to be conducted by UNICEF.

In 1977 and 1978 Dr. H.R. Baral, Senior Paediatrician at Kanti Hospital, and member of the Medical Committee of Royal Drugs Ltd. attended conferences on Diarrhoeal Diseases in New Delhi and Bangkok. In these meetings he presented papers on the use of Royal Drugs Ltd. Rehydration Salts.

^{b/}Taking Science where the Diarrhoea is by Jon Eliot Rhode - page 346 (see also discussion) in "Acute Diarrhoea in Childhood" Ciba Foundation Symposium 42 Elsevier 1976.

^{c/}Development of Services benefiting Children in Nepal - Plan of Operations 1975-1980. H.C. of Nepal in Co-operation with UNICEF, WHO & UNESCO.

In February 1978 a formal agreement was signed between UNICEF and Royal Drugs Ltd. Long before that, UNICEF started to purchase Oral Rehydration Salts from Royal Drugs Ltd. for the Department of Health.

6.2 The purchase by UNICEF of selected basic drugs from Royal Drugs Ltd. for distribution to Health Posts.

On separate occasions UNICEF sent Royal Drugs Ltd. Chloroquine phosphate tablets and Isoniazide + Thiacezone tablets to New York and Berne respectively, for Quality Control. UNICEF informed Royal Drugs Ltd. that the above products conformed to official standards.

Basic drugs like Aspirine tablets and Piperazine adipate tablets are now purchased by UNICEF from Royal Drugs Ltd. It is hoped that in the future other products will follow.

7.0 Medicinal Plants

Close contacts were maintained with the Director-General of the Department of Medicinal Plants and his Senior Officers at the Royal Drugs Research Laboratories.

7.1.0 The following topics were discussed and their commercial possibilities explored.

7.1.1 The exploitation of Pine oleoresin for industrial production of turpentine, rosin, and camphor.

7.1.2 The industrial production of reserpine, ajmaline and other alkaloids from the roots of Rauwolfia serpentina.

7.1.3 The industrial production of different Essential Oils.

7.1.4 The industrial production of Pyrethrum extract.

7.2 Discussions were held with the two member mission from ESCAP^d that explored in situ the potentialities of Essential Oils production in Nepal and neighbouring countries. Possibilities of local production and exports of medicinal plants were discussed.

Discussions were also held with members of the UNIDO Rumania Mission for Medicinal Plants.

8.0 The Medical Committee

The Medical Committee is formed of four senior physicians, one of whom represents the Armed Forces Health Services. Eight new preparations were approved for production in the future, at the new factory:

Propranolol tablets B.P.
Methyldopa tablets B.P.
Hydrochlorothiazide tablets B.P.
Frusamide tablets B.P.
Nitrofurantoin tablets B.P.
Ethanbutol tablets B.P.
Vitamin B Complex tablets
Cold tablets.

9.0 Training Programmes

The Chief Production Officer was awarded a UNIDO fellowship that was specially adapted to the needs of the factory. He spent six weeks in July-August 1977 in England and West Germany on a training programme on Pharmaceutical technology. In England he worked for three weeks at a well known factory manufacturing machines for tablets production (compressors, mixers, granulators, automatic tablet coaters etc.). In Germany he visited the manufacturer of strip packing machines from whom Royal Drugs Ltd. was purchasing an automatic machine.

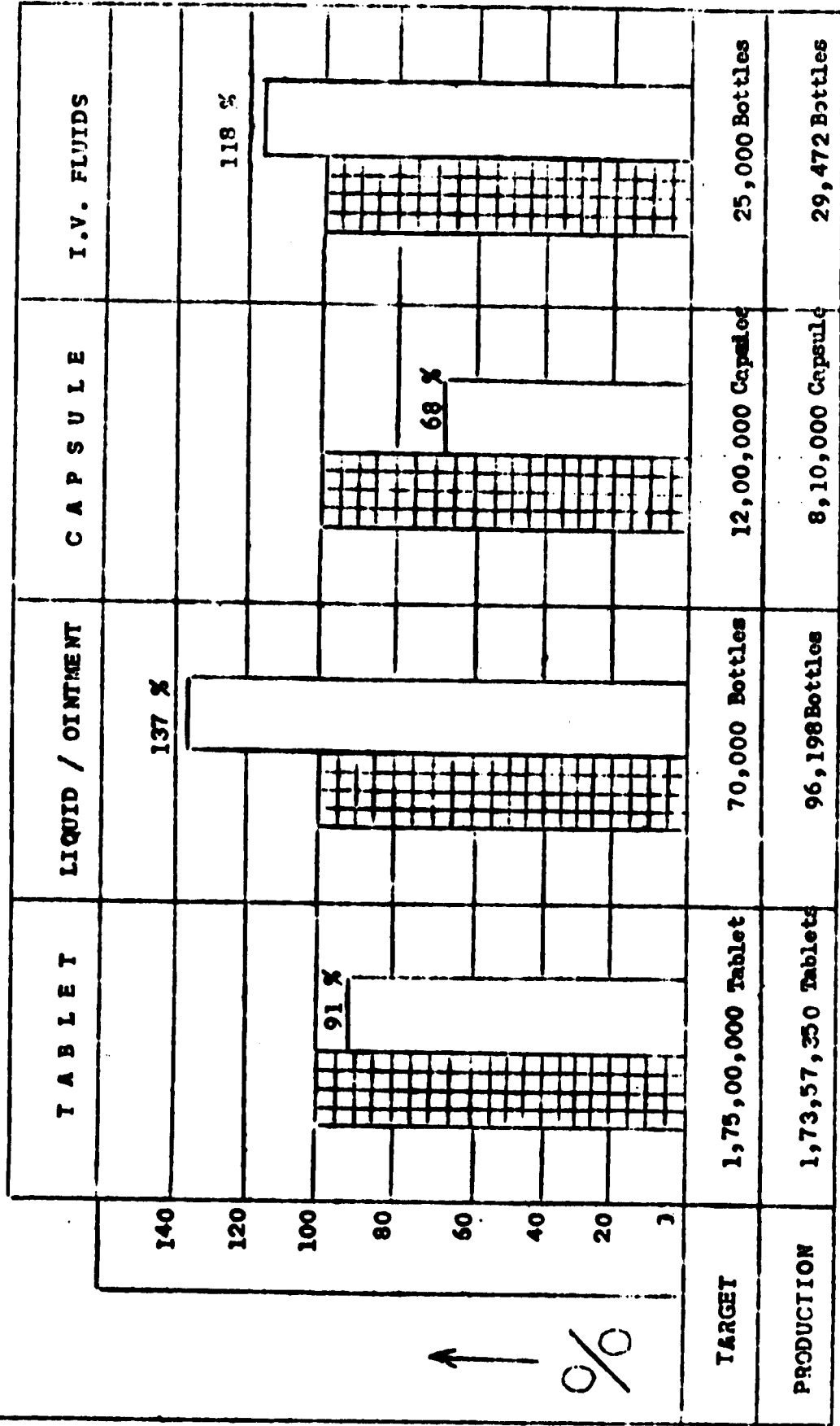
^d/Report of the ESCAP Consultative Mission on Essential Oil - Industry
United Nations, April 1977.

Annex III

ROYAL DRUGS LTD, PRODUCTION CHARTS

PROGRESS CHART

1972 / 1973



TARGET

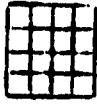
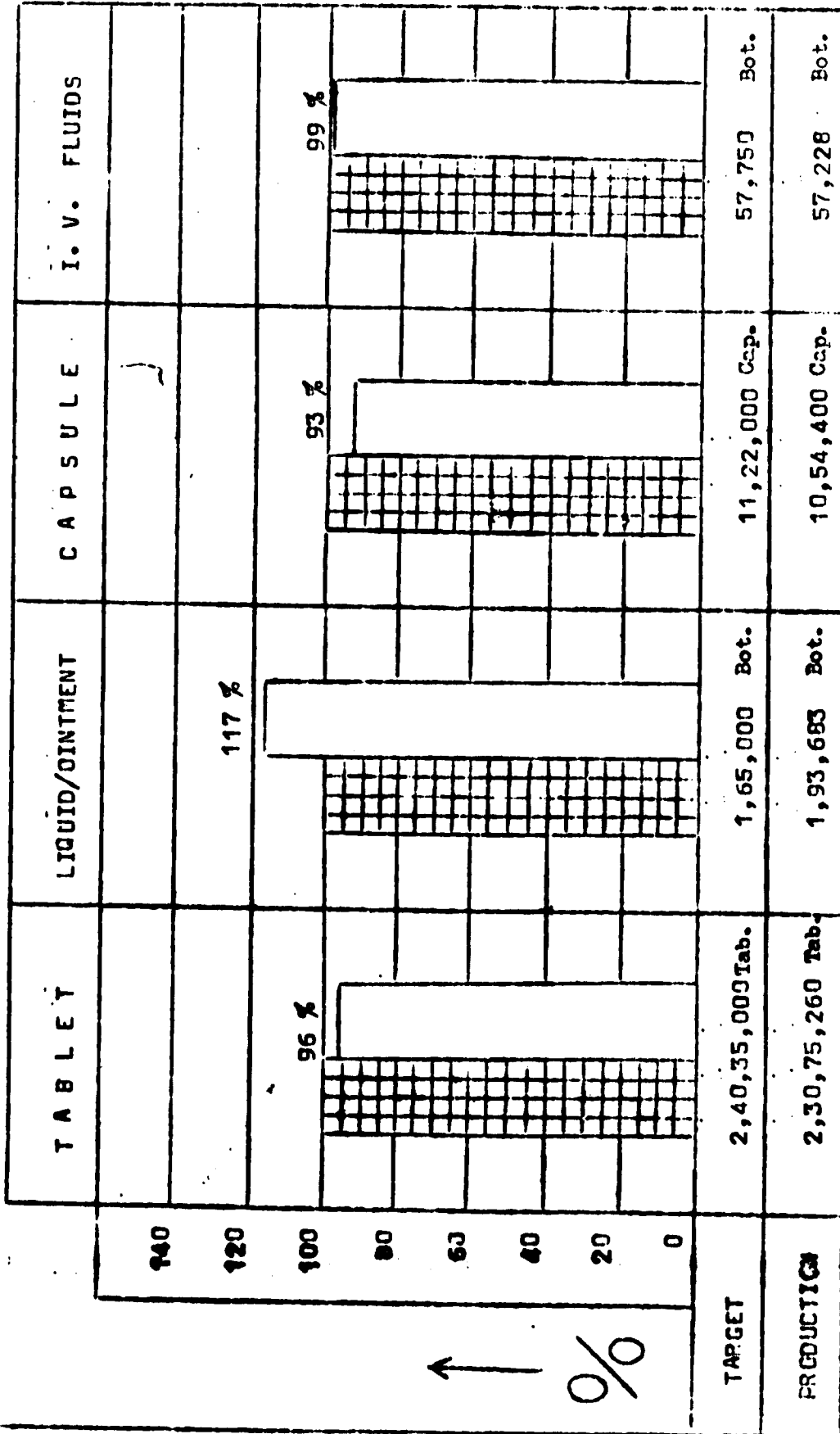


