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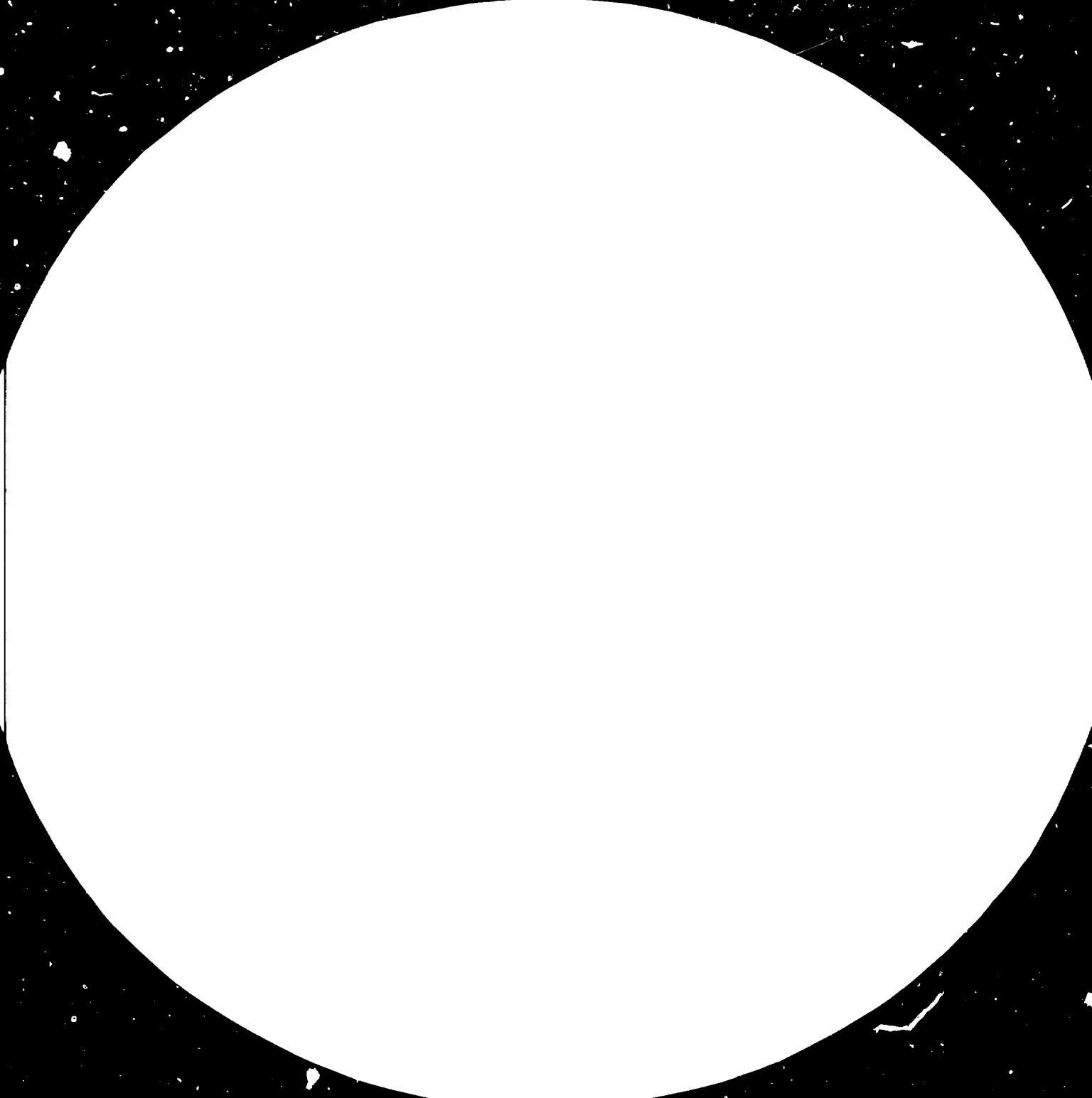
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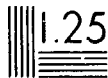
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PROGRAMME OF PHARMACEUTICAL ACTIVITY
FOR THE QUINQUENNIAL 1980/85* .

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6100.07

Submitted for consideration by governments
for special donation to UNIDO for
implementation of projects

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1. GENERAL BACKGROUND

The pharmaceutical industry is one of the most important industries which had a phenomenal growth during the last 30 years, as a result of which significant achievements in social welfare could be registered in developed countries and some of the developing countries. The total world production of pharmaceuticals in 1977 was around US\$ 48 billion out of which about 68% was accounted for by developed countries, 20% by centrally planned economies and 12% by developing countries. The share of 12% of developing countries is almost all in formulation and packaging and not in chemical based industries; it is concentrated only in a few of the developing countries.

The annual rate of growth in this industry has been about 10%. Given the present distribution of world output and relatively small differences in performance between developed and developing countries, it is highly unlikely that the 25% reallocation of production called for in the Lima Declaration will be achieved. In order to attain the Lima target, the developing countries have to grow at about twice the rate of the developed world over the entire period to achieve a 25% share by the end of the century.

An important element in a programme of health care is the availability of suitable drugs for prevention as well as curative medicine. In addition the Alma Ata declaration calls for 'Primary Health for Everybody by year 2000'. If this slogan is to be translated into action, the availability of drugs to support the health programmes has to be ensured.

In many developing countries, pharmaceutical products are either not available in appropriate quantities or quality or their costs are excessively high. For developing countries as a whole, the expenditure on pharmaceuticals accounts for almost half of the total expenditure on health care; that is almost three times the proportion found in many developed countries. Even so, the total amount available for health care in developing countries is very limited and it represents only 2% of the Gross National Product (GNP) and between 40% - 60% of this expenditure is on pharmaceuticals. In comparison, the developed countries' health care budget represents 6% - 8% of their GNP from which 15% - 20% is spent on

pharmaceuticals. Hence a more rational way of supplying pharmaceuticals has to be planned to cope with the actual demand. In this connection, the first step would be the establishment of National Pharmaceutical Industry, which will operate in the interests of the country and will produce drugs necessary. Apart from resulting in positive economic benefit in saving about 40% of foreign exchange through simple formulations of drugs, this will create infrastructure for further industrial growth and development of skills.

UNIDO has therefore developed policies and strategies for the development of pharmaceutical industry in the developing countries as a result of which there has been a phenomenal growth in UNIDO activities in this sector. For example, there was only one project of the value of US\$ 90,000 during 1974, whereas there are 50 active projects during 1979 and projects under implementation are mainly large ones with a total value of US\$ 4 million.

This could be easily enlarged based on the programmes and strategy already developed, should the financial resources be available. Due to the limitation of funds many programmes cannot be implemented. Provision, therefore, of additional funds is the only way of implementing the projects designed by UNIDO.

2. SOCIAL

Besides the benefits to the industrialisation process which the development of the pharmaceutical industry will bring, there are quite distinct social benefits which an indigenously based production programme may offer. A relatively independent drug industry will give the developing countries more freedom to form health care policies and to ensure 'Primary Health for Everyone' by the turn of the century as envisaged. Such a programme can only be effective if the tools of implementation are available. One of the major tools for the success of primary health is the availability of adequate quantity of drugs of the required quality. Therefore the pharmaceutical industry provides products which are essential to the immediate welfare of the population (and which cannot be replaced

by other products) and the industry is vital for the provision of health care and effecting long term improvement of standards of living. A healthy population is an essential pre-requisite for achieving the desired progress in developing countries.

3. TRADE AND ECONOMICS

The developing world having only 12% of the share of world production is heavily dependent on imports of these products from the international market. The development of social health programmes in developing countries will naturally mean an increase in imports. This statement is better illustrated by studying the world trade in this industry.

*The total exports of developed market economies are 92.3% while the corresponding figure for developing countries is 6.3%. The latter is mostly based on the export of plants used for medicinal purposes. As compared to the world production, the developing countries imported 51.8% compared to 11.7% for developed countries and 20.7% for Southern European countries.

4. UNIDO POLICIES AND STRATEGY

The establishment of a pharmaceutical industry is not a simple task since this industry is based on sophisticated techniques and calls for substantial investment. To assist the developing countries establish this industry, UNIDO has elaborated a range of policies for the developing countries such as a drug policy, production policy, basic principles for transfer of technology, strategy on replacement of chemical raw materials by natural raw materials such as medicinal plant extracts and multipurpose plant for the production of several drugs of small volume. The development and promotion of pharmaceutical industry in developing countries is with the objective of becoming self-sufficient in the essential drugs required by the Governments for their health programmes. However, self-sufficiency at the national level is not always feasible due to the market and infrastructure. In view of this, UNIDO has developed strategy to attain self-sufficiency at sub-regional and regional levels. Due to the different

* Source: United Nations Year Book of International Trade Statistics.

levels of development obtained in the developing countries, pharmaceutical industry has to be planned in a phased manner starting from simple formulation and packaging and progressing towards backward integration to chemical synthesis from intermediates and raw materials.

In the absence of co-operation and co-ordination between developing countries in the development of pharmaceutical industry, many developing countries in different regions are producing the same drug in limited quantities with the result that no exchange of finished product or raw material is possible and very often one comes across abuse of the market, as well as lack of basis for co-operation leading to increase in the cost of drugs. In view of this, the main strategy of UNIDO has been the development of pharmaceutical industry in a complementary and co-ordinated manner to avoid unhealthy competition between neighbouring countries as well as to make it possible to reach self-sufficiency in sub-regional and regional levels, as mentioned above.

Another objective and strategy of UNIDO is to assist developing countries in the creation of research and development which is a basis for future expansion of this industry. For this purpose regional centres have been developed of which details are given on the Pharmaceutical Centres in latter pages. All the strategies of UNIDO for the development of pharmaceutical industry in developing countries are based on technical co-operation between developing countries as well as developing and developed countries. The latter is in particular of special importance for transfer of technology, training and designing. UNIDO's efforts will always be to find dialogue for reinforcing these co-operations.

Based on the above strategies UNIDO has developed and implemented projects in this special field in quite a number of the developing countries. However the needs are far larger compared to the limited resources available within United Nations system, including UNIDO. Therefore it is important for UNIDO to receive additional contributions from Governments for financing pharmaceutical projects in the interest of developing countries and mankind.

5. PROJECT PROPOSALS FOR IMPLEMENTATION BY UNIDO

Project proposals suggested by UNIDO for implementation by sources other than United Nations could be divided as follows :

- I. Formulation and packaging of drugs (tablets, capsules, injectibles and oral rehydration salts)
 - II. Production of bulk drugs starting from intermediates/ raw materials and multipurpose plant
 - III. Drugs based on medicinal plants and other natural resources
 - IV. Pharmaceutical Development Centres (regional and sub-regional).
-
- I. Formulation and packaging of drugs (tablets, capsules, injectibles and oral rehydration salts)

This activity can start mostly in all developing countries based on established list of essential drugs. Those countries which are in the primary stage in this industry could enter by formulation and packaging of tablets, capsules and syrups. The detailed list of equipment for such activity, the design and layout, as well as cost are given in Annex I. Total cost for formulation and packaging for one unit in one country amounts to US\$ 1.5 million.

Countries which are on UNIDO list for establishment of such primary pharmaceutical industry are :

- | | |
|----------------------|---|
| <u>Africa</u> | Sudan*, Chad*, Uganda*, Gambia, Botswana, Burundi and Rwanda*, Upper Volta*, Niger and Cameroon. |
| <u>Asia</u> | Afghanistan*, Bhutan, Bangladesh, Nepal*, Sri Lanka, Vietnam, Peoples Republic of Yemen*, Democratic Republic of Yemen. |
| <u>Latin America</u> | Dominican Republic, El Salvador, Haiti*, Honduras and Nicaragua. |

The next step will be the expansion of formulation and packaging of tablets activity towards injectibles for which a detailed list of equipment, experts and training is given in Annex II.

* UNIDO has carried out feasibility studies on country level. The remaining countries are covered through regional studies, especially the recent ones in co-operation with WHO and UNCTAD.
Project No. INT/009/A/01/99.

Total cost for injectables for one unit in one country amounts to US\$1.2 million.

As this activity will be accommodated in the already constructed building, therefore no additional cost of building is required for those pharmaceutical units where such production activity has been foreseen. If not, an additional amount of US\$ 50,000 is required for the building.

II. Production of bulk drugs starting from intermediates/raw materials and multipurpose plant

As the production of drugs for intermediates and raw materials is more sophisticated technologically, and requires large capacities to justify investments which are not always available in developing countries, UNIDO has developed the concept of multipurpose plant which makes it possible to produce a group of drugs in the same unit for small individual drug capacity. As this activity is not known in the developing world and is a novelty, UNIDO is establishing a demonstration unit in Havana, Cuba (1980) in the interest of Latin American countries in order to train the personnel and develop technology for drugs in the interest of that region. The cost of equipment, building, technical assistance, training etc. is given in Annex III.

Total cost for one unit in one country amounts to US\$ 2.0 million excluding building, plus US\$ 0.5 million for building.+

UNIDO's aim is to establish 2 more such units, one in Asia and the other in Africa. The countries foreseen for this activity in the interest of the region are :

Nepal in Asia

Tanzania in Africa

III. Drugs based on medicinal plants and other natural resources

Most of the developing countries have rich flora of medicinal herbs and plants and essential oil bearing plants growing wild in many cases.

The medicinal plants can serve as a valuable source of raw materials for local pharmaceutical industry as well as for export either in the form of crude extracts or finished products. The pharmaceuticals based on

+ These projects are mostly sub-contracted on a turn-key basis.

medicinal plants can either be introduced in the existing pharmaceutical production units or a versatile multipurpose plant can be established for the extraction of medicinal plants or active ingredients. An essential drug list has been drawn up by UNIDO based on Technical Consultation meeting on production of drugs from medicinal plants in developing countries held in India in 1978. The list of equipment for extraction of active ingredients in the existing unit is given in Annex IVa.

Total cost for one unit in one country amounts to US\$ 350,000.

For extraction of different quantities of a variety of medicinal plants a multipurpose plant has been developed which is indicated in Annex IVb.

Total cost for equipment, including building for one unit in one country amounts to US\$ 680,000.

Countries suggested for development of such programmes are as follows :

Africa Botswana*, Burundi*, Central African Empire*,
Cameroon, Guinea, Guinea-Bissau*, Madagascar,
Rwanda*, Senegal, Zanzibar.

Asia Afghanistan*, Bhutan*, Nepal*, Thailand,
Vietnam.

Latin America Bolivia, Ecuador, Haiti*, Honduras, Nicaragua.

IV. Pharmaceutical Development Centres (regional and sub-regional)

As mentioned before, due to lack of research and development in developing countries as well as the difficulties of placing candidates for long period training abroad, mostly in developing countries due to the different level of industry, it has become very important to create a regional Pharmaceutical Centre equipped with pilot plants according to the region's production activity, in order to carry the applied research and development, especially in medicinal plants, up-dating of processes according to the needs and especially in the training of personnel.

UNIDO is establishing such a centre for French speaking Africa in Upper Volta which is financed by the Belgian Government. A second centre is planned for Asia which will be established in India under UNDP

* UNIDO has carried out feasibility studies on country level. The remaining countries are covered through regional studies, especially the recent ones in co-operation with WHO and UNCTAD.
Project No. INT/009/A/01/99.

financing and a third is planned for Latin America for the ANDEAN group of countries, again to be financed by UNDP.