Production

↑ %

PROGRESS CHART

1973-1974



TARGET

- 32 -

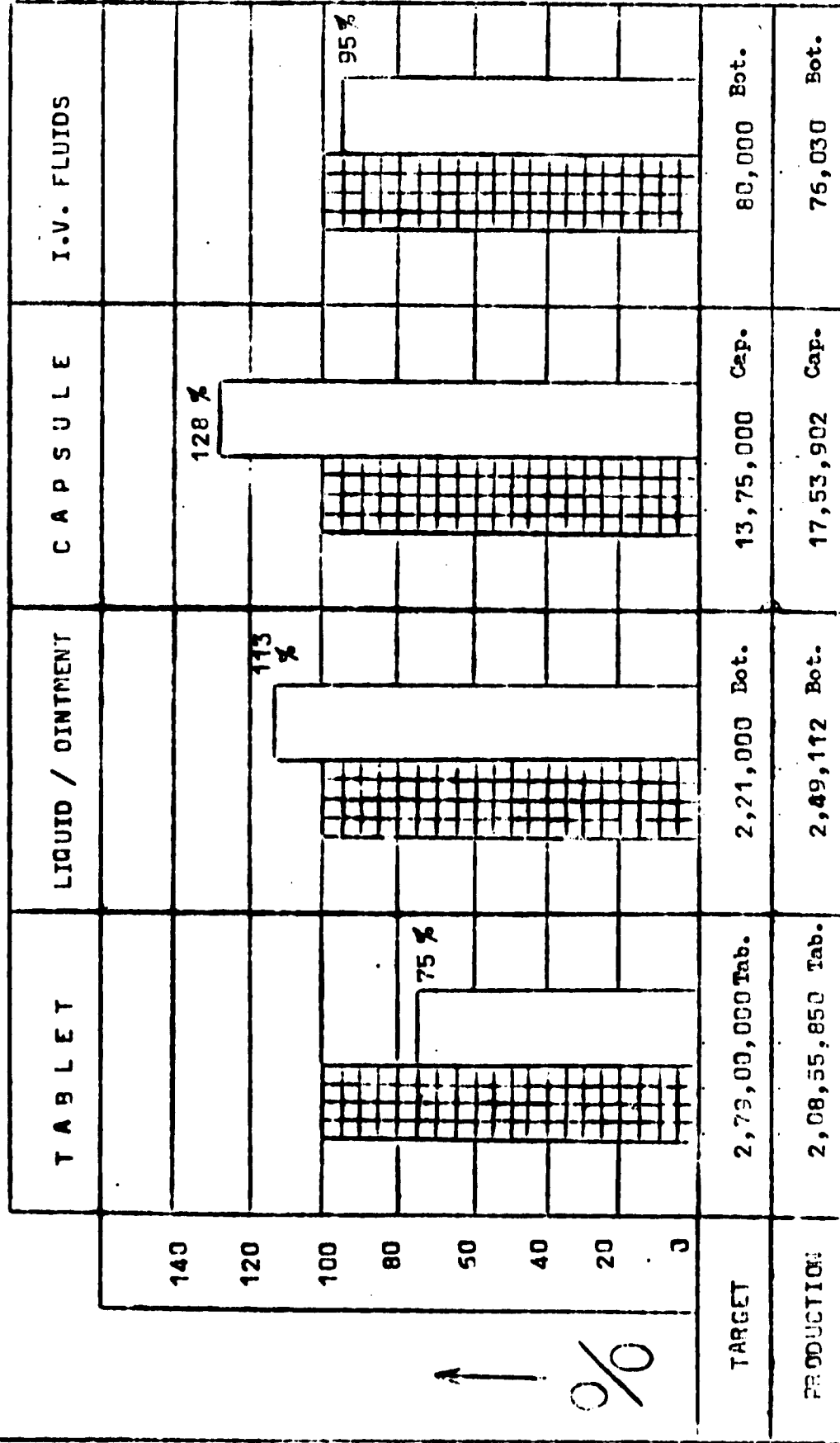


Production

↑
%

PROGRESS CHART

1974-1975



140
120
100
80
50
40
20
0

↑
%



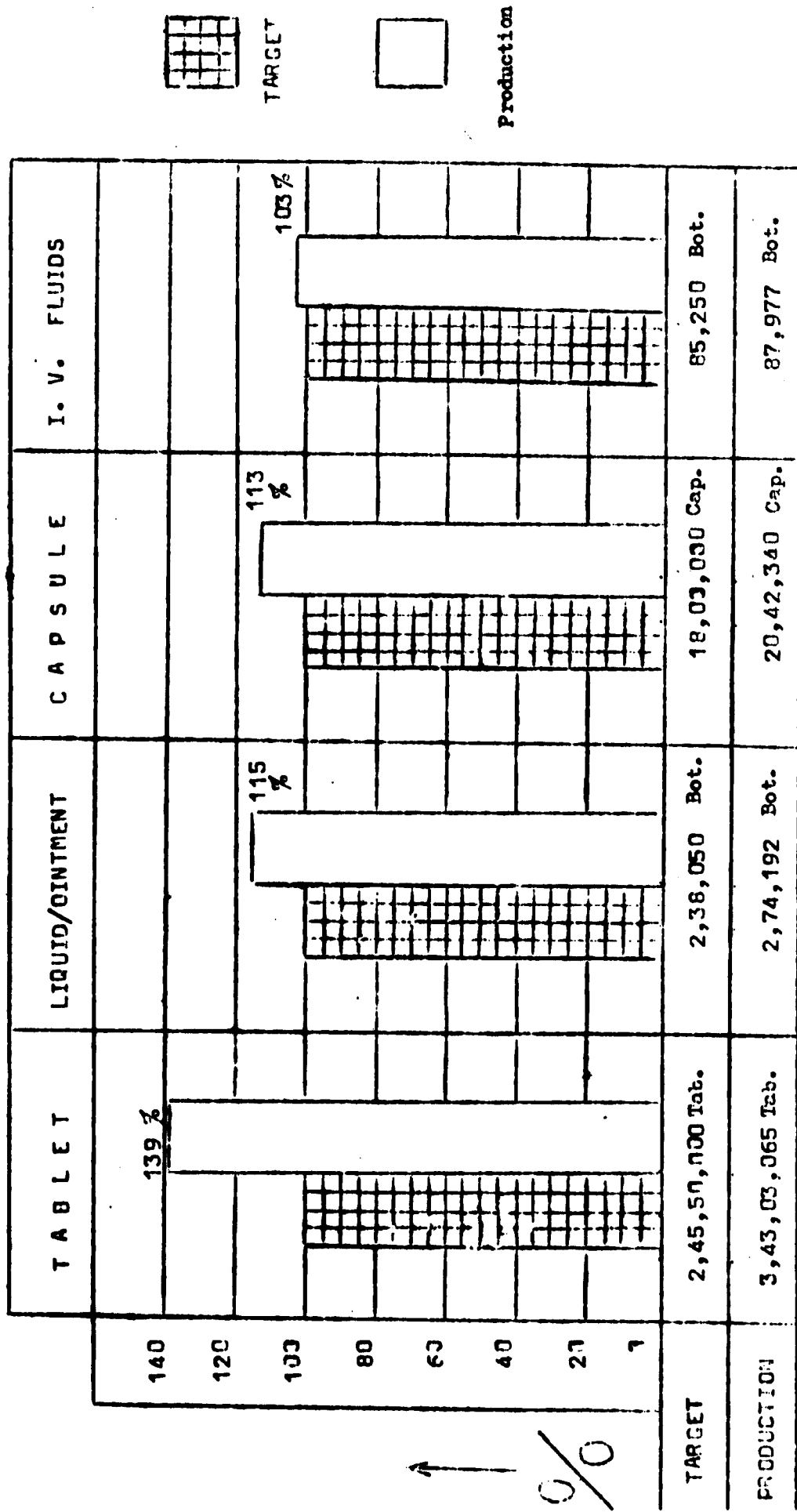
TARGET

- 33 -

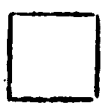


Production

PROGRESS CHART
1975-1976



TARGET



Production

139 %

115 %

113 %

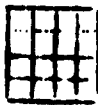
103 %

↑
%

140
120
100
80
60
40
20
0

PROGRESS CHART

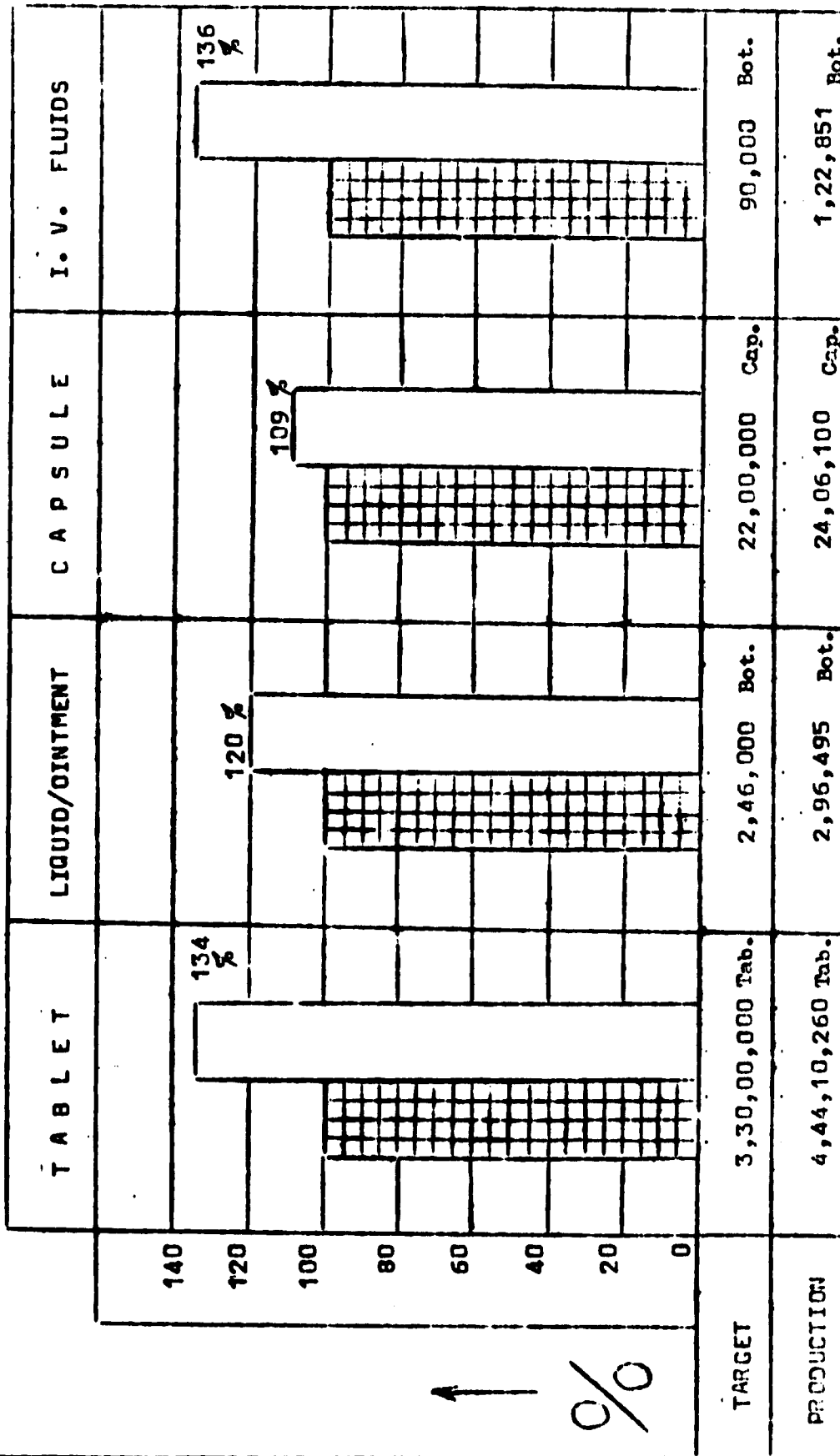
1976-1977



TARGET

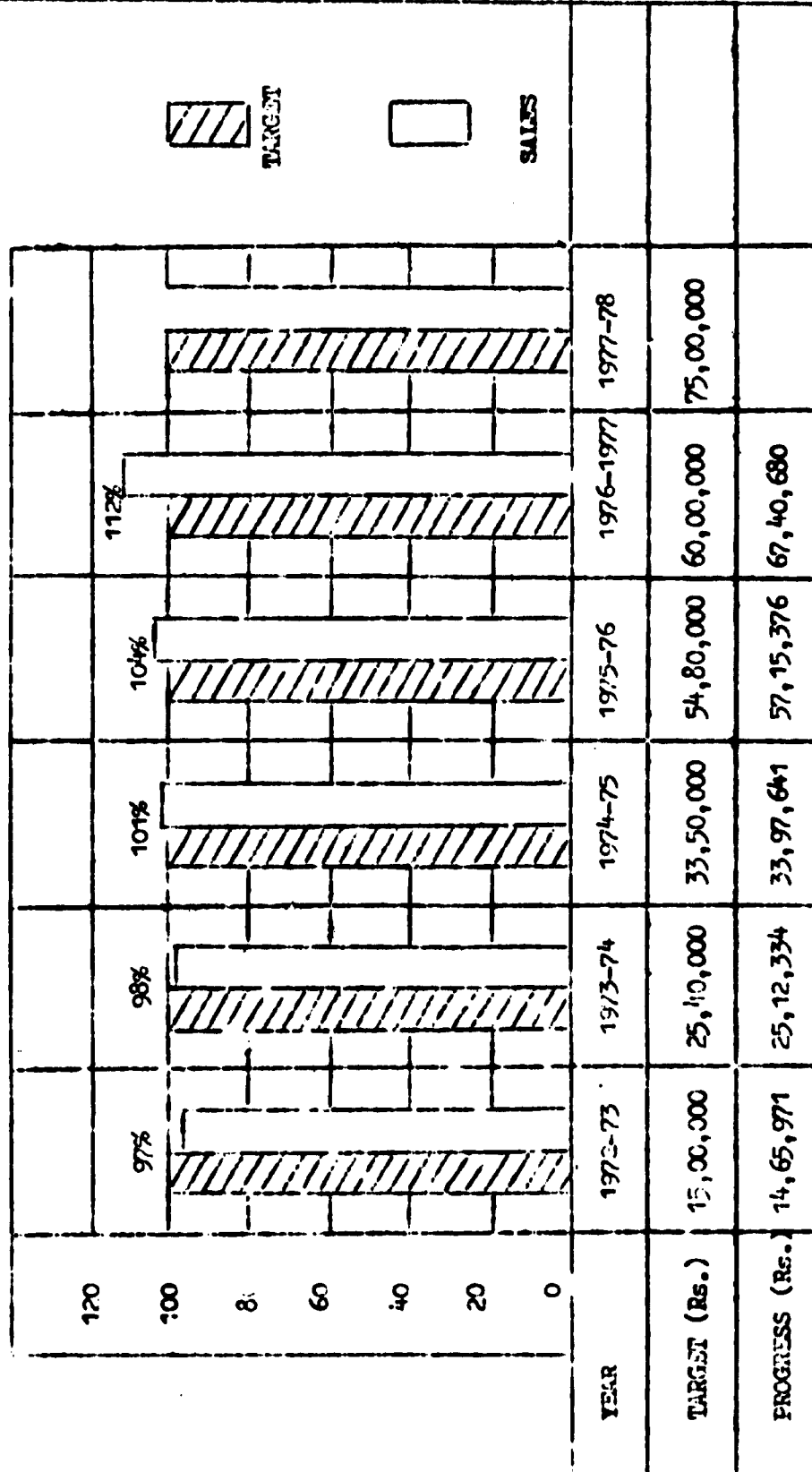


Production



↑
%

SALES PROGRESS CHARTS
1972-73 to 1977-78



Annex IV

ROYAL DRUGS LTD - EXISTING MAJOR EQUIPMENT, 1976-1977

1. Tablet Department

- one horizontal ribbon mixer 50 kg. capacity
- one horizontal ribbon mixer 100 kgs. capacity
- one hammer mill 5 H.P.
- one rotary wet granulator
- one extrusion type wet granulator
- one double-core mixer 150 kgs. capacity
- one Y mixer 50 kg. capacity
- two oscillating dry granulators
- one oven - 80 trays
- one oven - 40 trays
- one oven - 20 trays
- two rotary tablet compressors 16" stations each with tablet dedusters
- one coating pan 42"

2. Liquids and Ointments Department

- one liquids mixing tank 250 litres capacity with bottom side-stirrer, all stainless steel
- two heat treatment vats 250 litres capacity, stainless steel
- four stainless steel storage tanks, 250 and 500 litres capacity
- two filter presses
- one liquid filling machine, stainless steel
- one planetary mixer, vertical type
- one deaerator
- one water still

The Intravenous Fluids Section

- 3 water steels, different capacities, for production of pyrogen free distilled water.
- storage tank
- mixing tank
- 3 autoclaves, standing type, electrically operated.

The Capsules Section

- one Capsule sorter, semi-automatic
- two capsule filling machines, manual
- two capsule sealing machines
- two balances

Annex V

ROYAL DRUGS LTD, PRODUCTION UNITS - EXISTING AND ADDITIONAL
MACHINES AND EQUIPMENT REQUIRED BY THE END OF 1979

1.1 TABLETS DEPARTMENT

Estimated production target end 1979 = 250 million tablets.

1.1.1. Tablet compressors

Existing machines (a) Rotary, B₃B 16 stations^{a/} 2 machines

Date of purchase : 1964

Actual average output/machine : 25,000 tablets/hour

For a 5 hours/day and 200 working days/year : 25 million tablets/year

For 2 machines : 50 million tablets/year

(b) Rotary BB₃B 35 stations

Date of purchase : 1978

Average yearly output : 100 million tablets

Additional machines required

(a) Rotary, BB₃B 35 stations : 2 machines

Average output/machine : 90,000 tablets/hour

Average yearly output/machines : 100 million tablets

For two machines : 200 million tablets

(b) Rotary, D₃B 16 stations : 1 Machine

max. diameter 25 mm, for large chewable
tablets and for slugging.

Average yearly output : 15 million tablets

1.1.2. Drying Ovens

Average tablet weight at Royal Drugs Ltd. : 0.5 gm.

For 250 million tablets : 125 tons dry weight

For a wet mass with an average 40% water
content : 185 tons/year

^{a/}Two old compressors will have to be replaced by 1979 by one BB₃B 35 stations,
or one Express 25 or one ~~beta~~ 2,000 (W. Fette).

Existing Ovens

No. of Ovens	No. of trays	Date of purchase	Daily capacity	Yearly capacity
1	20 ^{b/}	1966	25 kgs.	5 tons
1	40	1973	50 kgs	10 tons
1	80	1976	100 kgs	20 tons
2	80	1978	200 kgs	40 tons

Total drying capacity for ovens : 70 tons/year
 Additional drying capacity required : 115 tons/year.

Additional ovens required

(a) Ovens, 80 stainless steel trays : 3 Units
 (b) Fluid-bed dryer^{c/} 60 kgs. capacity : 2 Units
 Average yearly output : 72 tons for 2 Units/yr.

1.1.3. Granulators

(a) Wet granulation for 185 tons of wet mass/year.

Existing machines

(a) Jackson-Crocket granulator ^{d/} (small model)

Date of purchase : 1963
 Actual output : 20 tons/year

(b) Apex Rotary Granulator (small model 1½ H.P.)

Actual output : 50 tons/year

^{b/} The old small 20 trays oven will be used only occasionally for small batches.

^{c/} Fluid-bed dryers will gradually replace conventional ovens when enough experience is acquired by the workers on the operation of such dryers.

^{d/} This old machine will be used only for low volume items.

(c) "Fitzmill" Hammer mill multipurpose, for wet and dry granulations actual capacity : 50 tons/year.

Additional equipment required

Combined, "mixer-granulator" of 170 litres : 2 Units
Estimated capacity : 100 tons/year.
for 2 units

(B) Dry granulation for 125 tons of dry granules/year.

Existing machines

(a) Oscillating granulators^{e/} : 2 machines
Date of purchase : 1966
Output/year for 2 machines : 50 tons

(b) "Fitzmill" (the same machine used above)
Multipurpose - output/year : 50 tons

Additional machines required

(a) Two "Tornado" rotary granulator, especially suited for dry granules.
Estimated capacity : 200 tons/year
for 2 Units
(b) Russel - mechanical sieve - For pre-sieving of delicate granules,
to assist the Fitzmill.

1.1.4 Wet Mixing of powders

For 125 tons of powders/year.

Existing machines

Type	Capacity/day	Capacity/year	Date of purchase
Manesty model "H" f/	120 kg.	25 tons	1966
Manesty model "300"	240 kg.	50 tons	1972
" "	" "	" "	1978

used

e/ The two old oscillating granulators will be/occasionally and only for small batches.

f/ The small capacity Mixer will be used only for low volume products.

Additional machines required

1. One manesty "300" mixer
2. One combined "mixer granulator" E/

1.1.5 Dry granules mixing

For 125 tons of dry granules/year.

Existing machines

Type	Capacity/day	Capacity/year	Date of purchase
Apex Yblender "C" <u>h/</u>	80-120 kgs.	16-24 tons	1966
Apex Double Cone	350 kgs.	70 tons	1973
Apex Yblender "D"	240 kgs.	48 tons	1978

Additional machines required

Apex Y blender type E, especially suited for blending granules having more than one active ingredient.

1.1.6 Coating equipment

For Coating of 30 million tablets.

Existing equipment

Type	Output/3 days	Output/year	Date of purchase
Coating pans <u>i/</u> 12" - 2 units	60,000 for 2 units	4 million for 2 units	1963
Coating pan <u>j/</u> 36" - 1 unit	100,000	7 million	1963
Polishing pan 36" - 1 unit	100,000	7 million	1963

E/ Only one machine is to be purchased for both wet mixing and wet granulation.

h/ The small Y mixer will be used for special low volume products.

i/ The two small coating pans will be used only for small batches.

j/ Output bigger for film coated tablets.

Additional machines required

1. Accela-cota coating machine 48", for easy, time-saving coating operations. Especially suited for film coating.
Capacity : 50 - 150 kgs.
2. Suitable spray-guns and ancillary equipment for coating pan 36".

1.1.7 Strip-packing machines

For strip packing 80 million tablets.

Existing machines

Type	Daily output	Yearly output	Date of purchase
Kilburn & Co. ^{k/} (India)	25,000	5 million	1968
U Hlmann ^{l/} HS ₄	200,000	40 million	1978

Additional machines required

1. Uhlmann HS₄ - one machine as above.
2. Blister packing machine. Especially for capsules, contraceptive pills, and selected tablets.

1.1.8 Miscellaneous equipment for tablet Department

- (a) Mixing vessels, stainless steel, of 50 and 100 litre capacity, for preparing starch paste and gelatin solution - with suitable overhead stirrer.
- (b) Storage tanks with tight lids, stainless steel, of different capacities for storage of granules and tablets.

^{k/}The old Kilburn machine will not serve our purpose for long.

^{l/}The machine arrived in mid 1978 and if declared output will be reached gradually by the end of 1978 - beginning 1979.