UNIDO's objective is to establish a similar unit as in Upper Volta for the English speaking African countries. The country chosen is Tanzania. The project document for the establishment of a pharmaceutical industry development centre for a developing country giving details of equipment, experts and training cost is given in Annex V, as an example. This activity, after being carried by United Nations for 4 years, will be financed through IPF of participating countries. Total cost for one unit in one country, including building, amounts to US\$ 2.5 million.

6. TECHNICAL CO-OPERATION AMONGST DEVELOPING COUNTRIES (TCDC)

The implementation of pharmaceutical industry projects under TCDC is feasible as well as advantageous because of similarity of infrastructure and production programmes. UNIDO has carried out studies for establishing such a programme of co-operation. Further, UNIDO has signed agreements with the National producers in Argentina, Peru, Mexico, Egypt and India. These countries are fairly advanced in the field of pharmaceutical industry and are in a position to transfer technology. On this basis, and under the auspices of UNIDO, India is transferring technology for the manufacture of fifteen different synthetic drugs in a multipurpose plant to Cuba. In a similar manner, UNIDO is fostering co-operation between developing countries in the pooling of markets and this exercise will be extended to other countries. Examples are co-operation between Cape Verde and Guinea-Bissau to be extended to Sierra Leone and Gambia; between Tanzania and Mozambique; between Cuba, Guyana, Jamaica, Costa Rica and Mexico and between Nepal and Burma.

7. CO-OPERATION WITH DEVELOPED COUNTRIES

UNIDO has been making efforts to promote co-operation between developed and developing countries since the former can make a significant contribution towards the development of pharmaceutical industries in the developing countries. The developed countries can co-operate in the above projects in the matter of supply of machinery, technology, experts and training which are not available in the developing world. Such a

co-operation has been successful. For example a training programme in Pharmaceutical Technology is being conducted at Ghent, Belgium in co-operation with the Belgian Government and the pharmaceutical industry of Belgium and a number of technicians from the developing countries have already been trained. Similarly Kabi Vitrum of Sweden is co-operating in the fields of production of insulin, synthetic drugs and blood derivatives; Vifor of Switzerland has been co-operating in the establishment and operation of infusion production units. Dumex of Denmark has offered co-operation in the production of synthetic drugs. Hungary is providing know-how for the manufacture of anti-malarial drugs.

8. ORGANIZATIONAL SUPPORT IN UNIDO

The Pharmaceutical Industries Unit of Chemical Industries Section is composed of the following staff :

1. Dr. A. Tcheknavorian-Asenbauer, Chemical Engineer, Chief of the Unit
2. Mr. C.N. Chari, Chemist, Biochemical Engineer
3. Ms. M.E. Quintero, Pharmacist

The following are being inducted into the Unit in the near future :

4. Mr. M.K. Polyevktov, Chemical Engineer
5. Ms. O. Valdes, Chemical Engineer
6. Prof. F. Sandberg, Pharmacognocist

This staff is implementing right now 50 active projects and developing policies, new concepts as well as projects for future programmes and activities. In case UNIDO could obtain additional funds for implementing the above presented programme, UNIDO is prepared to provide adequate number of qualified staff in order to secure smooth and efficient implementation of these projects.

9. SUMMARY AND CONCLUSIONS

UNIDO is involved in the establishment of pharmaceutical industry projects for developing countries financed through UNDP, UNIDF, SIS and special contributions. However, the needs of the developing countries

are much larger and the limited budgets of Governments are not adequate for the purchase of drugs to meet the ever increasing demands of the social health programmes of the countries. A rational way of supply of drugs has, therefore to be introduced to attain self-reliance in this vital field which is essential for improving the quality of life, which in turn is the backbone for the development of any nation. UNIDO is giving technical assistance to most of the developing countries particularly the least developed countries, wherever the Governments are not in a position to finance these programmes. UNIDO is, therefore, making efforts to obtain special donations from developed and developing countries for financing these projects.

The necessity for the projects given under paragraph 5 has been established by UNIDO through studies by individual international experts to the concerned countries or at the national and regional levels. The project proposals are divided into four categories based on the level of production, sophistication and infrastructure available in the developing countries. The investment required for each unit along with the countries which are suitable for receiving such assistance have also been indicated as summarized below :

- (a) Formulation and packaging of drugs
 - (i) Tablets, capsules, syrups and oral rehydration salts - Total cost per unit per country US\$1.5 million
 - (ii) Injectables and infusions - Total cost per unit per country US\$1.5 million (including building)

- (b) Production of bulk drugs starting from intermediates/raw materials and multipurpose plant

Total cost per unit per country US\$2.5 million (including building)

- (c) Drugs based on medicinal plants
 - (i) Expansion of production in existing unit - Total cost per unit per country US\$350,000
 - (ii) Multipurpose plant - Total cost per unit per country US\$680,000

In view of this, the donor Governments could choose out of these the countries and the level of production to find out the contribution required for implementing these projects. For example if one chooses group (a) (Formulation and packaging) countries such as Botswana, Burundi, Afghanistan and Nicaragua, the total amount of contribution required for implementing four projects in the above four countries will be US\$ 6.0 million (4 x US\$ 1.5 million). If these projects should include injectables and infusions, an additional contribution of US\$ 4.8 million (4 x US\$ 1.2 million) will be necessary making a total of US\$ 10.8 million for the establishment of both these projects in all the four developing countries mentioned above. Similar calculations can be made for projects for the multipurpose plant and unit for production of drugs from medicinal plants.

COST OF UNIT FOR FORMULATION AND PACKAGING

Annual Capacity

Tablets - 400 million
Hard gelatin capsules - 40 million
Oral liquids - 5 million bottles (100 ml each)

<u>PARTICULARS</u>	<u>COST</u> <u>US \$</u>
Building (Typical layout enclosed)	400,000
Equipment for Production (Detailed list enclosed)	500,000
Equipment for Quality Control Laboratory (Detailed list enclosed)	70,000
International Experts (Production, Quality Control and Maintenance)	450,000
Training	80,000
	<hr/>
<u>TOTAL</u>	<u>US\$1,500,000</u>
	<hr/> <hr/>

EQUIPMENT FOR ORAL REHYDRATION SALTS.

<u>Type of Equipment</u>	<u>Number Required</u>
Granulator	1
Automatic Dial Scale	1
Drying Installation	1
Dry Blend Mixer	1
Stainless Steel Drums	2
Polyethylene Drums	10
Powder Feeding Machine	1
Sealing Machine	1

REQUIREMENTS OF EQUIPMENT

Equipments for tableting section

<u>Type of machine</u>	<u>Number required</u>
(1) Sifting machine For sifting powder like starch, talcum powder etc. Capacity approx. 200 kg/hour.	One
(2) Comminuting machine - With suitable sieves, for pulverising sugar, calcium gluconate etc. and also for dry sifting of granules (similar to Fitz mill).	One

	<u>Type of machine</u>	<u>Number required</u>
(3)	Planetary mixer For wet mixing of powders for granulation capacity of the mixing vessel - 125 litres (working capacity for approx. 100 kg mass).	One
(4)	Planetary mixer Working capacity - 50 kg mass.	One
(5)	Oscillating granulator - With variable speed, sieves of different size, made of perforated stainless steel or plastic wiremesh and not of stainless steel wire mesh.	Two
(6)	Hot air oven - With two trucks having 20 - 24 stainless steel trays in each truck. Working capacity 100 kg of dried granules; heating with steam and electricity.	Two
(7)	Fluid bed drier - Designed to have required safety measures, heating with steam; capacity 100 kg.	One
(8)	Stainless steel Blender, double cone or 'V' type - For mixing granules with lubricating agents. Working volume 200 litres. (Working capacity about 200 kg of granules).	One
(9)	Blender similar to No.8 - Working volume 100 litres.	One

	<u>Type of Equipment</u>	<u>Number required</u>
(10)	Rotary tablet compressing machine - Capacity 30,000 to 40,000 tablets per hour	Two
(11)	Rotary tablet compressing machine - Capacity 80,000 to 100,000 tablets hour	Two
(12)	Dust remover for tablets - For removing dust from tablets as they come out of the compressing machines.	Four (One for each tablet compressing machines)
(13)	Visual inspection belt - For inspection of tablets and coated tablets.	Three
(14)	Hot water bath - About 30 cm diameter for making granulating solution.	Two
(15)	Punch polishing unit -	One
(16)	Aluminium storage tank - Capacity 2000 lit - for storing denatured spirit or Isopropyl alcohol required for granulation.	One
(17)	Pump with flame proof motor - For pumping alcohol.	One

Equipment for tablet coating section

<u>Type of Equipment</u>	<u>Number required</u>
(1) Stainless steel coating pan - Complete with hot air supply and exhaust system. Capacity 100 kg of tablet cores.	One
(2) Stainless steel coating pan - Similar to No 1. Capacity 50 kg of tablet cores.	One
(3) Polishing Drum - For polishing coated tablets capacity 100 kg of coated tablets.	One
(4) Room dehumidifier - For the dehumidified room of the coating section.	Two
(5) Stainless steel pan - Electrically heated, with tilting device or bottom outlet. Capacity 25 lit for making sugar syrup for coating.	One
(6) Portable high speed stirrer, medium size - For mixing colour or talcum powder in sugar syrup.	One
(7) Stainless steel storage tank - Side or bottom outlet. Capacity 100 lit, for storing syrup.	One

Note: If conventional sugar coating is replaced by film coating then item No 5 and 7 will not be required.

-- Requirement of equipments for the in process control in the tableting and coating section.

	<u>Type of Equipments</u>	<u>Number required</u>
(1)	Weighing machine dial type - Capacity 200 kg.	One
(2)	Weighing machine dial type - Capacity 25 kg.	One
(3)	Balance - For checking average weight of tablets	Three
(4)	Monsanto hardness tester for tablets -	Two
(5)	Vernier Callipers -	One
(6)	Apparatus for testing friability of tablets -	One
(7)	Apparatus for testing disintegration time for tablets -	One
(8)	Magnifying glass -	Two

Equipment for oral liquids and drop solution

<u>Type of Equipments</u>	<u>Number required</u>
(1) Stainless steel syrup kettle - Jacketed for heating with steam or cooling with cold water, suitable for applying pressure (about 1kg) or vacuum; fitted with high speed stirrer (flame proof motor), thermometer, deep stick for measuring volume, bottom out let, working capacity 1000 lit; for making syrup and suspension.	One
(2) Stainless steel jacketed pan - Jacketed for heating or cooling; bottom outlet, working capacity 250 lit, for making auxiliary solutions for syrup or suspension.	One
(3) Stainless steel solution kettle - Suitable for applying pressure (about 0.5kg) or vacuum, fitted with high speed stirrer, deep stick. For making drop solution working capacity - 100 lit.	One
(4) Portable high speed stirrer medium size -	Two
(5) Turbine homogenizer - with variable speed for batch size 250 lit.	One

- | | | |
|------|--|-----|
| (6) | Filter press -
With stainless steel plates
capacity for normal syrup 500 lit per hour. | One |
| (7) | Stainless steel transfer pump
fitted with flame proof motor. | Two |
| (8) | Milipore filter unit -
316 mm diameter for filtering drop solution. | One |
| (9) | Stainless steel mixing tank -
suitable for applying pressure or vacuum,
fitted with high speed stirrer (flame
proof motor) bottom outlet.
capacity 2000 lit. | One |
| (10) | Stainless steel mixing tank
similar to No.9 capacity 1000 lit. | One |
| (11) | Stainless steel storage tank
similar to No.9 but without stirrer capacity
2000 lt. | One |
| (12) | Stainless steel storage tank
similar to No.9 but without stirrer
capacity 1000 lit. | One |
| (13) | Stainless steel portable vessel
suitable for applying pressure or
vacuum capacity 250 lt. | One |
| (14) | Stainless steel portable vessel
similar to No. 13 capacity 100 lt. | Two |

	<u>Type of equipments</u>	<u>Number required</u>
(15)	Weighing machine dial type capacity 200 kg.	One
(16)	Weighing machine dial type capacity 25 kg	One
(17)	Hydrometer for checking specific gravity of syrups.	Two
	Requirement fo equipments for capsule.	
(1)	Stainless steel Blender double cone or 'V' type capacity working volume 100 lit for mixing capsule mixture.	One
(2)	Automatic hard gelatin capsule filling and closing machine capacity 20,000 capsules/hour.	One
(3)	Room dehumidifier for dehumidifying the filling room -	One
(4)	Small vacuum cleaner.	One
(5)	Visual inspection belt for inspecting filled capsules.	One
(6)	Balance for checking fill weight of the capsules.	One

Equipment for packaging of tablets granules and capsules
(most of the tablets and capsules are to be packed in strips)

	<u>Number required</u>
(1) Strip sealing machine with automatic feeding attachments for tablets and coated tablets. Capacity 60,000 tablets/hour.	One
(2) Strip sealing machine similar to No. 1, capacity 30,000 tablets/hour	Three
(3) Strip sealing machine with automatic feeding attach- ment for capsule, capacity 20,000, capsules/hour	One
(4) Batch printing attachments for strip sealing machine	Five (one for each machine)
<p>Note: Capacity of the strip sealing machines has been calculated on the basis of two shifts working per day.</p>	
(5) Semi automatic counting machine for tablets and capsules.	Two
(6) Semi automatic counting machine for coated tablets.	One
(7) Semi automatic heat sealer for polyethylene bags.	Two
(8) Automatic packaging for granules for packaging granules in sachets, 50 grams to be grams of granules in each.	One

Requirement of equipments for packaging oral liquids and drop solution.

	<u>Type of Equipment</u>	<u>Number required</u>
(1)	Bottle washing machine Capacity 3000 - 3500 bottles/hour for washing 60ml to 200ml bottles.	One
(2)	Bottle brushing machine for cleaning occasional dirty bottles or bottles for reuse.	One
(3)	Turn table for transferring washed bottle to the filling machine.	Three
(4)	Automatic liquid filling machine 4 to 6 heads piston type, capacity 3500 bottles/hour, size of bottles 60 ml to 200 ml.	One
(5)	Semi automatic liquid filling machine two head piston type for filling bottles of 60 ml to 200 ml.	One
(6)	Semi automatic liquid filling machine Capacity 2000 vials/hour for filling 10ml to 20ml vials of drop solution.	One

	<u>Type of Equipment</u>	<u>Number required</u>
(7)	Automatic capping machine for sealing bottles with pilferproof caps.	One
(8)	Semi automatic capping machine for sealing bottles with pilferproof caps.	One
(9)	Automatic labelling machine for round bottles, size 60ml to 200ml. Capacity 3500 to 4000 bottles/hour.	One
(10)	Semi automatic labelling machine for round and flat bottles, capacity about 2000 bottles/hour.	One
(11)	Semi automatic capping machine for closing vials of drop solutions.	One
(12)	Automatic labelling machine for ampoules and vials. Ampoule size 1ml to 10ml, vial size - 25-30 mm diameter. Capacity 4000-5000/hour.	One