EXISTING AND ADDITIONAL MACHINES REQUIRED BY THE
TABLETS DEPARTMENT

	1975-1976		1976-1977		1977-1978		1978-1979		1979-1980		1980-1981	
	Unit	Yearly Capacity	Unit	Yearly Capacity	Unit	Yearly Capacity	Unit	Yearly Capacity	Unit	Yearly Capacity	Unit	Yearly Capacity
<u>Tablet Compressors</u>												
B ₃ B	2	50 Mil.	2	50 mil.	2	50 mil.	2	50 mil.	-	-	-	-
BB ₃ B	-	-	-	-	-	-	1	100 mil.	2	200 mil.	3	300 mil.
D ₃ B	-	-	-	-	-	-	-	-	1	15 mil.	1	15 mil.
Total		50 mil.		50 mil.		50 mil.		150 mil.		215 mil.		315 mil.
<u>Drying Ovens</u>												
20 Tray	1	5	1	5	1	5	1	5	-	-	-	-
40 Tray	1	10	1	10	1	10	1	10	1	10	1	10
80 Tray	-	-	1	20	1	20	3	60	5	100	6	120
<u>Fluid Bed Dryer</u>												
	-	-	-	-	-	-	-	-	1	36	2	72
Total		15		35		35		75		146		200

EXISTING AND ADDITIONAL MACHINES REQUIRED BY THE
T.S. SLETS DEPARTMENT

Granulators	1975-1976 2032-2033		1976-1977 2033-2034		1977-1978 2034-2035		1978-1979 2035-2036		1979-1980 2036-2037		1980-1981 2037-2038	
	Unit	Yearly Capacity	Unit	Yearly Capacity	Unit	Yearly Capacity	Unit	Yearly Capacity	Unit	Yearly Capacity	Unit	Yearly Capacity
a) <u>DI</u>												
Jackson Crock-	1	20 tons	1	20 tons	1	20 tons	1	20 tons	-	-	-	-
ett												
Apex	-	-	1	50 tons	1	50 tons	1	50 tons	1	50 tons	1	50 tons
Fitzmill (50% time)	-	-	1	50 tons	1	50 tons	1	50 tons	1	50 tons	1	50 tons
Mixer granulator	-	-	1	-	-	-	-	-	2	100 tons	2	100 tons
Total	1	20 tons		120 tons		120 tons		120 tons		200 tons		200 tons
b) <u>DEY</u>												
Oscillating	2	100 tons	2	100 tons	2	100 tons	2	100 tons	-	-	-	-
"Tornado"	-	-	-	-	-	-	-	-	1	100 tons	2	200 tons
"Fitzmill" (50% time)	-	-	1	50 tons	1	50 tons	1	50 tons	1	50 tons	1	50 tons
Total		100 tons		150 tons		150 tons		150 tons		150 tons		250 tons

EXISTING AND ADDITIONAL MACHINES REQUIRED BY THE
TABLETS DEPARTMENT

Mixer	1975-1976 2032-2033		1976-1977 2033-2034		1977-1978 2034-2035		1978-1979 2035-2036		1979-1980 2036-2037		1980-1981 2037-2038	
	Unit	Yearly Capacity	Unit	Yearly Capacity	Unit	Yearly Capacity	Unit	Yearly Capacity	Unit	Yearly Capacity	Unit	Yearly Capacity
a) <u>WET</u>												
"M" Mixer	1	25 ton	1	25 ton	1	25 ton	1	25 ton	-	-	-	-
"300" mixer	1	50 ton	1	50 ton	1	50 ton	2	100 ton	2	100 ton	2	100 ton
Mixer/grind-lator	-	-	-	-	-	-	-	-	1	50 ton	2	100 ton
Total		75 ton		75 ton		75 ton		125 ton		150 ton		200 ton
b) <u>DRY</u>												
Double Cone	1	70 ton	1	70 ton	1	70 ton	1	70 ton	1	70 ton	1	70 ton
Y mixer "C"	1	24 ton	1	24 ton	1	24 ton	1	24 ton	-	-	-	-
Y mixer "D"	-	-	-	-	-	-	1	50 ton	1	50 ton	1	50 ton
Y mixer "E"	-	-	-	-	-	-	-	-	1	80 ton	1	80 ton
Total		94 ton		94 ton		94 ton		144 ton		200 ton		200 ton
c) <u>STRIP-PACKING</u>												
Indian	1	5 mil.	1	5 mil.	1	5 mil.	1	5 mil.	-	-	-	-
Unilcan HS ₄	-	-	-	-	-	-	1	40 mil.	2	80 mil.	2	80 mil.
Total		5 mil.		5 mil.		5 mil.		45 mil.		80 mil.		80 mil.

(c) Top-loading balances.

(d) Heavy duty Platform balances of 150 - 200 kgs. capacity, and 300 kg. capacity.

1.2 CAPSULES

Projected production for end of 1979 : 8 million capsules

Existing equipment

(a) Capsule inserter, automatic Model A/B, (Dott. Bonapace)

Capacity : 10 mil/year.

(b) Capsule filler semi-automatic - same firm.

Capacity : 4 million/year

(c) Capsule sealing machines^{m/} automatic - from above firm - 2 machines.

Capacity : 6 million/year for
2 Units

Additional equipment required

Capsule filler Model AB/7 from same manufacturer.

1.3 LIQUIDS AND OINTMENTS DEPARTMENT

A liquids projected output of bottles for end of 1979 : 1.75 mil/bottles

Average bottle size : 120 ml.

1.75 million bottles x 120 ml : 210,000 litres/year

1.3.1 Mixing tanks

Existing capacity

Type	Production/year	Date of purchase
250 litres, side agitator	12,000 litres	1968
100 litres, water jacket	4,800 litres	1968
40 litres, water jacket	2,400 litres	1968

Total capacity : 20,000 litres

Remaining capacity : 190,000 litres

^{m/} Sealing of capsules shall be discontinued after the arrival of the blister packing machine.

New equipment required

1. Mixing tank, 1000 litres capacity, with side-entry agitator -
yearly capacity : 48,000 litres
2. Three jacketted mixing tanks of 1000 litres each
capacity of three units : 144,000 litres
3. Three treatment vats, 250 litres each electrically heated,
with stirrer, capacity of three units : 48,000 litres

1.3.2 Storage tanks

Existing equipment

Stainless steel tank 250 litres = 2 units
Stainless steel tank 500 litres = 2 units

Additional tanks required

Stainless steel tank 1000 litres = 4 units
Stainless steel tank 500 litres = 2 units
Stainless steel tank 250 litres = 2 units

1.3.3 Filtration equipment

Existing equipment

Filter press Zenith 40" from Carlson^{n/} : 2 units
Date of purchase : 1966
Filtering capacity of 2 units : 600,000 bottles/year
(average size 120 ml) : 72,000 litres/year

New equipment required

Filter-press "Zenith 40" as above : 4 units

^{n/}These two units will have to be replaced by 1979 by 2 additional units.

1.3.4 Bottle-filling machines

Existing equipment

"Filomatic" filling machine, 2 pumps : 1 unit
Date of purchase : 1968
Output/year : 72,000 litres

New equipment required

"Filomatic" filling machine, 4 pumps, 520 ml each pump, with
conveyor belt : 1 unit

1.3.5 Cap-Sealing machines

Existing machines

Semi-automatic, for pilfer-proof cap : 1 unit
(Indian made)

Additional machines required

As above : 2 units

1.3.6 Miscellaneous equipment

1. Transfer pump, stainless steel : 2 units
2. Colloid mill : 1 unit
3. Agitators "Silverson type" : 2 units
4. Label printer & coding machine
'Code "O" Matic' : 1 unit

OINTMENTS

Projected production for 1979/80 : 2 million tubes and
jars of toothpaste,
antiseptic creams and
ointments.

Existing machines

(a) Horizontal mixer "Hobart"^{o/} : 1 unit
Date of purchase : 1966

o/Old machines, will be used in the future for small batches, when required.

- (b) Ointment filling machine, ^{p/} manual type
Date of purchase : 1963
- (c) De orator : 1 unit
Date of purchase : 1968

New machines required

1. "Hobart" mixer, horizontal with
different bowls and paddles : 1 unit
2. Ointment filling, crimping and coding
machine, semi-automatic from "Flexile"
with output of : 2 million tubes/year

1.4 STERILE PRODUCTS UNIT

A. Intravenous fluids

Projected output for end 1979

Bottles of 540 ml. : 400,000 bottles
or
216,000 litres.

Existing machines

(a) Distillation units

- Still, electrical, 5 gall./hour^{g/} : 2 units
- Still, electrical 10 gall./hour^{g/} : 1 unit

(b) Mixing tanks

250 litres stainless steel : 1 unit

(c) Sterilizers

'Drayton Castle' 21 cu.ft. quick cooling
type : 1 unit

Output : 100,000/year

(d) Filling machines Filamatic type, 2 pumps: 1 unit

^{p/}Old machines, will be used in the future for small batches, when required.

^{g/}The cost of operation of ^{these} stills is prohibitive for commercial production.
They will be replaced.

Additional equipment required

1. Thermocompressor distillation plant, European or American make,
Capacity : 225 litres/hour
with pneumatic diverter and suitable storage tanks from same
manufacturer.
The above unit will be exploited also for final bottle rinsing,
as well as for the liquids and tablet sections.
2. Bottle washing machine, heavy duty, with derating unit, from Thomas
Hill, type 160 : 1 unit
3. Sterilizer, "Drayton Castle" type : 2 units
28 cu.ft. double door. With steam generator unit attached,
Rapid cooling type.
4. Mixing tank stainless steel, 500 litres : 1 unit
jacketted.
5. "Filomatic" filling machine 4 pumps : 1 unit
6. Transfer pump, stainless steel : 1 unit
7. Inspection units : 4 units

B. Small-volume injectible, including antibiotic-powder in vials

For the minimum requirements of the above, a small complete unit
is necessary to start production. (see list attached under
itemised list and Cost of Production units).

Annex VI

ROYAL DRUGS LTD. EXPANSION PROGRAMME -
ENVISAGED UNIDO/UNDP CONTRIBUTION

Quality Control Unit and Research and Development (Pilot Plants)

UNIDO/UNDP Contribution, First Stage Programme

Quality Control, Research and Development Units

approximate US\$ 175,000

Followships, technical assistance

approximate US\$ 25,000

Total: US\$ 200,000

ROYAL DRUGS LIMITED
Quality Control
&
Research and Development Section

S.No.	Description	Quantity	Approximate FOB Price(In \$)
1.	ULTRAVIOLET SPECTROPHOTOMETER Range 200-800 nm automatic start stop with manual scanning, complete with voltage stabilizer extra cells and dessicator tubes, spare lamps and other accessories.	1	20,000
2.	POTENTIOMETER Electrometric Titrator complete set with amplifier, electrodes and necessary spares.	4	3,500
3.	KARL - FISCHER MOISTURE DETERMINATION APPARATUS Complete set with necessary spares and accessories.	1	1,200
4.	PH METERS Ranges 0 to 14 PH, 0 to 1400 MV, accuracy ± 0.01 PH, complete set with combination electrode, temperature compensator and six pairs of spare electrodes for each set.	6	2,300
5.	POLARIMETER For tubes upto 400 mm long, reading by double vernier to 0.01 complete set with spare polarimeter tubes and sodium lamp.	2	2,600

S.No.	Description	Quantity	Approximate FOB Price(In \$)
6.	REFRACTIVE INDEX High accuracy of 0.00004 complete set with necessary spares.	2	2,200
7.	MICRO - MELTING POINT APPARATUS Complete set with necessary spares.	2	240
8.	MELTING POINT APPARATUS Electrically heated, complete with spare lamps heaters and thermometers.	6	700
9.	LABORATORY CENTRIFUGE		2,000
	a) Maximum capacity 200 ml. with different swing-out head and spare tubes.	2	
	b) Maximum capacity 1000 ml. maximum speed 5000 RPM complete set with different swing-out head and spare tubes.	1	
10.	FLAME PHOTOMETER Complete set with sodium, potassium and calcium filter with necessary spares and accessories.	2	2,200
11.	LOVIBOND TINTOMETER Complete set with extra cells and colour filters and necessary spares.	2	2,200
12.	THIN LAYER CHROMATOGRAPHY Complete set with accessories.	4 sets	1,600
13.	GAS CHROMATOGRAPHY Complete set with all accessories and spares.	1	5,000

S.No.	Description	Quantity	Approximate FOB Price (In \$)
14.	INFRA - RED SPECTROPHOTOMETER Complete set with all accessories and spares.	1	8,000
15.	PARTICLE - COUNTER Coulter type with accessories and spares.	1	5,000
16.	LAMINAR FLOW CABINET Bench type, vertical.	2	4,000
17.	BALANCES Complete with spare lamp bulbs and accessories.		
	a) Analytical Weighing range 160 g. precision ± 0.05 mg.	4	7,000
	b) Top loading balance capacity 160g. precision ± 1 mg.	2	2,500
	c) Precision Weighing range 1200g. Readibility 10 mg. capacity 1300 g. precision ± 5 mg.	2	3,000
	d) Compression spring capacity 10 kg. x 50 g.	2	100
	e) Sliding mass. double pan capacity 2 kg. Sensitivity 0.1 g.	2	200
	f) Double pan Capacity 250 g. sensitive to 2 mg.	2	150
18.	NESSLERISER Complete set with colour standards.	2	200

S.No.	Description	Quantity	Approximate FOB Price (In \$)
19.	COLORIMETER Linear scale with Y 1 ford Bright spec- trum and filter disc with necessary spares.	1	600
20.	FLASK SINKER Complete set with necessary spares.	2	500
21.	DESSICATOR Vacuum type, electrically heated, with spare heaters.	1	300
22.	ROTARY THIN FILM EVAPORATOR Complete set with necessary spares.	1	250
23.	HYDRONETERS Range 0.7 to 2.00	6 sets	50
24.	ULTRAVIOLET LAMP For Chromatography Wavelength 366 and 234 nm. complete with spare U.R. tubes.		
25.	COLONY COUNTER	1	400
26.	PETRIDISH ILLUMINATOR	4	250
*27.	DISSECTING SETS All instruments are of stainless steel.	6 sets	150
28.	MEMBRANE FILTER HOLDER For gravity or vacuum filtration capacity 100 ml. with spare filters.	2	150

S.No.	Description	Quantity	Approximate FOB Price (USD)
29.	MANIPULATOR GLOVE BOX External dimensions 690 x 450 mm. high	1	500
30.	MAGNIFIER, diameter 100 mm,	6	50
*31.	MICROSCOPE		
	a) Binocular, oil immersion type with accessories.	2	800
	b) Low power, stereoscopic, with all accessories.	2	800
*32.	MICROTOME Rotary Rocking Type with spares.	1	1,500
33.	HIGH VACUUM PUMP	1	500
34.	ZONE READER Projection Type.	1	2,000
35.	WATER BATH		
	a) 6 place, aluminium, 410 x 270 x 100 mm deep with spare heaters.	6	300
	b) Thermostatic + 120 ± 0.01°C. capacity 20 litres, with analog temperature setting and electronic temperature control.	2	1,000
36.	INCUBATORS		
	a) Fan/gravity convection Temperature range 5°C above ambient to 100°C Internal dimensions 760 x 605 x 455 mm	2	2,000
	b) Cooled Temperature range 0 to 40°C working volume 180 litres.	1	1,200

S.NO.	Description	Quantity	Approximate FOB Price (In \$)
37. OVENS			
a)	Fan convection, 300.C maximum with stainless steel interior working volume 210 litres, Internal dimensions 760 x 605 x 455 mm.	2	2,000
b)	Dry sterilisers, fan convection 250.C maximum with stainless steel interior. Working volume 210 litres dimensions 760 x 605 x 455 mm.	2	2,000
c)	<u>Vacuum Oven</u> Temperature range + 5 to 150.C internal dimensions 370 x 50 mm.	1	1,000
d)	<u>Hot Box</u> Temperature 200.C maximum, working volume 97 litres internal dimensions 470 x 480 x 430 mm.	2	800
e)	<u>Drying Cabinet</u> 120.C maximum, working volume 170 litres. Internal dimensions 720 x 670 x 370 mm.	2	1,100
f)	Wax Embedding, max. temp. 100.C	1	2,000
38. FURNACE			
a)	<u>Muffle</u> Capacity 9.5 litres, automatic proportional control for 1000/1100.C maximum. Internal Diameter 135 x 190 x 380 mm.	2	2,300
b)	<u>Tube</u> For temperature upto 1300-1500.C tube dimensions 40 mm. dia. 600 mm. length, heated length 500 mm, with essential accessories.	1	2,000

S.No.	Description	Quantity	Approximate FOB Price (In\$)
39.	AUTOCLAVE Vertical type, electrically heated with spare heating elements and accessories, Depth of boiler = 460 mm. Internal diameter of boiler = 458 mm.	2	6,000
40.	WATER STILL Thermo-compressor type, capacity 20 litres electrically heated with necessary spares and accessories.	2	2,000
41.	DRYER For glass apparatus, 12 point with spare heaters accessories.	2	700
42.	SAND BATH, Electrically heated With energy regulator. Maximum effective sand temperature = 325.C Bath dimensions 470 x 270 x 25 mm. deep	1	250
43.	TUBE HEATING BLOCK Temperature range 30 to 100.C temperature control \pm 0.1.C	1	200
44.	BURNER, Bunsen for coal gas.	12	150
45.	BLOWER, hot air portable	4	250
46.	MANTLES		
	a) Heating/stirring capacity 500 ml.	2	100
	2 litres	2	200
	b) <u>Multi type</u> Capacity 50-2000 ml.	2	100
	Capacity 500-6000 ml.	1	150