	<u>Number required</u>
Equipment for the packaging section	
(1) Conveyor table 6 meter long	Four
(2) Happa batch printing machine for over printing labels and cartons	Two
(3) Leaflet folding machine	One
(4) Gluing rollers for applying adhesive on the labels	Six
(5) Gum tape dispenser	Six
(6) Balance capacity - 12 kg for checking weight of the finished packets	Four
Equipments for material handling and central weighing centre	
(1) Fork lift capacity 3 ton	Two
(2) Stacker capacity 1 ton	One
(3) Hand operated pallet truck capacity 1 ton	Six
(4) Weighing machine dial type 250 kg (with large platform)	One
100 kg	One
30 kg	Four
4 kg	Four
2 kg	Four
Equipment for production area	
(1) De mineralising column capacity 1000 lit/hour	Two
(2) Distilled water plant Thermocompression Distillation type capacity 200 lit/hour	One

	<u>Type of equipment</u>	<u>Number required</u>
(3)	Stainless steel storage tank for demineralised water capacity 2000 lit	One
(4)	Stainless steel storage tank for distilled water, insulated and with heating arrangement for maintaining the temperature of the distilled water at 80°C. capacity 1000 lt.	One
(5)	Stainless steel pump for pumping demineralised and distilled water.	Two
(6)	Compressor to produce oil free air capacity 100 m ³ /hour, pressure 4 kg.	Two
(7)	Storage tank for the compressed air.	One
(8)	Floor washing machine	One
(9)	Industrial vacuum cleaner with different attachments.	Two
(10)	Fire extinguishers as per the advise of the fire prevention department.	

IV 3. Accessories required for production.

	<u>Type of accessory</u>	<u>Number required</u>
(1)	Aluminium containers	
	50 kg capacity	12
	25 kg	20
	15 kg	15
	for transporting weighed materials from the weighing centre to the manufacturing areas.	

	<u>Type of accessory</u>	<u>Number required</u>
(2)	Aluminium drums capacity about 50 kg of granules for storing granules and powders	50
(3)	Stainless steel buckets	6
(4)	Storage containers for tablets made of plastic or stainless steel or aluminium; suitably shaped for easy stacking of empty containers.	200
(5)	Cardboard boxes each holding 400 ampoules of 2 ml for storing sterilised filled ampoules, awaiting quality control approval.	2000
(6)	Pallets made of light but strong metal	500
(7)	Stainless steel scoop	
	large	12
	medium	20
	small	12
(8)	Wooden or stainless steel paddle	
	large	3
	medium	3
	small	3
(9)	Stainless steel spatulas	
	large	6
	medium	6
	small	3

<u>Type of accessory</u>	<u>Number required</u>
(10) Ampoule washing trays made of aluminium or stainless steel each holding 100 ampoules	150
(11) Trolley large	8
small	12
for carrying materials and small equipment within the production area	
(12) Trolley for carrying drums	4
(13) Stainless steel containers capacity 10 lit for taking coating syrup	6
(14) Large spoons for putting syrup on the tablet cones.	6

<u>Equipment for quality control laboratories</u>	<u>Number required</u>
(1) Electric Shaker	One
(2) Micro melting point apparatus with microscope	One
(3) P.H. meter	Two
(4) Polarimeter with accessories	One
(5) Refractometer - Abbe type	One
(6) Viscometer	One
(7) Spectrophotometer U.V. and visible range	One
(8) I.R. Spectrophotometer	One
(9) Flame photometer	One
(10) Colorimeter	One
(11) Electric sensitive analytic balance	Two
(12) Physical balance	Two
(13) Balance, Mettler make 2 or 4 kg capacity	One
(14) Hot water bath - electrically heater	Two
(15) Sand bath	One
(16) Hot air oven for drying washed glass apparatus	Two
(17) Hot air oven small	One
(18) Vacuum oven	One
(19) Muffle furnace about 2000 w. for operating temperature - 1100°C.	One
(20) Laboratory microscope with binocular	One
(21) Karl Fischer apparatus	One
(22) Moisture determination balance infrared heating	One
(23) Rotatory evaporator	Two
(24) Centrifuge table type 6000 R.P.M.	One
(25) Disintegration tester	Two
(26) Hardness tester	One
(27) Friability tester	One
(28) Vacuum desiccator	Two
(29) High vacuum pump	Two
(30) Refrigerator large size	One
(31) Bunsen burners	Twelve
(32) Heating mantles 500 ml	Four
(33) Magnetic stirrer with hot plate	Two

<u>Equipment for quality control laboratories</u> (Cont'd)	<u>Number Required</u>
(34) Laminar flow system	Two
(35) Membrane filter system	
(36) Incubator - water heating with thermostat control	Three
(37) Hot air sterilising oven temperature range 30° - 200°C.	One
(38) Hot air oven for drying washed apparatus	Two
(39) Turbidimeter	One
(40) Projector (Zone reader)	One
(41) Microscope with binocular	One
(42) Refrigerator	One
(43) Physical balance glass apparatus	One

Note: No provision has been made for a biological laboratory. It is recommended that samples for pyrogen tests are sent to the Central Public Health Laboratory.

COST OF UNIT FOR INFUSIONS AND INJECTABLES

Annual Capacity

Infusions - 500,000 bags of 500 ml. each

Injectables - 15 million ampoules

<u>PARTICULARS</u>	<u>COST</u> <u>US \$</u>
Building	300,000
Equipment) (Production, Laboratory)) (Detailed list enclosed))	1,200,000
International experts)	
Training)	
	<hr/>
<u>TOTAL</u>	US\$ 1,500,000
	<hr/>

Equipment for Injectables

Number required

- | | | |
|-----|--|------|
| (1) | Semi automatic ampoule washing machine capacity 12000 to 15000 ampoules/hour for washing 1 ml to 10 ml ampoules and 10 ml vials for ophthalmic drop solution | One |
| (2) | Conveyor belt
5 meter long
for transporting empty ampoules (arranged on washing trays) from the arranging room to washing room. | One |
| (3) | Drying tunnel
with suitable conveyor belt
supply of filtered cool air for cooling the ampoule after drying;
for drying and heat sterilising the washed ampoules and vials | One |
| (4) | Ampoule filling and sealing machine
two filling needles, capacity 3000 ampoules/hour size 1 ml to 10 ml. | Four |

Note: Ampoule filling and sealing machines can work only 6 hours out of 8 hours shift because the ampoules filled and sealed must be sterilised on the same day. Filling of ampoules therefore has to stop early.

Equipment for Injectables (Cont'd)

Number required

- | | | |
|-----|---|------|
| (5) | Two door autoclave suitable for applying vacuum before letting in steam. Fitted with manometer and automatic temperature recording device; should have its own vacuum pump capacity being enough to hold 50,000 2 ml ampoules for sterilising filled ampoules and drop solution vials. | One |
| (6) | Stainless steel solution kettle jacketed for applying steam or cold water, mirror finish inside for proper cleaning, suitable for applying pressure (about 0.5 kg) or vacuum, fitted with manometer, thermometer deep stick, high speed stirrer, kettle to be emptied through a discharge pipe going upto the bottom of the kettle; no outlet at the bottom or at the side. Working capacity - 100 lit for making solution. | Two |
| (7) | Round bottom glass flask fitted with stainless steel lid, suitable for applying vacuum or pressure for sucking in or pressing out solution from the flask. Flask is protected with a cylindrical stainless steel casing, mounted on wheels. Capacity 25 lit, for transporting solution. | Four |
| (8) | Spare flasks for No. 7 | Four |

Equipment for Injectables (Cont'd)

Number required

- | | | |
|------|--|--------|
| (9) | Milipore filter unit
316 mm diameter, for sterile
filtration of solution | |
| (10) | Lamps
for visual inspection of filled
ampoules | Twelve |
| (11) | Weighing machine
dial type, capacity 50 kg. | One |