S.No.	Description	Quantity	Approximate FOB Price (In ³)
47.	HOT PLATE		
	a) Circular thermostat 275.C	2	200
	b) Rectangular with energy regulator controller. Dimensions 457 x 305 mm.	2	400
48.	VISCOMETER, with timer necessary spare and accessories. Overall dimensions 600 x 590 x 410 mm.	1	1,600
49.	DISSOLUTION TESTER	1	2,000
50.	LAMINAR FLOW TESTING EQUIPMENT To check air velocity, 8 particulate meter in air (Air monitor)	1	2,000
51.	STIRRER		
	a) Thermo with compenstat temperature controller dimensions 280 x 80 x 120 mm.	1	500
	b) Handilab Maximum speed approx. 1200 RPM.	2	150
	c) Variable speed Speed upto 2500 RPM	1	125
	d) Magnetic Speed 1300 RPM	2	150
	e) Magnetic/Hot Plate 1300 RPM & 450.C maximum with energy regulator.	2	250
52.	BALL MILL, 2 litres	1	500

S.No.	Description	Quantity	Approximate FOB Price (In₹)
53.	MIXERS		
a)	For mixing paste and viscous material speed approx. upto 200 RPM capacity 3 litres overall dimensions 380 x 270 x 305 mm.	2	250
b)	For blending, grinding, liquefying and disintegrating, stainless steel bowl overall dimensions 160 x 200 x 380 mm.	2	150
c)	Emulsifier, heavy duty model for process- ing viscous materials.	1	700
d)	Powder capacity approximately 3 litres speed approx. 40 rev./minute	1	600
54.	MOISTURE BALANCE Infrared. completely automatic capacity 10g. sensitivity 0.01g & 0.10 g.	1	1,200
55.	SIEVES standard, different mesh size	6 pc.each	500
56.	SIEVE SHAKER with 0-60 minute time switch accommodates 12 sieves overall dimensions 550 x 550 x 800 mm.	1	600
57.	STOP CLOCK 60 mm x 60 seconds.	5	100
58.	GRANULATOR SMALL (Hammer type)	1	2,000
59.	BOWL MIXER, Planetary	1	2,000
60.	TABLE OVER	2	2,000

S.No.	Description	Quantity	Approximate FOB Price(Inr)
61.	CHOPPER/COMMINUTOR		
	a) For Herbs.	1	2,000
	b) For Roots	1	2,000
62.	HOMOGENISER - Colloid Mill	1	1,000
63.	SOXHLET EXTRACTOR Stainless Steel - small		
64.	Mechanical Sieve abhcally operated, + 2 year spares	1	5,000
65.	EXTRACTION SOXHLET STILL Vaccum, stainless steel with solvent recovery system	1	
66.	DISTILLATION STILL For essential oils, oil fired or electric.	1	
			<hr/>
	Estimated Cost About		155,000
	Glassware, etc. ,,		20,000
	TOTAL:		<hr/> 175,000
	Balance for Scholarship etc.		<hr/> 25,000
	GRAND TOTAL :		<hr/> <hr/> 200,000

Annex VII

ROYAL DRUGS LTD. EXPANSION PROGRAMME - ENVISAGED
CONTRIBUTION BY DONOR COUNTRY/UNDP
Production Units

Donor Country/UNDP Contribution

Primary Health Support Services Programme Project NEP/78/009

<u>Production Units</u>	US\$ 400,000
<u>Ayurvedic Production Unit</u>	US\$ 80,000
<u>Regional Intravenous Fluids</u>	
<u>Production Unit - at Nepalgunj</u>	US\$ 50,000
	<hr/>
Total:	<u>US\$ 530,000</u>

A. TABLET DEPARTMENT AND CAPSULES

	<u>C.I.F.</u>
1. <u>BB₃B Manesty Tablet Compressor 35 stations, complete with dust-extraction unit, Deduster, 5 sets of punches and dies, and 2 years spare parts.</u>	\$ 25,000
2. <u>D₃B heavy-duty tablet compressor, Manesty, Sixteen stations, complete with 5 sets of punches and dies, deduster and 2 year spare parts.</u>	\$ 10,000
3. <u>Fluid-bed Dryer, Manesty, 60 kgs. capacity Electrically or Steam operated model, with extra trough and carriage and spare parts</u>	\$ 25,000
4. <u>"Mixer-Granulator", Drydispenser or Diosna type, 170 litres, complete with 2 year spare parts.</u>	\$ 30,000
5. <u>Y mixer from Apex, Type E, with all spares</u>	\$ 10,000
6. <u>Tornado Mill from Stokes, for dry granulation</u>	\$ 10,000
7. <u>Blister packing machine, automatically operated, from Uhmann or Bosch. For capsules and tablets, with all necessary spare parts.</u>	\$ 40,000
8. (a) <u>Top Loading balances capacity 2 kg. to 6 kg. Mettler.</u> (b) <u>Heavy-duty balances 150 kgs. and 300 kgs. from Avery.</u>	\$ 15,000
9. <u>Mixing Tanks Stainless Steel 50 litres & 100 litres, for starch paste and Gelatin preparations.</u>	
10. <u>Storage tanks of 200 and 100 litres</u>	
	<u>Total for tablets \$150,000</u>
<u>Capsules</u>	
1. <u>Capsule polishing machine</u>	\$ 2,000
2. <u>Y Mixer model C from Apex.</u>	\$ 8,000
	<u>Grand Total : \$ 160,000</u>

B. OINTMENT AND LIQUID DEPARTMENT

	<u>C.I.F.</u>
1. <u>Mixing Tank 1000litres SP₅₆</u> Guisti type, stainless steel, with side entry agitator. Full length sight glasses, adjustable legs, air fillers.	\$ 5,000
2. <u>Syrup Mixing and Filtering Unit 1000litres</u> Guisti-type, with separate motors operating mixer and pump, flame proof motors, vacuum gauge, vacuum filter under vessel	\$ 10,000
3. <u>"Filamatic" filling machine DAB₃₂</u> Including 4 pumps, 520 ml. each pump, and conveyor belt.	\$ 4,000
4. <u>Carlson Pressure filters Zenith Princess: 2 units</u> 40 cms. type, including Stainless Steel Plates, Stainless Steel R.E.C. pump Filter sheets of different grades and material.	\$ 10,000
5. <u>Transfer "Mono-pumps": 2 units</u> Stainless Steel for fluid transfer, from Carlson 2 units	\$ 5,000
6. <u>Storage tanks, Guisti SS₅₆ Stainless Steel</u> 4 units of 1000 litres 2 units of 500 litres on Castors 2 units of 250 litres on Castors	\$ 10,000 \$ 3,500 \$ 2,500
7. <u>Colloid Mill from "Premier"</u>	\$ 6,000
8. <u>"Kalyx Dupuy" Semi-automatic Ointment filling, Crimping and Coding machine from Flexile" England</u>	\$ 10,000
9. <u>Treatment Vats 250 litres, 3 units</u> From Guisti, electrically heated, with Stirrer.	\$ 8,000
10. <u>Labeller, "Codeo-Matic", 2 units</u> Label printer and Coding machine from G.D. Peters	\$ 1,000
Total:	<u>\$ 65,000</u>

STERILE PRODUCTS UNITS

a.	<u>Intravenous Fluids</u>	<u>C.I.F.</u>
1.	<u>Thermo Compressor Distillation Plant</u> 225 litres/hour, from Bernstead or Mascarini, complete with automatic pneumatic Diverter, accessories, spares for 2 years	£ 40,000
2.	<u>Mixing Tank, 500 litres</u> From Mascarini, jacketted, stainless steel, specifically for Sterile fluids	£ 4,000
3.	<u>Storage Tanks - 2 units, 500 litres</u> From Mascarini, jacketted heated to 85°- 90° C. stainless steel	£ 5,000
4.	<u>Sterilizer "Drayton Castle, 23 cu.ft. double door</u> Including a Steam Generator unit	£ 38,000
5.	<u>Bottle Washer, Heavy-duty, from Thomas Hill</u> 160 model with derating unit attached.	£ 26,000
6.	<u>Filamatic 520 ml. 4 pumps filling machine</u>	£ 2,000
7.	<u>"Sartorius" pressure pump, stainless steel</u>	£ 1,500
8.	<u>Transfer pump, stainless steel</u>	£ 1,500
9.	<u>Laminar, Flow, Console type</u>	£ 5,000
10.	<u>Inspection Units, 4 units</u>	£ 1,000
11.	<u>Cap-sealing Machine</u>	£ 1,000
Total :		<u>£125,000</u>

C.I.F.

- b. Injectibles: Ampoules & Vials
1. Ampoules sorter.
 2. Ampoules washing machine.
 3. Dry steriliser-oven 80 trays.
 4. Filling and sealing machine for ampoules, 2 units.
 5. Therocompressor Distillation Unit, small capacity.
 6. Mixing tanks 200 litres.
 7. Mixing tanks 100 litres.
 8. Sterilizer 21 cu.ft.
 9. Ampoule labeller
 10. Ampoule printer.
 11. Seal tester.
 12. Vial washing machine.
 13. Cube mixer 10 kgs.
 14. Vial filler, semi-automatic.
 15. Vial sealler semi-automatic.
 16. Vial labeller.
 17. Cap-former, for aluminium caps

Total: \$ 50,000

AYURVEDIC PRODUCTION UNIT

1. Tableting machine D₃B type complete with punches and 2 years spare parts.
2. Mixer/granulator machine.
3. Oven - 40 Trays Stainless Steel.
4. Y Mixer D model.
5. Liquid filling machine, 2 pumps.
6. Filter press, Zenith 40.
7. Storage vessels, Stainless Steel different sizes.
8. Mixing vessel 250 litres, with side-entry agitator.
9. Russel Sieve, complete.
10. (a) Tablet Hardness Tester.
(b) Tablet Disintegration tester.
(c) Tablet Fibrillator.

Total : US\$ 80,000

Annex VIII

ROYAL DRUGS LTD - DRUGS LISTS

List of Existing Drugs Up to July 1978

A. Antiprotozoal Drugs (antimalarials, antiamoebics)

1. Di-iodohydroxyquinoline	tablet	200 mgm.
2. Metronidazole	..	200 mgm.
3. Chloroquine phosphate	..	250 mgm.

B. Anthelmintics

4. (a) Piperazine Adipate	tablet	300 mgm.
(b) Piperazine Citrate	syrup	5 %

C. Sulfonamides

5. Sulfadiazine	tablet	500 mgm.
6. Sulfaguanidine	..	500 mgm.
7. Sulfadimidine	..	500 mgm.
8. Sulfathiazole	..	500 mgm.
9. Triple Sulfa	..	167 mgm. of each
10. Phthalylsulfathiazole	..	500 mgm.

D. Antibiotics

11. (a) Tetracycline hydrochl	capsule	250 & 500 mgm.
(b) Tetracycline base	syrup	125 mgm/5 ml
12. (a) Chloramphenicol	capsule	250 mgm.
(b) Chloramphenicol palmitate	syrup	125 mgm/5 ml.
13. (a) Ampicillin	capsule	250 & 500 mgm.
(b) Ampicillin	syrup	125 mgm/5 ml

E. Tuberculostatics

14. Isoniazide	tablet	100 & 300 mgm.
15. Isoniazide + Thiacetazone	..	150 & 300 mgm.
16. Para-aminosalicylic acid	granules	80 %

17. Ethionamide	tablets	250 mgm.
18. Cycloserine	"	250 mgm.

F. Analgesics and Antipyretics

19. Aspirin	tablets	300 mgm.
20. Aspirin comp.	"	
21. (a) Paracetamol	"	500 mgm.
(b) Paracetamol	syrup	120 mgm/5 ml
22. Codein phosphate	tablet	20 mgm.

G. Central Nervous System (CNS) Drugs

23. Diazepam	tablet	5 mgm.
24. Phenobarbitone	"	15, 30, 100 mgm.
25. Phenobarbitone + Belladonna comp.	"	

H. Vitamins

26. Ascorbic Acid	tablet	500 mgm.
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I. Autonomic System Drugs

27. Aminophylline	tablet	100 mgm.
28. Ephedrine hydrochl	"	30 mgm.

J. Gastrointestinal tract (G.I.) Drugs

29. Aluminium hydroxide + Magn. Trisilic	tablet	
30. Dicyclohydroxyquinoline + Belladonna extract + Phthalylsulfathiazole + Kaolin + Pectin	syrup	
31. Aluminium hydrox. + Magn. trisilicate + Belladonna extract	tablet	
32. Sodium bicarbonate	"	
33. Infant gripe mixture	liquid	

K. Antidiabetics

34. Chlorpropamide tablet 250 mgm.

L. Antiallergies

35. Chlorpheniramine maleate tablet 2 mgm.

M. Alkali Mixture and Mild Diuretic

36. Disodium hydrogen Citrate 26.2% solution

N. Intravenous fluids and Rehydration Salts

37. Jeevan Jal (RD-Sol) powder
38. Normal Saline i.v. fluid 540 ml.
39. Dextrose Saline 5% Dextrose in Normal Saline 540 ml.
40. Dextrose 5% Dextrose i.v. fluid 540 ml.
41. Sodium Chloride + Dextrose BP 1973 i.v. fluid 540 ml.
42. Sodium lactate i.v. fluid 540 ml.
43. Intra-peritoneal dialysis Sol 1.36% & 6.60% 540 ml.
44. ACD Solution i.v. fluid 540 ml.
45. 2.5% Dextrose in 1/4 normal saline " 540 ml.
46. Distilled water " 540 ml.

O. Over the Counter (OTC) Drugs

(a) 47. Codeine phosphate + tolu + chlorpheniramine mal. Syrup
48. Codeine phosphate " "
49. Vasaka expectorant " "
50. Antitussive + ephedrine " "
51. Expectorant syrup " "

(b) Ear, Nose and Throat

52. Chloramphenicol ear drops
53. Ephedrine + Camphor + Menthol nose drops
54. Camphor, menthol, iodine throat paint
55. Clove oil, camphor, phenol dental paint

(c) Ophthalmic preparations

56. Sulfacetamide sodium eye drops 10, 20, 30%

(d) Ointments and Rubbing lotions

57. Iodine + methyl salicylate ointment

58. Menthol, camphor etc. "

59. Benzoic and salicylic acids emulsion

60. Benzyl benzoate "

61. Liniment camphor

62. Liniment ABC

List of Drugs, existing and proposed for manufacture, in a
stepwise manner at the new factory
by 1981

<u>Existing</u>	<u>Proposed</u>
<p>A. <u>Antidiarrhoeals, amoebic and other dysenteries, Anthelmintics</u></p> <p>1. <u>Nodiquin</u> - tablets (Di-iodohydroxyquinoline)</p> <p>2. <u>R.D. Chloroquin</u> - tablets (Chloroquin phosphate)</p> <p>3. <u>Amgit</u> - tablets (Metronidazole)</p> <p>4. <u>Sulphaquin</u> - suspension (Di-iodohydroxyquinoline + Phthalylsulphathiazole + Belladonna + Kaolin + Pectin)</p> <p>5. <u>Pipracite</u> - tablet, liquid (Piperazine citrate/adipate)</p>	<p>1. <u>Mebendazole</u> - tablets</p> <p>2. <u>Diethylcarbamazine citrate</u> tablets</p> <p>3. <u>Amgit</u> syrup</p> <p>4. <u>Sulphaquin</u> tablets</p>
<p>B. <u>Sulfonamides</u></p> <p>6. <u>Sulphadiazine</u> - tablet</p> <p>7. <u>Sulphadimidine</u> - tablet</p> <p>8. <u>Phthalylsulphathiazole</u> - tablet</p> <p>9. <u>Sulphaguanidine</u> - tablet</p> <p>10. <u>Sulphathiazole</u> - tablet</p> <p>11. <u>Sulphastin</u> - tablet (Triple sulpha combination)</p>	<p>5. <u>Trimethoprim + Sulphamethoxazole</u> - tablet</p>

<u>Existing</u>	<u>Proposed</u>
<p>C. <u>Antibiotics</u></p> <p>12. <u>Necycline</u> 250 mg, 500 mg, Capsules, (Tetracyclin) <u>Necyclin</u> for suspension (Tetracyclin)</p> <p>13. <u>Nephenicol</u> Capsule and suspension (Chloramphenicol)</p> <p>14. <u>R.D. Ampic</u> Capsule and for suspension (ampicillin)</p>	<p>6. <u>Benzyl penicillin</u> (Penicillin G) vials for injection in several strengths.</p> <p>7. <u>Streptomycin</u> vials for injection several strengths</p> <p>8. <u>Penicillin + Streptomycin</u> vials for injection</p> <p>9. <u>Benzylpenicillin</u> tablets</p> <p>10.a) <u>Erythromycin Stearate</u> Tablet b) <u>Erythromycin ethylsuccinate</u> syrup</p>
<p>D. <u>Urinary Antiseptics</u></p>	<p>11.a) <u>Nitrofurantoin</u> tablet b) <u>Nitrofurantoin</u> syrup</p>
<p>E. <u>T.B., Leprosy</u></p> <p>15. <u>R.D. Niazide</u> (Isoniazid) 100 mg.</p> <p>16. <u>R.D. Niazide Forte</u> (Isoniazid) 300 mg.</p> <p>17. <u>R.D. Sodipas</u> tablet granules (P-aminosalicylic acid) (Sodium salt)</p> <p>18. <u>R.D. Ethio</u> tablet (Ethionamide)</p> <p>19. <u>R.D. Zone Forte</u> tablet (Isoniazid + Thiacetazone)</p> <p>20. <u>R.D. Zone Forte</u> tablet (Isoniazid + Thiacetazone)</p> <p>21. <u>Neserine</u> tablet (Cycloserine)</p>	<p>12. <u>Ethambutol</u> tablet</p> <p>13. <u>Rifampicin</u> tablet</p> <p>14. <u>Dapsone</u> tablet (for leprosy)</p>