Equipment for packaging injectables and
Ophthalmic drop solution

- | | | |
|-----|---|-------|
| (1) | Inprinting machine for ampoules
for ampoule size 1 ml to ml capacity
3000 ampoules/hour | Three |
| (2) | Semi automatic liquid filling machine
capacity 2000 vials/hour
for filling 10 ml vials. | One |
| (3) | Semi automatic capping machine
for closing vials of ophthalmic
drop solution. | One |

Equipment for Infusions

Basic Equipment

- 1 Air compressor 120 m³/h. ; complete with air cooler and tank of 1600 L. capacity. Automatic regulation.
- 1 Water overcharger 5.5 CV. ; 4 m³/h.
- 1 Steam generator complete with feeding tank ; 150 kg./h. Automatic regulation.
- 1 Dosing pump for the steam generator
- 1 Set of piping valves and fittings for the steam generator
- 1 Steam manifold with inlet-outlet valves and manometer
- 1 Set of connecting pieces and fittings for the section

Preparation of water for injection

- 1 Scavenger filter ; max. output : 2.0 m³/h.
- 2 Water softeners ; max. output : 3 m³/h.
- 1 Deioniser plant - double columns - Max. output : 3 m³/h.
- 1 Switchboard for the deioniser plant with control instruments
- 1 Neutralizer 3 m³/h.
- 1 Thermocompression water-still - 100 L./h.
- 1 Storage tank for distilled water ; 1500 L. capacity
- 50m. stainless steel connecting pipe 1"
- 7 Stainless steel water-gates
- 1 Transfer pump ; 50 L./minute
- 1 Air compressor with 60 L. tank capacity - Pressure : 6 kg./cm²
- 1 Set of connecting pieces, fittings and miscellaneous for the section

Preparation of Solutions

- 1 Scale for raw materials ; 0-200 kg.
- 1 Vat for the preparation of solutions ; stainless steel ; 1500 L. capacity
- 1 Electric stirrer with stainless steel propeller

- 1 Filtration unit and transfer pump and filter holder in stainless steel
- 50m. stainless steel connecting pipe ; 1"
- 5 Stainless steel water-gates integral passage
- 1 Portable pH-meter
- 1 Electrode for the pH-meter
- 1 Set of connecting pieces for the section

Filling of the Bags

- 1 Washing machine for the stoppers
- 2 Composing sticks for batch numbering
- 2 VIFOR's volumetric filling units
- 5 Stainless steel water-gates ; integral passage
- 1 Scale to check the FLEX-FLAC weight ; 0-5 kg.
- 2 Conveyor belts adapted to the filling section
- 1 Filter holder for the stoppers washing machine
- 1 Plastic vat 150 L. for the stoppers washing machine
- 1 Set of connecting pieces and miscellaneous for the section

Sterilization of the Bags

- 5 Sets of carriages and trays for filled bags
- 1 Square autoclave ; VIFOR's specific model
- 1 Set of steam valves, steam reducers, steam traps, manometers, thermometers, safety discharge valves, etc... for the autoclaves
- 1 Equipment for automatic VIFOR's sterilization process and control with temperature recorder for the sterilization cycle
- 1 Set of connecting pieces for the section

Control Sections

- 1 Polarimeter complete
- 1 Spare sodium lamp for polarimeter
- 2 Observation tubes ; 200 mm.
- 2 Observation tubes ; 100 mm.
- 1 Flame photometer
- 1 Titrimetric equipment

- 1 Laboratory pH-meter
- 1 Spare electrode for the pH-meter
- 1 Analytical scale
- 1 Vacuum drying stove
- 1 Incubator
- 1 Electric stove
- 2 Vacuum pumps for laboratories
- 1 Polarized lamp
- 1 Temperature monitor with recorder
- 9 Monitor gauges for rabbits
- 9 Rabbits holders
- 4 Rabbits cages in stainless steel of 9 rabbits each
- 1 Bacteriological kit for sterility tests
- 1 Laminar-flow bench
- 1 Scale for rabbits
- 1 Set of connecting pieces for the section

Packaging

- 2 Impulse sealing machines
- 1 Packaging table with conveyor belt
- 2 Polarized lamps
- 1 Manual fork lift
- 1 Complete bag with tools and measuring instruments
- 1 Set of connecting pieces for the section

COST OF A MULTIPURPOSE PLANT

Annual Capacity - 240 tons of 15 synthetic drugs

<u>PARTICULARS</u>	<u>COST</u> <u>US \$</u>
Building	500,000
Equipment (including installation) (Detailed list enclosed)	1,200,000
Instruments	200,000
Spare parts	100,000
International experts Training)	500,000
<u>TOTAL</u>	<u>US\$ 2,500,000</u>

LIST OF PROCESS EQUIPMENT

	<u>ITEM</u>	<u>QUANTITY</u>
1.	500 L Glass-lined Reactor, jacketted with anchor agitator, condenser/receiver	2
2.	500 L Glass-lined Reactor, jacketted, with anchor agitator	1
3.	600 L SS Reactor, jacketted, with agitator, condenser/receiver	3
4.	600 L SS Reactor, jacketted with agitator	1
5.	150 L High Vacuum, SS Distillation unit	1
6.	160 LPH MS Alcohol fractionation still	1
7.	2500 L MS rubber-lined Crystalliser with Stirrer	1
8.	2000 L SS Crystalliser, jacketted with Stirrer	1
9.	300 L MS rubber-lined vessel with stirrer	1
10.	1000 mm. MS rubber-lined Basket Centrifuge	2
11.	800 mm. SS Basket Centrifuge	1
12.	300 L MS rubber-lined filter-box with receiver	1
13.	SS Pressure-leaf filters (capacity: 10 kg.solids filtration)	2
14.	Steam-heated tray-dryer (Drying rate: 3 kg/hr. of water)	3
15.	Steam-heated vacuum dryer (Drying rate: 1 kg/hr. of water)	1
16.	Water-ring Vacuum Pump-sets (700 mm Hg)	4
17.	High Vacuum Pump-set (750 mm Hg)	1
18.	SS Pump-sets: i) 50 LPM - 10 M	2
	ii) 20 LPM - 25 M	1

19.	MS rubber-lined Pump-sets 50 LPM - 10 M	2
20.	200 L Glass Reactor assemble with necessary ancillaries	1
21.	SS Pulverizer (25kg/hr.)	1
22.	SS Blender (25 kg Batch)	1
23.	Ion Exchange Resin Column SS, (0.5 M Dia x 2.0 M Ht. approx.) c	1

LIST OF SERVICES EQUIPMENT

1.	750 Kg/Hr Steam boiler	1
2.	3.0 M ³ /Hr. DM Water Plant	1
3.	3.5M ³ /Hr. DA Water Plant	1
4.	10 TR Brine Chilling Plant	1
5.	30 TR Chilled Water Plant	1
6.	200 T 2-Cell Cooling Tower (400 IGPM-9 ⁰ F drop - 5 ⁰ F approach)	1
7.	400 IGPM x 25 M Water Pump-sets	2
8.	Air Compressor - 30 cfm x 150 psi	2
9.	400 KVA Electrical Distribution Panel	1

ANNEX IV(a)

COST OF EXPANSION OF EXISTING UNIT FOR PRODUCTION OF
EXTRACT FROM MEDICINAL PLANTS

<u>PARTICULARS</u>	<u>COST</u> <u>US \$</u>
Equipment (Detailed list enclosed)	207,000
International experts	100,000
Training	24,000
Miscellaneous	19,000
	<hr/>
<u>TOTAL</u>	<u>US\$ 350,000</u>
	<hr/> <hr/>

Equipment for botany section

Equipment needed for general collection:
(Axes, machetes, secators, binoculars,
pocket lenses, rifle with lens etc.)

Equipment for the drying of specimens:
(Undulated alaminion sheets, gas heater,
metallic press etc.)

For the collection trips:
Toyota landcruiser

Equipment for pharmacology section

Equipment for general pharmacology:
4-channel polygraph with different adapters
Operating table
Surgical instruments
Glassware

Equipment for experiment with isolated organs:
Polygraph with 1 recorder
Strain-gage with different sensitivity range
Organbath with regulator for constant temperature
Surgical instruments
Glassware

Equipment for weighing:
Analytical balance
Balance 1-200 g (Sartorius)
Balance 1-5 kg

Equipment for pharmacological screening
Observation rinks, thermometers, etc.

Equipment for phytochemistry section

Glassware
Soxlet extractors in glass up to 20 liters
Balances
Compressor
Vacuum pumps
Ice Machine
Rotavapors
Fraction collectors
Amermill for laboratory
Stainless steel extraction plan endowed with two multipurpose
extractors (capacity about 100 liters), pumps, solvent containers,
solvent concentrators, faucets
Heating and cooling reactor, concentrator (150 liters) with suitable
stainless steel refrigerator
Pilot scale centrifuge

ANNEX IV(b)

COST OF MULTIPURPOSE PLANT FOR MEDICINAL PLANTS

Daily Capacity - one ton of material per day

<u>PARTICULARS</u>	<u>COST</u> <u>US \$</u>
Building	150,000
Equipment and Machinery (Detailed list attached)	300,000
International experts	180,000
Training	50,000
	<hr/>
<u>TOTAL</u>	US\$ 680,000
	<hr/> <hr/>

Equipment for multipurpose plant for medicinal plants

<u>Item</u>	<u>Capacity</u>	<u>Number required</u>
<u>Process equipment</u>		
Weighing balance		1
Hammer mill with sieving arrangement	100 kg/h	1
Percolator, stainless steel	1 500 l	5
Circulation pump, stainless steel, head 10 m	500 l/h	8
Storage tank, stainless steel	3 000 l	1
Concentrator, stainless steel, jacketed with agitator	500 l	2
Shell-and-tube heat exchanger, stainless steel, surface area 2 m ²	250 l	2
Receiver, stainless steel		1
Solvent recovery plant		1
Filter		1
Dryer		1
<u>Service equipment</u>		
Boiler, pressure 10 bar	300 kg/h	1
Vacuum pump, water-ring type, vacuum up to 0.06 bar	80 m ³ /h	2
Chilled-water circulation unit	20 t	1
<u>Analytical instruments</u>		
pH meter		1
Thin-layer chromatography equipment with ultraviolet lamp		1
Spectrophotometer, ultraviolet		1
Centrifuge, laboratory model		1
Soxhlet apparatus with bath		1
Vacuum pump, oil		1
Vacuum oven and muffle furnace		1
Microscope		1

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATIONPROJECT DOCUMENT

TITLE: Pharmaceutical Industry Development Centre

PROJECT NUMBER:

DURATION: Five years

PRIMARY FUNCTION: Institution Building

SECONDARY FUNCTION: Direct Support

SECTOR: UNDP class and Code 35 Industry

SUB-SECTOR: Pharmaceuticals
UNDP class and Code 3520 Industrial Services and Institutions

GOVERNMENT IMPLEMENTING AGENCY: _____

EXECUTING AGENCY: United Nations Industrial Development Organization (UNIDO)

ESTIMATED STARTING DATE: January 1980

GOVERNMENT INPUTS: _____ **UNDP INPUTS:** US\$ 1,506,000

GOVERNMENT COST SHARING (IF ANY): _____
(US dollars or other freely available currency)

SIGNED:_____
On behalf of the GovernmentDATE: __________
On behalf of the Executing AgencyDATE: __________
On behalf of the United Nations Development ProgrammeDATE: _____

PART I - LEGAL CONTEXT

The project document shall be the instrument (herein referred to as plan of operation) envisaged in the agreement between the Government of developing country and the United Nations Development programme.

PART II(A) - DEVELOPMENT OBJECTIVE

The development objectives of the project are to improve the operational efficiency of the local Pharmaceutical Industry and to provide a reliable basis for sharing the experience with the pharmaceutical industry in the other developing countries in the region

with a view to remove the wide gap between demand and indigenous production of life saving drugs which is presently being met through imports causing a drain on the meagre foreign exchange resources of some of these countries.

PART II(B) - IMMEDIATE OBJECTIVE

The immediate objective of the project is to establish a pharmaceutical Industry Development centre within the country to serve the Pharmaceutical Industry in the region by providing facilities for :

- (i) Expansion, modernization of the existing units as well as planning of new units
- (ii) Study of operational problems in production of pharmaceuticals and quality control
- (iii) Systemization of methods and techniques of operating the pharmaceutical plants; and

(iv) Manpower and technical skill development by organizing training courses / seminars in the following specific areas :

- (a) Production of synthetic drugs; antibiotics and phytochemicals
- (b) Formulation and infusion
- (c) Safety and quality control
- (d) Plant maintenance
- (e) Packaging
- (f) Marketing and distribution.

PART II(C) - SPECIAL CONSIDERATION

With the growing importance of health care as an integral aspect of economic development, there is an increasing realization among the countries in the region of the need to establish their own pharmaceutical industry to meet their requirements of drugs and pharmaceuticals. While some of the countries made a modest beginning in this direction, the majority of them, however, continue to depend on import of the drugs and pharmaceuticals to meet their requirements. The proposed centre would enable the countries to share their experiences and would thus promote technical co-operation and transfer of technology in the field of drugs and pharmaceuticals among themselves for their mutual benefits. There is a genuine interest of the countries involved in setting up a pharmaceutical centre in the region which may ultimately assist in creating nuclei for research and development in their own countries.

TABLE II

PROJECT BUDGET COVERING UNIDO CONTRIBUTION

	TOTAL COST		1980		1981		1982		1983		1984	
	m/m	US \$ '000	m/m	US \$ '000	m/m	US \$ '000	m/m	US \$ '000	m/m	US \$ '000	m/m	US \$ '000
10. <u>Project Personnel</u>												
11. Experts	54	243	6	27	15	67.5	15	67.5	15	67.5	3	13.5
13. Mission cost	.	7		1		2		1		2		1
19. Component sub-total	54	250	6	28	15	69.5	15	68.5	15	69.5	3	14.5
30. <u>Training</u>												
31. Fellowship	50	75	5	7.5	10	15	10	15	10	15	15	22.5
32. Study Tour	40	80	5	10	10	20	10	20	10	20	5	10
39. Component sub-total	90	155	10	17.5	20	35	20	35	20	35	20	32.5
40. <u>Equipment</u>												
42. Non-expendable		1063		625		438		-		-		-
49. Component sub-total		1063		625		438		-		-		-
59. Miscellaneous		38		9		7		7		7		8
99. GRAND TOTAL	-	1506		679.5		549.5		100.5		111.5		55

Details of UNDP Input - Equipment

Item

1. Equipment for Pilot Plants
 - (a) Antibiotics
(Details in Appendix A)
 - (b) Synthetic Drugs
(Details in Appendix B)
 - (c) Phyto-chemicals
(Details in Appendix C)
 - (d) Formulations
(Details in Appendix D)
 - (e) Process Control Laboratory
(Details in Appendix E)

Equipment for Pilot Plant for Antibiotics

Sl. No.	Equipment	Specification
1.	Systronic or Klett	For general use for taking O.D. of different solutions.
2.	Filter press-polypropylene	Total area $2 M^2$ with roughly 5 plates.
3.	Basket type continuous discharge centrifuge.	Roughly to be handle 4-5 kg. of wet material.
4.	Autoclave	Capacity 50 Lts. roughly with automatic temperature and pressure control. This will be utilized for sterilization of 5 Lt. and 14 Lt. fermenters also.
5.	Glass column	To run as fluid bed with flexibility of varying L:D Ratio roughly 4" and height up to 3-4 ft.
6.	Reaction vessels Nos. 3	Glass with 10 Lt. Cap. provided with variable speed agitator.
7.	Filter Press Stainless steel	Roughly $2 M^2$ area.
8.	Counter-current Extractor separator	To have flow rate of both steam varying between 3-10 Lts./Hr.
9.	Sharples Centrifuge	To process 3-5 Lts./Hr. of material.