<u>Existing</u>	<u>Proposed</u>
<p>F. <u>Analgesics, Antipyretics</u> <u>antispasmodics, and Tranquillizers</u> <u>and Hypnotics</u></p> <p>22. <u>Aspirin</u> tablet</p> <p>23. <u>Cetamol</u> tablet (Paracetamol)</p> <p>24. <u>Halgesic</u> tablet (Aspirin, Caffein, Codein ph.)</p> <p>25. <u>R.D. Sonal</u> tablet R.D. Sonalettes tablet (Phenobarbitone)</p> <p>26. <u>Diazecalm</u> tablet (Diazepam)</p> <p>27. <u>Barbidona</u> tablet (Phenobarbitone + Belladonna)</p>	<p>15. <u>Pothidine Hcl Injection</u></p> <p>16. <u>Indomethacin</u> capsules</p> <p>17. <u>Oxymphenbutazone</u> tablet</p> <p>18. <u>Ibuprofen</u> tablet</p> <p>19. <u>Pentazocin</u> tablet</p> <p>20. <u>Diazecalm Injection</u></p> <p>21. a) <u>Chlorpromazine</u> tablet b) <u>Chlorpromazine</u> syrup c) <u>Chlorpromazine</u> Injection</p>
<p>G. <u>Cardiovascular and Anticoagulants</u></p>	<p>22. <u>Propranolol Hcl</u> capsules</p> <p>23. <u>Quinidine Sulf.</u> tablet</p> <p>24. <u>Warfarin</u> tablet</p> <p>25. <u>Heparin Injection</u></p> <p>26. <u>Procainamide</u> tablet and Injections</p>
<p>H. <u>Hypotensive drugs</u></p> <p>28. <u>Respina</u> tablet (Reserpine)</p>	<p>27. <u>Methyldopa</u> tablet</p> <p>28. <u>Guanethidine</u> tablet</p>

<u>Existing</u>	<u>Proposed</u>
<p>I. <u>Diuretics</u> 29. <u>Acitracol</u> (di-sodium Hydrogen citrate)</p>	<p>29. <u>Hydrochlorothiazide</u> tablet injection 30. <u>Frusenide</u> tablets & Injections 31. <u>Acetazolamide</u> tablet (especially to reduce ocular pressure in glaucoma)</p>
<p>J. <u>Antiasthmatic, Bronchodilator</u> 30. <u>Aminophylline</u> tablet 31. <u>Ephedrine Hcl.</u> tablet</p>	<p>32. <u>Salbutamol</u> tablet 33. <u>Adrenaline</u> injection 34. <u>Ephedrine Hcl.</u> injection</p>
<p>K. <u>Hematinics (Iron) and Vitamins</u> 32. <u>Ascorbic</u> tablet (Vitamin C)</p>	<p>35. <u>Ferrous Fumarate</u> tablet 36. <u>Calcium</u> tablet + vitamins D2 + B12 + C 37. <u>Vitamin A</u> injection 38. <u>Vitamin B6</u> tablet 39. <u>Folic Acid</u> tablet 40. <u>B. Complex</u> tablet and syrup and injection 41. <u>Multivitamins</u> tablet and syrup 42. <u>Vitamin K.</u> tablet & injection</p>
<p>L. <u>Antiemetic (anti vomiting)</u></p>	<p>43. <u>Promethazine Theoclate</u> tablets</p>

<u>Existing</u>	<u>Proposed</u>
M. <u>Gastro Intestinal</u> (Antacids, enzymes, antiseptics etc.)	44. <u>Dimagel liquid</u>
33. <u>Dimagel</u> tablet (Aluminium hydroxide gel and magnesum trisilicate)	45. <u>Dimagel</u> tablets and liquid + <u>Polysiloxane</u>
34. <u>Trimagel</u> tablet (As above + Belladonna)	46. <u>Triple enzyme</u> capsules
	47. <u>Furazolidone</u> susp.
	48. <u>Anti haemorrhoids</u> cream
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N. <u>Antiallergics, etc.</u>	
35. <u>Antillergin</u> tablet (Chlorpheniramine maleate)	49. <u>Antillergin</u> syrup, injection
	50. <u>Prednisolone acet.</u> tablet
	51. <u>Hydrocortisone acet.</u> inject.
<hr/>	
O. <u>Gynaecology</u>	
	52. <u>Progesterone</u> injections
	53. <u>Estradiol benzoate</u> injection
	54. <u>Ethynylestradiol</u> tablet
	55. <u>Methylergometrine maleate</u> , tablet and injection
	56. <u>Oxytocin</u> injection
	57. <u>Nystatin</u> tablet (antifungal)
	58. <u>Contraceptive pill</u>
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P. <u>Ophthalmic drugs</u>	
36. <u>Netrasol</u> drops (sulfacetamide)	59. <u>Pilocarpine Hcl.</u> solution drops in different strengths
	60. <u>Atropine sulphate</u> solution Drops in different strengths
	61. <u>Homatropine Hcl.</u> solution

<u>Existing</u>	<u>Proposed</u>
	<p>62. <u>Physostigmine Hcl. solution</u></p> <p>63. <u>Artificial tears</u></p> <p>64. <u>Tetracycline eye ointment</u></p> <p>65. <u>Fluorescein solution</u></p> <p>66. <u>Chloramphenicol eye ointment</u></p> <p>67. <u>Chloramphenicol prednisolone</u></p>
<p>Q. <u>Ear Nose, Throat</u></p> <p>37. <u>Nephenicol ear drops</u> (Chloramphenicol)</p> <p>38. <u>Nosola</u> Nose drops (Camphor, menthol, ephedrine)</p> <p>39. <u>Dentaik Toothache drops:</u> (Clove oil, camphor etc.)</p> <p>40. <u>Tongil Throat paint</u> (Camphor menthol, etc.)</p>	
<p>R. <u>Topical (Skin)</u> <u>Antiseptics and Antibiotics</u></p> <p>41. <u>Iodort ointment</u> (Codeine + methyl salicylate)</p> <p>42. <u>Mencalm ointment</u> (Menthol, camphor, thymol, oil of eucalyptus and turpentine)</p>	<p>68. <u>Chloramphenicol ointment</u></p> <p>69. <u>Tetracycline ointment</u></p> <p>70. <u>Necrycin ointment</u></p> <p>71. <u>Hydrocortisone ointment</u></p> <p>72. <u>Gentamycin ointment</u></p> <p>73. <u>Lassar Paste</u></p> <p>74. <u>Lassar + Dithranol paste</u></p>

<u>Existing</u>	<u>Proposed</u>
S. <u>Topical Fungicides and Scabicides</u> 43. <u>Bensal lotion</u> (benzoic + salicylic acid) 44. <u>Scaben</u> (benzyl benzoate)	
T. <u>Liniments</u> 45. <u>Liniment ABC</u> (Aconite, belladonna, camphor) 46. <u>Liniment camphor</u>	
U. <u>Cough syrups</u> 47. <u>Cufnas Antitussive</u> syrup 48. <u>Ephotin</u> antitussive with ephedrine 49. <u>Phencodin</u> cough + antihistamine 50. <u>Vasaka</u> Expectorant syrup 51. <u>Codeine Phosphate</u> antitussive 52. <u>Cufhist</u> antiallergic	
V. <u>Intravenous Fluids</u> 53. <u>Normal saline</u> 54. <u>Dextroso saline</u> 55. <u>Dextrose</u> 56. <u>ACD solution</u> 57. <u>Intraperitoneal</u> 58. <u>Sodium lactate</u> 59. <u>Compound sodium lactate</u> (Hartmann, ringer lactate)	75. <u>Dextran</u> 76. <u>Potassium Chloride</u>

<u>Existing</u>	<u>Proposed</u>
W. <u>Over the counter</u> 60. <u>Gripe mixture</u> 61. <u>Sodamint tablet</u> (sodium bicarbonate)	77. Tonic 78. <u>"Cold" tablet</u> 79. <u>Efferescent salts</u>
X. <u>Toilet</u>	80. <u>Toothpaste</u> 81. <u>Beauty cream</u>

Proposed Essential Drugs List for Nepal by GENERIC Names

A. <u>Antiprotozoal Drugs (antimalarials, antiamoebics)</u>			
1.	Di-iodohydroxyquinoline	tablet	200 mgm.
2.	Metronidazole	"	200 mgm.
3.	Emetine hydrochl	inject.	50 mgm.
4.	Quinine hydrochl	tablet	100-300 mgm.
5.	Primaquine	"	15 mgm.
6.	Amodiaquine hydrochl	"	200 mgm.
7.	Chloroquine phosphate	"	250 mgm.
B. <u>Anthelmintics</u>			
8.	(a) Piperazine Adipate	tablet	300 mgm.
	(b) Piperazine Citrate	syrup	5%
9.	Mebendazole	tablet	100 mgm.
10.	Niclosamide	"	500 mgm.
11.	Mepacrine	"	100 mgm.
12.	Diethyl-Carbamazone Citrate	"	50-100 mgm.
C. <u>Sulfonamides</u>			
13.	Sulfadiazine	tablet	500 mgm.
14.	Sulfaguanidine	"	500 mgm.
15.	Triple Sulfa	"	167 mg. of each tablet
16.	Trimethoprim + Sulfamethoxazole	"	
16.a	Phthalylsulfathiazole	"	
D. <u>Antibiotics</u>			
17.	a) Benzyl Penicillin (Penicillin G)	inject.	10 m. units
	b) " " "	"	½ - 1 m. units
	c) " " "	"	5 m. units
	d) " " "	tablet	250 mgm.
18.	Streptomycin Sulphate	inject.	1 gm and 5 gm.
19.	Penicillin + Streptomycin	"	
20.	a) Tetracycline hydrochl	capsule	250 & 500 mgm.
	b) " base	syrup	125 mgm/5 ml.

21.	a) Chloramphenicol	capsule & tablet	125 mgm & 250 mgm.
	b) Chloramphenicol Palmitate	syrup	125 mgm/5 ml.
22.	a) Ampicillin	capsule	250 & 500 mgm.
	b) Ampicillin	syrup	125 mgm/5 ml.
23.	a) Erythromycin Stearate	tablet	125 & 250 mgm.
	b) Erythromycin Ethyl Succinate	syrup	125 mgm/5 ml.
E. <u>Urinary Antiseptics</u>			
24.	Nitrofurantoin	tablet	50 mgm. & 100 mgm.
	"	syrup	25 mgm/5 ml.
F. <u>Antifungal Antibiotics</u>			
25.	Nystatin	tablet (vaginal)	500,000 units
26.	Griseofulvin	"	125 mgm
27.	Tolnaftate Cream	cream	1%
G. <u>Tuberculosis and Leprosy</u>			
28.	Isoniazide	tablet	100 & 300 mgm.
29.	Isoniazid + Thiacetazone	"	
30.	P.A.3. Granules		
31.	Rifampicin	capsule	150 & 300 mgm.
32.	Pyrazinamide	"	500 mgm.
33.	Dapsone	"	100 mgm.
34.	Ethambutol	"	400 mgm.
H. <u>Analgesics and Antipyretics</u>			
35.	Aspirin	tablet	300 mgm.
36.	Aspirin comp.	"	
37.	Codein phosphate	"	20 mgm.
38.	a) Dipyrone	"	500 mgm.
	b) "	inject.	

39.	Ibuprofen	tablet	200 mgm.
40.	Indometacin	capsule	25 mgm.
41.	Oxyphenbutazone	tablet	100 mgm.
42.	a) Paracetamol	"	500 mgm.
	b) " Paediatric	syrup	120 mgm/5 ml.
43.	Morphine sulphate	inject.	10 & 20 mgm.
44.	a) Pethidine hydrochl	tablet	50 mgm.
	b) "	inject.	50 mgm & 100 mgm.

I. Central Nervous System (CNS) Drugs

45.	a) Diazepam	tablet	5 mgm.
	b) "	inject.	10 mgm.
46.	Phenobarbitone	tablet	15, 30, 100 mgm.
47.	a) Chlorpromazine	tablet	25 mgm.
	b) "	inject.	25 mgm/5 ml.

J. Cardiovascular + Anticoagulants

48.	Dicoumarol	tablet	100 mgm.
49.	Warfarin	"	5 & 10 mgm.
50.	Heparin	inject.	1 mgm.
51.	a) Digoxin	tablet	0.25 mgm.
	b) "	inject.	0.5 mgm.
52.	a) Procainamide hydrochl	capsule	250 mgm.
	b) "	inject.	100 mgm/1 ml.
53.	Quinidine Sulphate	tablet	200 mgm.
54.	Propranolol hydrochl	"	40 mgm.

K. Anti-hypertensive Agents

55.	Methyldopa	tablet	250 mgm.
56.	Guanethidine	"	10 mgm.
57.	Roserpine	"	1 mgm.

<u>L. Diuretics</u>			
58.	Hydrochlorothiazide	tablet	25 mgm.
59.	Frusenide	"	40 mgm.
60.	Triamterine	capsule	100 mgm.
61.	Mannitol	inject.	20%
<u>M. Antianemic Drugs</u>			
62.	a) ferrous sulphate	tablet	200 mgm.
	b) ferrous fumarate	"	300 mgm.
	c) ferrous fumarate and vitamins	"	
	d) ferrous gluconate paediatric	liquid	
63.	Calcium + vitamins	tablet	
<u>N. Vitamins</u>			
64.	Vitamin A	inject.	300,000 units
65.	Folic Acid	tablet	5 mgm.
66.	Pyridoxine hydrochl	"	10 mgm.
67.	a) Ascorbic Acid	"	500 mgm.
	b) "	inject.	500 mgm.
68.	a) Menaphthonium (Vit. K)	tablet	10 mgm.
	b) Phytomenadione (Vit.K)	inject.	10 mgm.
69.	a) Vitamin B Complex	tablet	
	b) " "	syrup	
	c) " "	inject.	
70.	a) Multivitamins	tablet	
	b) "	syrup	
<u>O. Autonomic Drugs</u>			
71.	a) Atropine Sulphate	tablet	0.5 mgm
	b) "	inject.	1 mgm.
72.	Belladonna Dry Extract	tablet	20 mgm.
73.	Propanteline HBr	"	15 mgm.
74.	Adrenaline	inject.	1 mgm.
75.	a) Ephedrine Hydr.	tablet	50 mgm.
	b) "	"	50 mgm.

76.	Salbutamol	tablet	2 mgm.
77.	Aminophylline	"	100 mgm.

F. Gastrointestinal Tract (G.I.) Drugs

78.	Aluminium Hydroxide + Magn. Trisilic	tablet	
79.	Aluminium Hydroxide + Magn. Hydr. Gel.	liquid	
80.	Triple Enzyme	tablet	
81.	Laxative	tablet and syrup	
82.	Furazolidone	suspension	
83.	Diphenoxylate + Atropine	tablet	
84.	a) Di-iodohydroxyquinoline + Sulfa	"	
	b) " "	liquid	
85.	Anti-haemorrhoidal	cream	
86.	Glycerine	suppositories	
86.a	Sodium bicarbonate	tablet	

Q. Antidiabetics (Hypoglycaemics)

87.	One oral Hypoglycaemic	tablet	
88.	a) Insulin	inject.	40 & 80 units
	b) Insulin Zinc Suspension	"	40 & 80 units
	c) Protamin Zinc Insulin	"	40 & 80 units

R. Thyroid and Antithyroid Drugs

89.	Iodine solution (Iugol)		5 %
90.	Liothyronine sodium	tablet	5 & 10 unit
91.	Propyl Thiouracil	"	50 mgm.

S. Estrogens etc. + Gynaecological drugs

92.	Progesterone	inject.	25 & 50 mgm.
93.	Estradiol benz.	"	1 & 5 mgm.
94.	Ethinylestradiol	tablet	10 & 50 mgm.
95.	Contraceptive pill	"	
96.	a) Methylergometrine maleate	"	
	b) " "	inject.	
97.	Oxytocin	"	

T. Anticonotics

98. Promethazine Theoclate tablet
99. One Anticonotic preparation inject. & syrup

U. Antiallergics - Antihistamines

100. a) Chlorpheniramine Maleate tablet
 b) " " syrup
 c) " " inject. 10 cgm.

V. Ear, Nose, Throat, Eye Preparations

101. Sulfacetamide solution 10, 20, 30%
102. Pilocarpine hydrochl " 1-6 %
103. Atropine sulphate " 0.1% to 4%
104. Homatropine hydrochl " 1%, 2%
105. Physostigmine " 0.5%, 1%
106. Ephedrine hydrochl " 0.5%, 1%, 2%
107. Antazoline hydrochl
108. Artificial tears
109. a) Chloramphenicol ear drop 1%, 2%
 b) " eye ointment 5%
110. Chloromphenicol + Prednisolone eye drop
111. Tetracycline eye ointment 1%
112. Adrenaline solution 1%, 2%
113. Xylocaine local inject. 2%
114. Fluorescin solution 2%

W. Topical Preparations

115. Chloramphenicol ointment 3%
116. Tetracycline hydrochl " 3%
117. Neomycin sulphate " 0.5%
118. Gentamycin sulphate " 0.1%
119. Hydrocortisone Acetate " 1%, 2%
120. Neomycin + Bacitracine " "

121.	Nitrofurazone	ointment	0.2%
122.	Lassar	paste	
123.	Lassar + Dithranol	..	
124.	Whitfield	ointment	
125.	Salicylic acid	paste	
126.	Coal Tar	ointment	
127.	Triamcinolone acetonide	..	0.1%
128.	Selenium sulfido	suspension	2.5%

X. Ectoparasites

129.	Gamma Benzene Hexachloride cream	cream	1%
130.	Benzyl Benzoate Emulsion		

Y. Glucosteroids

131.	Prednisolone Acetate	tablet	5 mgm
132.	Hydrocortisone Acetate	injection	

Z. Intravenous Fluids, and Rehydration Salts

133.	RD Sol (Jeevan Jal)	powder	
134.	Normal Saline	fluid	
135.	Saline Dextrose	..	
136.	Dextrose	..	
137.	a) Darrow's solution	..	5%
	b) Half Darrow's solution	..	
138.	Hartmann solution	..	
139.	Dextran	..	
140.	Potassium Chloride	..	
141.	Mannitol	..	
142.	Water for injection	..	
143.	Intraperitoneal fluid	..	

Over the Counter Preparations

144.	Cold tablet	tablet
145.	Tonic	liquid
146.	a) Cough syrup (several) adult	liquid
	b) " " (several) children	liquid
147.	Yeast tablet	tablet
148.	a) Antirrhumatic (several)	ointment
	b) " " "	rubbing lotion
149.	a) External Antiseptics (several)	lotions
	b) " " "	ointments
150.	Toothpaste	paste
151.	"Aperient" Effervescent Salt	

Annex IX

DEPARTMENT OF HEALTH SERVICES - CORE DRUGS AND STANDARD SUPPLY LIST FOR HEALTH POSTS

A. "Core" drugs required for 1980

Description	Requirement	Unit Packing
<u>Anesthetics and Antiasthmatics</u>		
1. Tab. Ephedrin HCL 30 mg	1,780,000	1000/tin
2. ,, Aminophyllin 300 mg	1,650,000	1000/tin
3. Ephedrin Nasaldrops 30 ml	37,000	each
<u>Analgesics and Antipyretics</u>		
4. Tab. Aspirin 300 mg	10,000,000	1000/tin
5. ,, Paracetamol	9,000,000	1000/tin
6. Dentaldrops 30 ml	46,000	each
<u>Antacids</u>		
7. Tab. Sodalint 300 mg	17,400,000	1000/tin
8. ,, Dimagel	4,020,000	500/tin
<u>Anthelmintics</u>		
9. Tab. Thiabendazole 500 mg	1,570,000	500/tin
10. ,, Niclosanide 500 mg	50,000	20/phial
11. ,, Piperazin Adipate 500 mg	2,750,000	1000/tin
<u>Antibiotics</u>		
12. Cap. Tetracyclin 250 mg	485,000	100/tin
13. ,, Chloramphenicol 250 mg	460,000	100/tin
14. Eardrops Chloramphenicol 5%, 30ml	42,000	each
15. Eyeointment Chloramphenicol 1%, 3.5 g	6,500	each
16. ,, Tetracyclin 1%, 3.5 g	41,000	each
<u>Antifungal</u>		
17. Lotio Benzole acid d Salicylic acid, 30 ml	140,000	each

Source: Department of Health Services, HMG.

Description	Requirement	Unit Packing
<u>Antihistamins and Antiemetic</u>		
18. Tab. Chlorpheniramin maleate 4 mg	2,920,000	500/tin
19. ,, Promethazin HCL 25 mg	240,000	100/phial
<u>Antihypertensives & Diuretics</u>		
20. Tab. Hydrochlorothiazide 25 mg	240,000	500/tin
21. ,, Reserpin 0.5 mg	70,000	500/tin
<u>Antileprae and Antituberculosis</u>		
22. Tab. Dapsone 100 mg	9,900,000	1000/tin
23. ,, Isoniazide 100 mg	45,000,000	1000/tin
<u>Anti-inflamatorics</u>		
24. Tab. Prednisolon 5 mg	61,000	100/phial
<u>Antiprotozoals and Antimalarial</u>		
25. Tab. Chloroquin phosphate 250 mg	1,190,000	1000/tin
26. ,, Di-iodohydroxyquinolin 200 mg	3,150,000	1000/tin
27. ,, Metronidazole 200 mg	3,150,000	1000/tin
<u>Antiseptics</u>		
28. Tr. Benzoin Co. 500 ml/btl.	5,600	each
29. ,, Iodine 500 ml/btl.	12,000	each
<u>Antispasmodics</u>		
30. Tab. Belladonna extract, dry 20 mg	1,510,000	500/tin
<u>Antitussive</u>		
31. Tab. Codein phosphate 15 mg	2,340,000	500/tin

Description	Requirement	Unit Packing
<u>Hematinics</u>		
32. Tab. Ferrous sulphate 200 mg	21,390,000	1000/tin
<u>Oxytocic</u>		
33. Tab. Ergonovine maleate 0.2 mg	350,000	100/phial
<u>Laxative</u>		
34. Tab. Phenolphthalein 125 mg	1,000,000	500/tin
<u>Sedative & Anticonvulsant</u>		
35. Tab. Phenobarbitone 30 mg	1,070,000	500/tin
<u>Sulphadrugs</u>		
36. Tab. Sulphadimidin 500 mg	1,215,000	1000/tin
37. ,, Trisulpha 500 mg	8,550,000	1000/tin
38. ,, Sulphaguanidin 500 mg	10,100,000	1000/tin
39. Eyedrops Sulphacetamide 20%, 10ml	57,000	each
40. Sulphathiazol sterile 20 g/pkt.	10,000	each
<u>Vitamins</u>		
41. Tab. Brewer's yeast 300 mg	4,450,000	1000/tin
42. ,, Multivitamin	8,760,000	1000/tin
43. ,, Vitamin Bcomplex	1,780,000	1000/tin
44. ,, Ascorbic acid 500 mg	200,000	500/tin
<u>Antidiarrhoeal</u>		
45. Oral Rehydration Salt 35 g/each	198,000	50/box
<u>Scabicides & Pediculicides</u>		
46. Ointment Gamma benzene hexachloride 1%, 50 g/tube	68,000	each

B. Standard supply list for health posts

<u>Particulars</u>	<u>Packing</u>	<u>Unit price</u>	<u>Q'ty</u>	<u>Amount</u>	<u>Remarks</u>
<u>I. Analgesics</u>					
1. Tab. Aspirin 500 mg	1000/tin	18.50	12	222.00	RDL
2. Tab. Codein Phosph 150 mg	1000/tin	126.50	1	126.50	
3. Inj. Pethidin 100 mg	10amp/pkt	15.60	1	15.60	
<u>II. 4. Tab. Iperasin adip. 500 mg</u>					
	1000/tin	44.76	1	44.76	
5. Tab. Bitescarbate 100 mg	10x3/pkt	26.61	7	186.27	
6. Tab. Niclosamide	4/strip	49.00	5	245.00	(Hills only)
<u>III. Amoebicides</u>					
7. Tab. Di-Iodoxy quinolin 250 mg	1000/tin	71.05	3	213.15	RDL
7a. <u>Contraceptives, Pills, Condoms and Depo Provera</u>					To be discuss with FP/MCH project.
<u>IV. Antimalaria</u>					
8. To be discussed with NMED.					
<u>V. Antileprosy</u>					
9. To be discussed with Leprosy Control Project.					
<u>VI. Antituberculosis</u>					
10. To be discussed with TB Control Project					
<u>VII. Antacids</u>					
11. Tab. Sodamint	2500/tin	21.87	4	87.448	See also Ayurvedic
<u>VIII. Antihistaminics</u>					
12. Tab. Chlorpheniramin Mali	500/tin	11.98	3	35.94	RDL
13. Inj. Prophepyridomin Mali	10amp/pkt	13.42	2	26.84	

IX. Antiseptics

14. Tr. Iodine 2%	450ml/btl.	8.32	8	66.56	
15. Phenol cryst.	2.5kg/tin	28.53	1	28.53	
16. Gentian violet	25g/phial	8.00	1	16.16	
17. Acriflavine	25g/phial	26.79	2	53.58	
18. Carbolic soap	dozen/pkt	34.20	2	68.40	

X. Diuretics

19. Tab. chlorthalidone	100/tin	52.00	2	104.00	
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XI. Antispasmodics

20. Inj. Atropine sulph. 0.5 mg	50amp/pkt	20.24	1	20.24	
21. Tab. Bardidonna	100/tin	12.70	8	101.60	RDL.

XII. Laxative

see
Ayurvedic

XIII. Oxitocics

22. Tab. Ergometrin maleate 0.2 mg	50/phial	3.25	1	3.25	
23. Inj. Ergometin maleate 0.2 mg	25/pkt	25.90	1	25.90	

XIV. Sulphonamide

24. Tab. Trisulfa 500 mg	1000/tin	111.65	6	669.90	RDL
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XV. Antibiotics

25. Inj. Proc. Penicillin G 4,00,000 U	10 vial	9.85	40	394.00	
26. Cap. chloramphenicol 250 mg	100/btl	44.00	2	88.00	

VI. Vitamins

27. Tab. Brewer's Yeast	1000/tin	23.82	3	71.48	
28. Cap. Vit A	1000/tin				
29. Tab. Multivitamins	1000/tin	21.16	4	84.64	

XVII. Analgetics

30	Inj. Adrenalin Chlor. 2ml	1/1000 12 amp/box	8.40	1	8.40	
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XVIII. Serums

31.	ATS 1500 U					
	Inj. Anti snake venom	1 amp/pkt	3.90	10	39.00	
	polyvalent	10ml/vial	43.14	4	172.56	(Total HP only)

XIX. Local Anaesthetics

32.	Inj. Procain Hydrochl.					
	2%	30ml/vial	3.51	4	14.04	

XX. Hematinics

33.	Tab. Ferrous Sulphate	1000/tin	8.35	10	83.50	
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XXI. Bronchodilator

34.	Tab. Ephedrin Hydrochl					
	30 mg	500/tin	12.18	2	24.36	RDL

XXII. For Topical Application

35.	Tetracyclin eye ointment	10g/tube	1.46	20	29.20	
36.	Nephericol ear drops	15ml/vial	1.98	20	39.60	
37.	Netrasol eye drops	15ml/vial	2.35	30	70.50	
38.	Nosola nasal drops	15ml/vial	2.03	20	40.60	
39.	Bensol	30ml/vial	2.00	50	100.00	
40.	Dentaik dental drops	15 ml/vial	2.30	24	55.20	

XXIII. Miscellaneous

41.	RD-Sol (Joevan Jal)	35g/pkt	1.02	500*	510.00	RDL
42.	Inj. Dist. water 5 ml	100/box	12.25	8	98.00	
43.	Glycerine Suppos. child	12/pkt	1.92	1	1.92	
44.	Vaseline Yellow	3.5kg/tin	58.45	2	116.90	
45.	Lin. Terebinth	450ml/btl	6.26	4	25.04	
46.	Spirit methylated	5lt/tin	41.75	1	41.75	

*100 pkts for non-integrated health posts.

XXIV. Dressing and other Expendables

48.	Absorbent cotton	400g/pkt	9.74	10	97.40
49.	Absorbent Gauze cloth	56"x20 yds	13.39	7	93.73
50.	Adhesive plaster	10cm x 5cm	15.68	4	62.72
51.	All Glass Syringe 2 ml	piece	4.04	4	16.16
52.	All Glass Syringe 5 ml	piece	7.25	2	14.50
53.	Bandage gauze cloth	36"x18 yds	18.74	12	224.88
54.	Eye dropper, plastic	dozen	0.64	1	0.64
55.	Hypodermic needles ass.	dozen	8.00	3	24.00
56.	Rubber catheter No.2 and 10	set	1.87	1	1.87
57.	Measure glass, plastic 125 ml	piece	1.86	2	2.72
58.	Nylon gut	hank	1.56	1	1.56
59.	Thermometer, clinical, oral	piece	5.80	6	34.80
60.	Surgical needles ass.	6/pkt	5.90	1	5.90
61.	Surgical gloves	dozen	31.10	1	31.10
62.	Rubber mackint, double coated	meter	10.73	5	53.65
63.	Rubber tubing for double can	piece	2.17	3	6.51

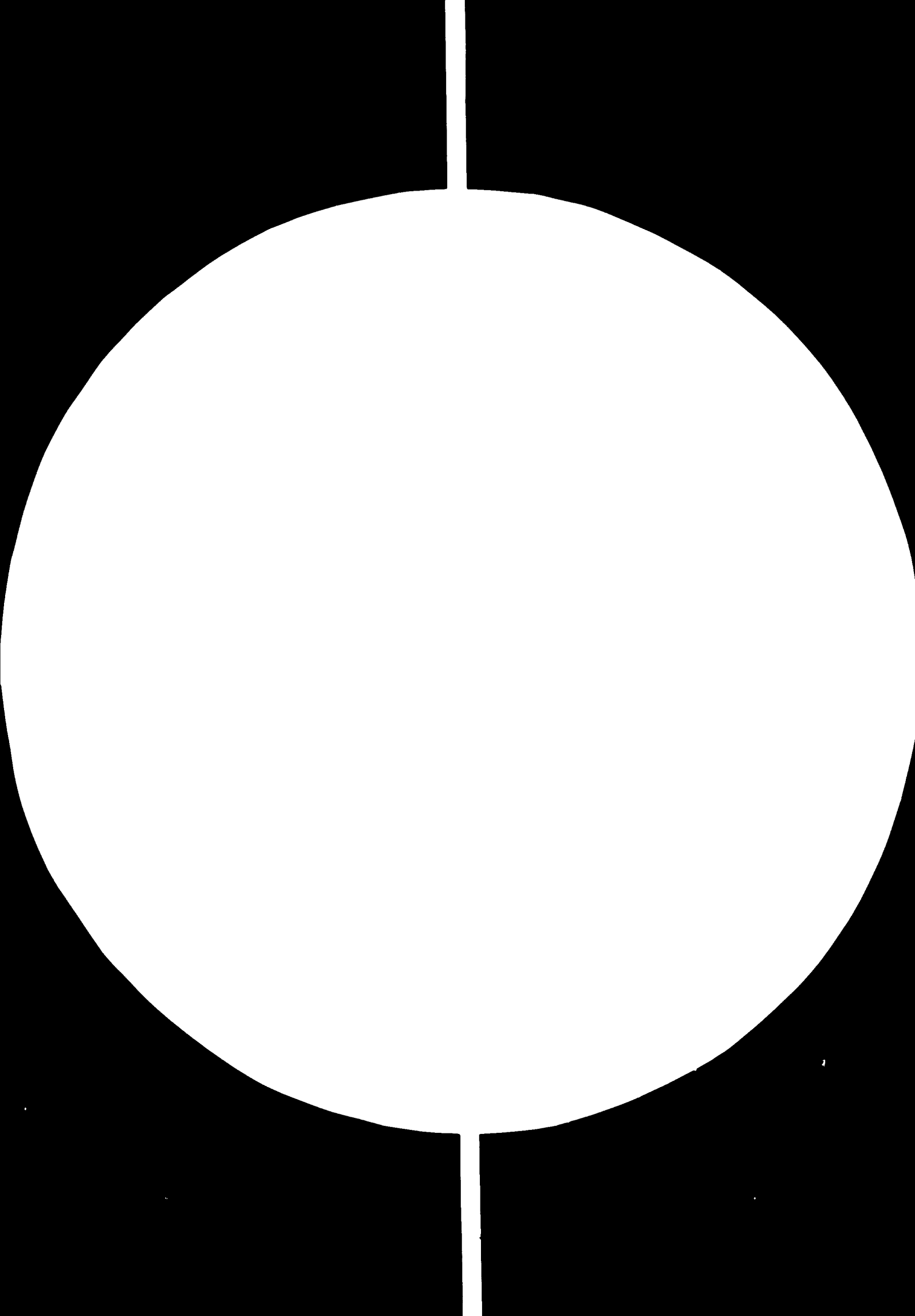
C: Suggested ayurvedic drugs for health posts

<u>Particulars</u>	<u>Packing</u>	<u>Unit Price</u>	<u>Q'ty</u>	<u>Amount</u>	<u>Remarks</u>
1. Pil. Pratishtyakar 0.5g (influenza, common cold)	125/btl	2.00	25	50.00	
2. Pil. Shilabati 375 gm (Jaundice)	70/btl	3.00	2	6.00	
3. Tab. Sriniditunjaya 0.5g (Fever)	12/btl	1.50	20	30.00	
4. Kriniharayoga powder (Roundworms)	12g/pkt	1.00	20	20.00	
5. Hingwastake powder (Anorexia, Dyspepsia)	25g/pkt	2.50	40	100.00	
6. Abipatikara powder (Hyperacidity)	25g/pkt	1.25	50	62.50	
7. Pamahara Tol (Scabies, Skin disorders)	1t/btl	15.00	10	150.00	
8. Shivetaparnati powder (Dysuria, Alkalizer)	12g/pkt	1.50	15	22.50	
9. Pil. Rasonapin-da 1g (Arthritis)	12/btl	1.00	40	40.00	
10. Ohotichouthi powder (Preventive and treatment of common cold and infant diarrhoea)	12g/pkt	1.00	25	25.00	
11. Tab. Laskhachakra 1g (Homostatic)	25/btl	2.00	5	10.00	
12. Mriganadashawa drops (Bronchitis, Dyspnoea)	8ml/vial	12.50	4	50.00	
13. Tab. Praneswara 1g (Intestinal colic & diarrhoea & fever)	6/btl	3.00	25	75.00	
14. Gunnakalpa paste (laxative)	12/phial	0.10	50	5.00	

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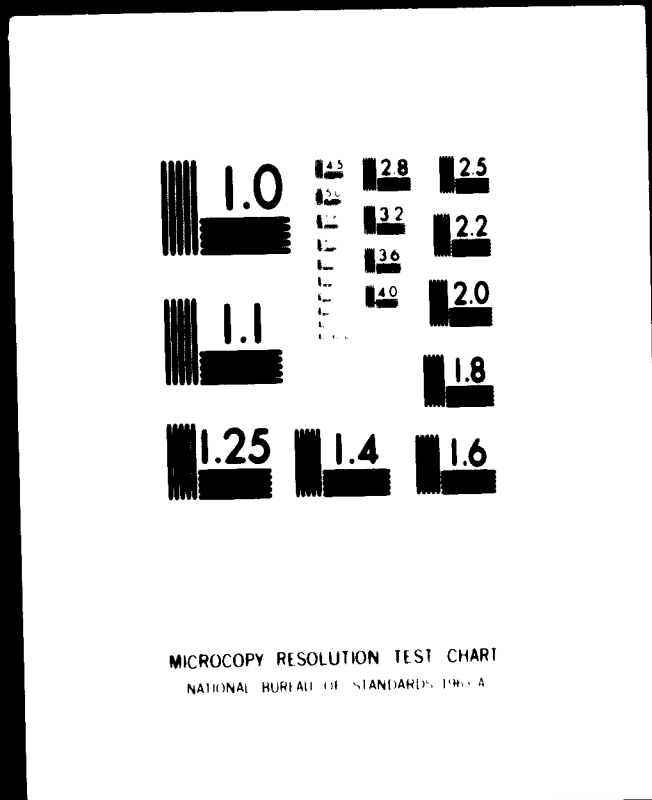


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Annex X

REPORT OF OFFICIAL STUDY TOUR TO BURMA WITH NEPALESE DELEGATION

A - INTRODUCTION

From 1962 to 1964 I served as Technical Adviser to Burma Pharmaceutical Industries (BPI) at Gyogon, Burma. Friendly ties with the original senior staff have been maintained for the last 14 years.^{a/}

In 1977 it was suggested to UNIDO and UNDP that a Nepalese Pharmaceutical team visits BPI and medicinal plants farms as an exploratory mission for future co-operation between Nepal and Burma on a TCDC basis.

The team that visited Burma with UNIDO fellowships consisted of the following:

- | | |
|-------------------|--|
| Mr. A.D. Shrestha | - Chief Production Officer, Royal Drugs Ltd. |
| Mr. D.R. Tuladhar | - Marketing Officer, " " " |
| Mr. Khanal | - Production Officer, Sterile Products Unit,
Royal Drugs Ltd. |
| Mr. Joel Amiran | - UNIDO Pharmaceutical Adviser |

^{a/}Please see UNIDO publication ID/WG. 37/13 "The Establishment of a Pharmaceutical Industry in a Developing Country - a case study - Joel Amiran, 1971.

B. SUMMARY.

A two week visit of different Institutions in Burma is described:

The Burma Pharmaceutical Industry (BPI) is presented as a Case Study of a National Industry striving to achieve for the country the goal of self sufficiency for Essential Drugs. The departments of special interest for future TOIC are highlighted: Planning, Sterile Products, Quality Control, Medicinal Plants Extraction and the production of Human Vaccines and Sera.

The Pharmaceutical Industry Corporation (PIC) and its activities in Pharmaceuticals in general, and Medicinal Plants in particular, are explained.

The visit to the Burma Medical Research Institute (BMRI), and interviews with the Director-General of the Ministry of Health, and with the Director-General of Medical Colleges, give an insight of the sound policy, both of the Ministry of Health and of Medical Doctors, concerning their understanding of the importance of Traditional Medicine and its slow integration with Allopathic Medicine.

A thorough visit of the Institute of Traditional Medicine at Mandalay confirms the eagerness of the Traditional Healers to collaborate closely with Medical Doctors. They continuously raise their standards through Refresher Courses and a newly implemented 3 year Diploma Course, in collaboration with the Medical College and the Ministry of Health.

1.0 RECOMMENDATIONS

- 1.1 Study tour, by the General Manager of Royal Drugs Ltd, to Burma Pharmaceutical Industry, Pharmaceutical Industries Corporation, and the Ayurvedic Institute at Mandalay. Period: 1 week
- 1.2 A fellowship to the Chief Production Officer of Royal Drugs Ltd, to study Planning (Materials, Technical etc.) at BPI. Period: 6 weeks
- 1.3 A fellowship to the Manager of the Quality Control Unit to study the organization and techniques of Quality Control at BPI. Period: 3 months
- 1.4 A fellowship to the Manager of the Sterile Products Unit to study the Manufacture of Sterile Products at BPI. Period: 3 months

Other recommendations, for long-term implementation:

- 1.5 One fellowship for a period of 6 months to a suitable candidate to study Industrial Production of Human Vaccines and Sera, and the production of Lyophilised Vaccines, at BPI.
- 1.6 A fellowship for a period of 2 months to a suitable candidate to study the organization and methods of Medicinal Plants Extraction and Distillation at Pilot and Semi-Industrial Scales. Both at BPI and at PIC.

2.0 FINDINGS

2.1 The UNDP Office in Rangoon

The Resident Representative and his staff went out of their way to help the team. Their advice and understanding was a key factor for the success of the mission.

2.2 The Pharmaceutical Industries Corporation (PIC)

Annual requirements for Pharmaceutical products are received from 5 different government departments, including Army Medical Stores and Central Medical Stores (for hospitals).

Pharmaceuticals which cannot be produced locally are imported by the Army and Central Stores with the approval of the Drugs Advisory Council.

The Pharmaceutical Industries Corporation (PIC) receives every year from the Burma Pharmaceutical Industry (BPI) their requirements of raw materials and packaging components. The value of the requirements is calculated and Foreign Exchange requested. When sanction is obtained, PIC will invite International Tenders for most of the raw materials, except for certain products like vitamins and antibiotics, where only certain suppliers are contacted. BPI will also indicate, according to its experience, preferred suppliers for each raw material. Where brokers are concerned, an inspection clause in the contract will give Burmese Missions abroad the right to inspect the premises of the broker.

Depending on the raw materials, special containers are demanded, and sometimes samples are requested in advance. When offers are received, a Purchase Committee, headed by the Managing Director of PIC will meet and review the offers.

2.3 The Drug Advisory Council

A body consisting of members from the 5 Government departments purchasing drugs from BPI, senior physicians and BPI. The council decides on the introduction of new preparations to be manufactured by BPI or of traditional medicines manufactured in two government hospitals. It decides also on the import of foreign drugs and the deletion of existing ones. It also approves the yearly Production Plan of BPI.

2.4 The Burma Pharmaceutical Industry (BPI)

General: BPI manufactures 50% of the country's needs for essential drugs. It operates on a three shift basis, at its total work force is 2,000, of which 700 are women. It is controlled by the Pharmaceutical Industries Corporation (PIC)

An expansion programme is under active study. If implemented with the financial help of International Organizations, BPI will be in a position to step up its production starting from 1980. By 1983 it would be able to produce all the country's needs for essential drugs.

2.4.1 The Tablet Department

Under the expansion programmes, new fast Rotary Tablet Machines will be purchased from either one or both manufacturers of the present rotary machines.

Of special interest is the automatic handling of the dry granules from the two Fluid-Bed Dryers, where the huge containers are lifted and tilted by a crane, so that the granules drop directly into a large size granulator hopper, and the final product is received into drums.

Some tablets are pres-coated, but the majority of the coated tablet are handled in large conventional coating pans, using conventional manual sugar coating procedures. Locally manufactured "Shellac" is used as protective coating.

2.4.2 The Galenicals Department

(a) A new Multipurpose emulsifier of 300 litres capacity has just been installed.

(b) Pure Reserpine is produced in the Extraction division. From 3 tons of Rauwolfia serpentina roots, 2 kgs. of Reserpine are produced every year. Tincture of Orange and Citrus pectin are produced from orange peel, and different extracts, such as Belladonna extract and Licuorice extract are also produced.

(c) Experiments are also done with local Cardamom, production of Avocado oil, Kurchi, etc.

(d) The whole cosmetic range (lipsticks, creams etc.) and toothpaste production are now produced by another government factory.

2.4.3 The Sterile Products Unit

(a) Powder Antibiotics. Formerly filled individually into vials by a simple machine and closed by a rotating cap-closing machine, are now filled and closed automatically. A whole range of Penicillin, Streptomycin, and Penicillin + Streptomycin products for intramuscular injections are prepared aseptically.

(b) Intravenous Fluids. Sintered glass and membrane filters are used to pass the different solutions before they are filled into bottles, four at a time, by a volumetric type filling machine. The bottles are closed and sealed individually with a hand operated crimping machine.

A new building is just being constructed, and when completed, intravenous fluids will be filled and closed automatically.

After labelling by hand, the bottles are quarantined for 2 weeks, Pyrogen and Sterility tests are performed within one week, but the bottles are kept an extra week and then checked randomly before being delivered.

(c) Eye Ointments. A complete unit for the preparation of Tetracycline HCL eye ointment has been recently received from UNICEF, which also supplies the Tetracycline micronized powder, the ingredients of the base and the tubes.

The unit consists of a rotary type jet washing machine for the tubes, a big planetary mixer, a roller mill, and a semi-automatic filling, crimping and coding machine.

The capacity of the unit is 4 million tubes a year.

2.4.4 The Planning Department

Managed by the Deputy General-Manager for Planning, this department is divided into three divisions, each headed by an Assistant General Manager.

- (a) Technical Planning, Division,
- (b) Materials Planning Division,
- (c) Maintenance and Power.

Yearly requirements of the different government bodies are received by the Planning Department.

Its Statistics Section compiles all the requirements of raw materials and components. This work is done in coordination with the different Production Managers.

The finalized Plan of Production is submitted to the Drug Advisory Council for approval, and from there to the Pharmaceutical Industries Corporation (PIC) for action (see under PIC).

(a) Technical Planning Division

The Manager prepares a Yearly Requirement Manual, which is sent to all Production Managers. He also prepares a Quarterly Production Plan for better follow-up of the actual production.

Production programmes for one week to one month are also prepared, according to the departments involved. These short-term programmes, termed Production Orders are typed in different colours for each item and sent to:

- One copy of the PO to the Production Department,
- One copy of the PO to Raw Materials Stores,
- One copy of the PO to the Quality Control Department.

On completion of one PO, the Quality Control Department will take samples, and then send a Quality Control Slip to the Bulk Store and the Technical Planning Division. If the slip shows that the item is passed, the Planning Department will issue a Packaging Instruction (PI) order to the relevant department with copies to the washing section, components section (for delivery of clean bottles, caps, etc.) and to the Filling Room Departments.

The Printing Press

As in the past, labels are individually checked, counted, coded and delivered with every PI (the correct label sample is stuck to the PI forms).

Under the initiative on the Technical Planning Manager, three printing presses were installed two years ago in the compound. All labels are now printed at BPI, using local paper. Labels are also designed at the factory, and colours are also used.

Glass bottles of different sizes are used for both tablets and liquids. Every effort is made to reduce the number of bottles range by standardizing containers. Bottle necks are also standardized so as to receive the same size caps. Modern glass and plastics factories exist in Burma. Some local bottles are used, but the majority is still imported from neighbouring countries. Plastic bottles are still not used because of the cautious attitude of the management concerning the use of plastic containers for the prevailing atmospheric conditions in Burma.

(b) Materials Planning Division

Visits were made to the different raw material stores, component stores, bottle washing department and the finished goods stores. Vitamins, Antibiotics, enzymes and other sensitive items are stored separately in a special store equipped with air condition units, with a temperature of about 24° C.

Corrosive liquids are kept separately and isolated in special sheds.

(c) Maintenance and Power Plant Division

It consists of an electronics and mechanical maintenance divisions, as well as a utility generation department.

The maintenance division with its modern lathes and high speed drills produces different spare parts for the machines in the production units, and also gears. The manpower in this department is highly skilled.

It is responsible for steam and gas generation, electricity distribution, and air conditioning.

Of special interest is the standby generator of 326 KW with 25% load. The manager recommended a standby generator of 40% load.

Underground steam pipes were installed at BPI at the beginning. These pose a difficult maintenance problem and for the new sterile units building overhead pipes have been installed. The manager strongly recommended the use of overhead pipes, even though it is not aesthetic.

(d) The Filling Room

All labels are manually stuck to bottles, although BPI used semi-automatic bottle labellers in the past. The drastic change was implemented after the Technical Planning Manager made a study tour in factories of an Eastern European Country. This study tour revealed that both time and foreign exchange were saved considerably by using labour intensive methods as well as locally produced semi-synthetic gum. In the past the bottle labelling machines used only a special imported gum.

Liquids are pumped into semi-automatic bottle filling machines and bottles are closed manually. Tables are adjusted for conveyor belts or for normal use, as required.

2.4.5 The Quality Control Department

(a) The following equipment were shown:

1. Recording UV Spectrophotometer
2. Recording IR Spectrophotometer
3. Recording Gas-liquid Chromatograph
4. Recording Thin Layer Chromatograph
5. Recording Densitometer
6. Recording Refractometer
7. Colorimeter
8. Fluorometer
9. Polarimeter

All the products manufactured at BPI are tested in this department which is well equipped, with qualified and well trained personnel.

Inspection Procedures of raw materials arriving at the factory are very efficient.

(b) Research and Development

Under the new re-organization, the different development activities performed in the Production Units were centralized and placed under the Quality Control Department. Under this system, the Quality Control staff use, when necessary, the premises formerly used by the tablet department.

In the past, development work was successfully performed in the tablet department spacious room, using new coating materials, film coating procedures, different tablet disintegrants, etc.

The room is fully equipped with all the machines necessary for development work on tablets and coating procedures.

At present it seems that development work for the different departments has been curtailed to a strict minimum.

2.4.7 Production 2.

This section consists of 3 departments.

- (a) Biological Department
- (b) Medical Information Department
- (c) Veterinary Department

(a) The Biological Department

It has the following functions:

- a. Provides services for the Sterile Products Units:

- Antibiotics Assay
- Biological testing
- Pyrogens test

(b) Production of Human Vaccines and Sera

The following vaccines and sera are produced, and approved by WHO.

Bacterial Vaccines: TAB, Cholera, Plague,

Viral Vaccines: Lyophilised Smallpox
Lyophilised Rabies

Toxoids: Diphtheria and Tetanus

Also produced: Tetanus Antitoxin BP
Diphtheria Antitoxin

Freeze-Dried Anti-Snake Venom Serum, monovalent, against either Cobra or viper bites. Freeze Dried Anti-snake venom serum, bivalent, against Cobra and Viper bites, are also produced.

New Equipment

1. High Capacity Lyophilizer received by a donor country. It produces Lyophilized Rabies Vaccine.
2. A special Fermentor donated by an International Agency. A National Campaign has just started for the immunization of children against Tetanus and with this fermentor, production will be boosted from 1 million doses/year to 4 million doses/year.

The department has 5 cold rooms and cold storage facilities.

(c) The Veterinary Department

It is responsible for the snake pit, milking of snakes, 150 horses farm, small animal breeding and small animals facilities. Very good hygienic conditions are maintained in these facilities.

Special dried food in extruded form is produced by the tablet department for the different animals, according to formulae supplied by the veterinary department.

2.5 The Burma Medical Research Institute (BMRI)

In the past, BMRI had made systemic pharmacological studies of selected indigenous plants on laboratory animals. When they purified the extracts the pharmacological actions were lost, and the programme was stopped after a few years. They still continue to follow leads in the Pharmacological Section. Their new approach:

A Collaborative Study of Traditional medicines is going to be started by BMRI in the near future. Clinical trials on selected patients will be made in the Indigenous Hospital in Mandalay, thus solving ethical problems of performing clinical trials in Allopathic Hospitals on drugs that have not been thoroughly tested on animals. The Deputy Director with consultants from both allopathic and traditional schools, will conduct the study.

In the beginning, Hepatitis and Asthma cases will be selected and approved for treatment at the Indigenous Hospital. The patients will be monitored daily by Allopathic doctors.

In the future promising drugs will be analysed to some extent, and crude extracts will be prepared from them. It is hoped that within a few years Allopathic Doctors will approve traditional drugs. Collaboration with BPI on pharmaceutical technology for the preparation of tablets, liquids, etc. is also planned.

Acute toxicity tests (LD 50 and 14 days acute toxicity tests in mice), are performed with various indigenous drugs.

Work is also proceeding on the identification and anatomical studies of Plantago major. The decoction of the whole plant is used by indigenous practitioners against high blood pressure.

The policy of BMRI, is to collaborate with the traditional healers, to follow-up what they were doing, and to raise their standards.

2.6 Visit to the Director-General of Medical Colleges and Head of Post Graduate Studies

The above visited China and was very impressed by the Integration of Allopathic and traditional medicines there. In December 1977 a Medical Conference will be held in Rangoon, grouping the four Medical Schools, the Institute of Indigenous Medicine at Mandalay, and well known traditional healers.

2.7 Ministry of Health - Rangoon

2.7.1 A meeting was held with the Director-General and his staff, as well as with a representative of the Institute of Indigenous Medicine.

The integration of Traditional and Allopathic Medicines in Burma was discussed.

A systematic organization for traditional healers has been done in Burma:

- In 1962 an Act was passed, ordering these practitioners to register within the Ministry of Health. After passing an examination, they are called Registered Practitioners.

- Refresher courses are being given since 1971 in Traditional Medicines. The Drug Advisory Council decides what traditional drug should be manufactured. There is also close collaboration with the Burma Medical Research Institute.

At the Rangoon General Hospital and the Mandalay Hospital, Traditional medicines approved by the Council, are prepared.

In the above hospitals there are two types of dispensaries: Traditional and Allopathic.

- At the Institute of Traditional Medicine at Mandalay, a 3-year course in Traditional Medicine is given.

- There is also a Traditional Medicines Council, and the Director-General of the Ministry of Health is the Chairman.

- It is the policy of the Ministry of Health to uplift the standards of Indigenous Practitioners as well as Indigenous Medicines.

2.7.2 The Rangoon General Hospital

The Hospital Pharmacy. A graduate Pharmacist is in charge of the pharmacy. High standards are observed in all the sections of Pharmaceutical Production. The Production Unit was started 5-years ago and comprises:

(a) Intravenous Fluids Section. A separate preparation room, under aseptic conditions, is used for the preparation of the above. The section contains 3 autoclaves of the upright type in excellent working condition. The Pyrogen Test, using rabbits, is performed, as well as sterility tests, on finished products.

This section prepares all the different intravenous fluids required by the hospital.

(b) Tablets Section. Fully equipped with well maintained machines and clean surroundings. The section comprises (a) a Ribbon mixer for mixing and wetting powders, (b) a hammer granulator for producing wet granules, (c) ovens for drying, (d) stainless steel mixer for mixing the finished dry granules and (e) a single-punch tablet press.

This section produces 30 Indigenous tablets.

(c) Liquid and Ointment Section. Two planetary mixers for ointments. Hospital solutions and mixtures are made here.

(d) Quality Control Section. Comprises an analytical balance, tablet disintegrator apparatus, tablet fibrillator, electrical hardness tester for tablets.

The school of pharmacy in Rangoon produces 10 pharmacists a year at Diploma level. These pharmacists are sent to Hospitals.

2.8 The Experimental Station at Hmawbi

The above is under the direct control of the Pharmaceutical Industries Corporation (PIC).

2.8.1 Distillation plant. This consists of two distillation units of 400 kgs capacity of plant material, and a compact boiler, 2ton, Kerosene fired and operated by furnace oil.

There is also a mechanical leaf cutter, still and condenser.

(a) Lemon Grass Oil from *Cymbopogon* sp. is being produced on a pilot scale. An average of 2 kg of oil/ton of leaves is produced and used by the Soap Industry.

(b) Rubber Seeds are also being expressed for the paints industry. Castor oil from Castor seeds is being expressed for Pharmaceutical uses, printing press, and lubrication. The castor seeds are grown at Shwe Sayin, near Mandalay.

(c) Safflower oil is also being expressed on an experimental scale.

(d) Menthol, from *Mentha arvensis* is produced, in crystalline form on a small scale. It is intended to grow the plant in Kalaw where more suitable crystals can be produced.

(e) Terpene Hydrate is also produced from Turpentine oil and sulfuric acid. Although grayish in colour, it is suitable for use by BPI in cough mixtures.

(f) Terpenolene, left in liquid state, is separated from turpentine and used by BPI in a germicidal preparation.

2.8.2 The Future Pesticide Formulation Plant at Hmawbi

Active negotiations are being held with UNDP/UNIDO concerning the setting up of a Pesticide formulation plant on an area of 70 acres at Hmawbi. Based on the latest requirements for 1977-78, the plant, when working on an 8 hour basis, will be able to produce the following - for one day:

1. Powder - Dust: 6.8 tons
2. Powder - Wettable: 1.0 ton
3. Granules 1.0 ton per month
4. Liquids - 1,000 gallons.

The bulk of the Dusting powders consists of Aldrin and Lindane in different concentrations.

The Wettable powders consist mainly of DDT 75%.

The liquids consist mainly of Endrin, Malathion, DDT, Dimercron and Household spray.

In addition to the above plant, the setting up of a Pyrethrum extraction plant at Hmawbi with the help of UNIDO is being seriously considered.

MANDALAY

2.9 The Institute of Indigenous Medicine

The different functions of the Institute were explained. Visits were made to the different departments: the Herbarium, the Hospital, the Lecture Rooms, the Library, the Museum, and the Production Unit.

2.9.1 The Institute was set up in 1966, and equipped in 1972. It consists of a staff of ten. It has given 5 Refresher Courses to Traditional Practitioners, and 237 have completed that course.

In 1976 the Institute started a 3 year course in Traditional Medicine.

Two batches of 30 graduates or undergraduates have started the course. The 3rd batch will start in January 1978. The lecturers and professors come from the Institute staff (Traditional Medicine). Subjects taught:

1st year: 5 Traditional subjects

- History of traditional Pharmacy
- Anatomy, traditional Pharmacy
- Physiology, traditional Pharmacy
- Fundamental knowledge of indigenous medicine
- Pharmacology, indigenous medicine

Also 5 Allopathic subjects

- Anatomy
- Physiology
- Biology
- Botany
- Chemistry.

2nd year: Only Traditional subjects

- Diagnosis and treatment
- Pharmacology
- Pharmacy - Dispensing
- Diagnosis
- Fundamental rules of traditional medicines
- Physiology
- Minor surgery
- Nervous Diseases
- Preventive Medicines and public health
- Herbarium

3rd year: Planned

2.9.2 The Hospital. There are 31 beds, of which 5 are reserved for monks.

Hepatitis and asthma cases are among the diseases treated. The outpatient clinic receives up to 200 patients a day, treated with Traditional Medicines.

The Hospitals records show that since 1976, 145 cases of Hepatitis have been treated with no deaths. The medicines used have been handed down since the time of the Burmese Kings and are of established plant origin. 57 Formulae have been accepted by the Indigenous Drug Council, whose chairman is the Director-General of the Ministry of Health.

The Institute has printed a list of medicinal plants used by them, using the traditional name as well as the botanical name. According to the Principal, the Government authorities will print in the future a Pharmacopoeia of Traditional Medicines.

2.9.3 The Manufacturing Unit

The equipment consists of a comminuting machine, a single punch tablet machine, etc.

2.10 Shwe Sayin Experimental Farm - near Maymyo

This farm belongs to the Pharmaceutical Industries Corporation.
Area: 1,000 acres, of which only 10% is at present exploited.

Main plants grown: Castor plants, whose seeds are expressed at Hmawbi and deodorized. The oil is used by BPI. Manpower shortage prevent the cultivation of larger areas of Castor plants.

Senna is also grown on a small scale. In the future an agronomist engineer will be engaged, in order to solve agro-technical problems involved in industrial production.

2.11 Institute of Medicine - Mandalay

Department of Pharmacology. Teaching and multidisciplinary research is being done on classic and Indigenous pharmacology. Screening of an antidiabetic drug of plant origin is being done at present.

There is close liaison with the Indigenous hospital.

The Director is a member of the Indigenous Drugs Committee.

2.12 The Timber Corporation - Ministry of Forests - Rangoon

2.12.1 Meeting was held at the Timber Corporation concerning the production of Turpentine in Burma, from pine oleoresin.

There are three distillation plants, 2 of which are in the Chin Hills, and 1 in the Shan State.

(a) The capacity of the plants at the Chin Hills are 200,000 Viss/year (1 Viss - 1.76 kg) of oleoresin.

(b) The capacity of the plant at the Shan State is 120,000 Viss/year of oleoresin.

The Tapping method

The 15 year cycle is used, where trees are tapped for 5 years and then given a rest of 10 years. There is a control by the Ministry of Forests concerning this tapping cycle, as well as the limit of cutting the tree below a certain height, for tapping.

Trees cut for tapping at 4 ft. yield 3 Viss/year

Trees cut for tapping at 5.5 ft. 11 ins. yield 4 Viss/year

Trees cut of tapping at 6.6 ft. 11 ins. yield 5 Viss/year

Trees cut for tapping at 7.7 ft. 11 ins. yield 6½ Viss/year

The Timber Corporation buys the oleoresin from local farmers and the price is fixed according to the quality of the resin (A.B.C. grades) the farmers are paid 2 Kyats/viss for A grade, 1.5 Kyats/viss for B grade and 1 Kyat/viss for C grade.

The quality differs when the tapping is done below 4 feet, or if the farmers heat the base of the trees (forbidden).

The oleoresin is collected by farmers in 4 gallons jerrycans holding about 11 viss. There is a problem of adulteration of turpentine by the farmers - mostly by placing stones and sand at the base of the tins.

The Pine trees are predominantly Pinus cassia, growing at high altitudes, and also Pinus markusi.

The Purchase Department of the timber corporation is situated in the forest. The jerrycans are transported to the distillation plants, also present in the forest, where the oleoresin is sieved from impurities and stored in concrete tanks. To prevent solidification in cold weather it is stirred with the addition of some turpentine.

The distillation is done in a copper distillation plant, using direct fire obtained from wood.

Recovery 80% of which 65% is Rosin and 15% Turpentine.

Problems encountered

- (a) Quality of Resin: compared to American and Red China Resin, the Burmese Resin is of inferior grade.
 - (b) Because of the crude distillation method used, both Turpentine and Resin have to be purified before use.
 - (c) Due to lack of supply of Oleoresin, the distillation plants run at only 50% capacity. It seems that the farmers do their own crude distillation on a small scale and sell privately their products. Although the government fixes annual quotas for local farmers to supply Oleoresin, control is very difficult. At present the government uses as incentive the supply of rice and clothing for all people engaged in collection and distillation of the Oleoresin.
- Consideration is being given to set up a modern distillation plant that would also be export oriented.

Appendix

1. PERSONS VISITED

1.1 At Rangoon UNDP Office

Mr. Kenneth Watts - Resident Representative
Mr. Hassan Amin - Deputy Resident Representative
U. Maung Maung Soe - Programme Officer

1.2 Ministry of Planning and Finance
Foreign Economic Relations Department

U. Khin Maung - Director

1.3 Ministry of No.1 Industry

1.3.1 Industrial Planning Department

U. Than - Deputy Director

1.3.2 Pharmaceutical Industries Corporation

* U. Mya Thaung - Deputy Director
Major Mya Sein - Assistant Director, Procurement

1.3.3 The Burma Pharmaceutical Industry (BPI)

Lt. Colonel Han Yin - General Manager
* U. Soe Hlaing - Deputy General Manager, Production 1
* Dr. Ko Ko Gyi - " " " " Production 2
* U Hla Thaung - " " " " Planning
* U Thein Hlaing - Asst. General Manager, Quality Control
* U Thein - Asst. General Manager, Tablet Department
* U Po Kya - Asst. General Manager, Galenicals Dept.
* U Ban Yi - Asst. General Manager, Sterile Products
* U Zaw Win - Asst. General Manager, Biological Dept.
* U. Kyaw Shein - Asst. General Manager, Technical Planning

* Names bearing an asterick are people I have known since 1962.

- * U. Kyaw Myint - Asst. General Manager, Material Planning
- * U Chit Lwin - Asst. General Manager, Maintenance and Power

1.4 The Ministry of Health

- Dr. U. Maung Maung Aye - Director General
- Dr. U. Lun Wei
- Se Soya U Khin Maung Win - Inst. of Indigenous Drugs

1.5 The Burma Medical Research Institute

- Dr. Aung San Ba Tu - Director General
- Dr. Khin Maung Tin - Deputy Director
- Dr. Saw Tha - Pharmacologist
- U Khin Maung - Chief Chemist
- Daw Mya Bwing - Botanist

1.6 The Medical Colleges

- * Dr. Khin Maung Win - Director General and Director of post graduate Studies.

1.7 The Rangoon General Hospital

- U Ohn Myint - Hospital Pharmacist

1.8 The Ministry of Forests

1.8.1 The Timber Corporation

- U Tun Wai - Manager, Planning and Operations
- U Kyaw - Liaison Officer and Planning

1.9 Mandalay and Nyaung U.

The Institute of Indigenous Medicines

- Se Soya U Han Tun - Principal
- Se Soya U Ohn Shwe - Councillor
- Se Soya U Aung Sin - Lecturer
- Se Soya U Nyan Tun - Lecturer
- Se Soya U Aung Myint - Inpatient Clinic
- Se Soya U Kya Sein - Inpatient Clinic

* Names bearing an asterisk are people I have known since 1962.

1.10 The Institute of Medicine

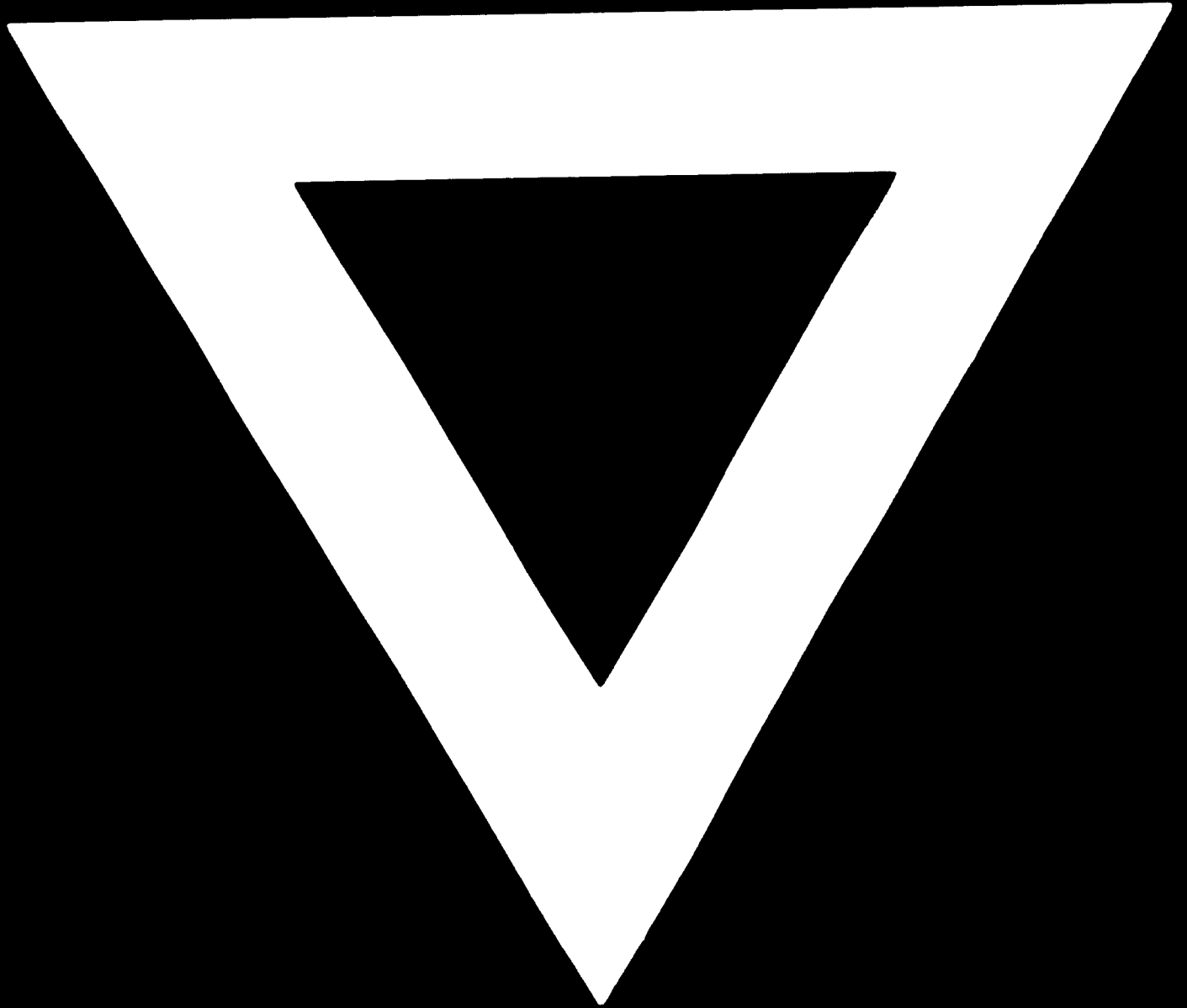
Dr. Khin Maung Tin - Prof. of Pharmacology

1.11 General Hospital - Nyaung U

Dr. Han Sein - Chief Medical Officer.



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