Equipment for Pilot Plant for Antibiotics

Sl.No.	Equipment	Specification
1.	5 Lt. Jar Fermenter glass fully automatic Nos. 2.	Magnetic drive 0-200 r.p.m. or Foam automatic control pH-automatic control within + 0.1 D.O. - monitoring Redox monitoring covering range - range - 500 to + 500 mv. Provision to run as chemistat. Autoclave sterilizable.
2.	14 Lt. Jar Fermenter glass, fully automatic Nos. 2	Same as 5 Lt except drive could be magnetic or motor with mech. seal provision.
3.	50 Lt. fully automatic bottom drive fermenter with effigas system provision and mechanical foam breaker Nos. 1	a) Stirrer r.p.m. b) pH Control with peripumps to feed c) D.O. control through air flow rate monitoring d) Provision for Redox measurement. e) Power input monitoring. f) Compatibility of all instruments to computer control.
4.	Gas analyser for O ₂ and CO ₂ in inlet and outlet air O ₂ - paramagnetic type CO ₂ - I.R. analyser.	O ₂ - Range 0-20% CO ₂ - 0-5%
5.	Autoanalyser.	With Cartridge provision for N-NH ₂ determination.
6.	Freeze dryer.	Temp. upto - 60°C. Vacuum upto = 1 u capacity - 5 Lts. of liquid.
7.	Spray dryer	2-3 Lts/Hr. charging capacity with complete hot air supply system and cyclone separator etc.
8.	Shaker to put around 300 flask at a time.	a) 1" to 2.5" stroke b) R.P.M. 100-300 c) With Temp. control d) Duty timers e) Flow pump f) Rocks changeable.

Sl. No.	Equipment	Specification
9.	Microscope with different attachments like camera for taking slide photographs etc.	Magnification 3000 maximum.
10.	Refrigerated Centrifuge of 40,000 r.p.m. for high volume centrifugation.	Sovall type

Equipment for Pilot Plant for Synthetic Drugs

Sl. No.	Description of the Item	Qty. (Nos.)
<u>I. SULFONATION/CHLOROSULPHONATION UNIT:</u>		
1.	Reactor, cap. 100 lts., St. Gl., anchor type Agitator, bottom discharge, Working pressure in shell and jacket 3 kgs/cm ² , explosion proof motor.	1
2.	Measuring tank, cap. 50 lts., St. Gl., built in klinger, bottom discharge.	1
3.	Heat exchanger, Bell type, Aht = 1 M ² , material of construction St. Gl.	1
4.	Receiver, cap. 50 lts., St. Gl.	1
5.	Absorption column, PVC, ϕ = 300 mm, H = 4000 mm.	1
6.	Decomposer, cap. 250 lts., St. Gl. bottom discharge, working pressure in shell and jacket 3 kgs/cm ² , Anchor type Agitator, suitable explosion proof motor.	1
7.	Centrifuge, material of construction Steel/Rubber lined, ϕ = 600 mm, top discharge, explosion proof motor.	1
8.	Amidator, cap 250 lts., S. St-316, Propeller type of stirrer, working pressure in jacket and shell 6 kgs/cm ² , explosion proof motor.	1
9.	Measuring tank, cap. 100 lts., S.St-316 bottom discharge, with level indicator.	1
10.	Pressure filter, S.St., ϕ = 600 mm jacketed.	1
11.	Receiver, cap. 100 lts., S.St-316, bottom discharge, with level indicator.	1
12.	Centrifuge, S.St-316, ϕ = 600 mm top discharges explosion proof motor.	1
<u>II. NITRATION UNIT:</u>		
1.	Reactor, cap. 100 lts., S.St-316 bottom outlet, jacketed, working pressure inside shell and jacket 3 kgs/cm ² , explosion proof motor, Turbine type stirrer.	1

Sl. No.	Description of the Item	Qty. (Nos.)
2.	Measuring tank, cap. 250 lts., St.Gl., Anchor type agitator, bottom discharge, jacketed, working pressure in the shell and jacket 3 kgs/cm ² , explosion proof motor.	1
3.	Crystalliser, cap. 250 lts., St. Gl., Anchor type agitator, bottom discharge, jacketed, working pressure in the shell and jacket 3 kgs/cm ² , explosion proof motor.	1
4.	Absorption column, S.St-316, Ø = 250 mm H = 3 meters, packed with rasching rings, and sieve plate.	1
5.	Measuring tank, cap. 50 lts., S.St-316, bottom discharge, with level indicator.	1
<u>III.</u>	<u>HALOGENATION UNIT:</u>	
1.	Reactor, cap. 100 lts., St. Gl., Propeller type agitator, jacketed, working pressure inside shell and jacket 6 kgs/cm ² , explosion proof motor bottom outlet.	1
2.	Evaporator, jacketed, cap. 100 lts., working pressure inside shell and jacket 3 kg/cm ² , steel, Ø = 450 mm, H = 2000 mm.	
3.	Receiver, steel, cap. 50 lts., bottom discharge. (Trap).	1
4.	Measuring tank, cap. 50 lts., bottom discharge, with level indicator, S.St. - 316.	1
5.	Heat exchanger, Aht = 1M ² , St.Gl., bell type.	1
6.	Column, Ø = 250 mm., r = 1500 mm. St. Gl.	1
<u>IV.</u>	<u>CYANIDATION UNIT:</u>	
1.	Reactor, cap. 100 lts., S.St-316/304, jacketed, turbine type agitator, Blow-over pipe, working pressure inside shell and jacket 6 kgs/cm ² .	1

Sl. No.	Description of the Item	Qty. (Nos.)
2.	Heat exchanger, S.St-316/304, Aht = 1M ² , shell and tube.	1
3.	Measuring tank, cap. 50 lts., S.St.-316/304, bottom discharge, with level indicator.	1
4.	Receiver, cap. 100 lts., S.St-316/304, bottom discharge, with level indicator.	1
5.	Crystalliser, cap. 250 lts., St.Gl., jacketed, Anchor type agitator, bottom outlet, explosion proof motor.	1
6.	Absorption column, S.St-361, ϕ = 250 mm, H = 4 metres.	1
7.	Holding tank, cap. 50 lts., Steel bottom outlet.	1
<u>V.</u>	<u>SODIUM HANDLING EQUIPMENT WITH KEROSENE CIRCULATION SYSTEM:</u>	
1.	Holding tank, steel, cap. 250 lts., with level indicator.	2
2.	Kerosene storage tank, cap. 500 lts., steel, with level indicator.	1
3.	Heat exchanger, Aht = 2M ² , steel, shell and tube type.	2
4.	Vortex pump, cap. 2-3M ³ /Hr., explosion proof motor.	2
5.	Separator/expansion tank, cap. 50 lts., with level indicator.	2
6.	Reactor, S.St-316, cap. 100 lts., blow over pipe, jacketed, turbine type stirrer, explosion proof motor, working pressure in shell and jacket 3 kgs/cm ² .	1
7.	Measuring tank, jacketed, cap. 50 lts. bottom outlet, with level indicator, S.St-316.	1
8.	Heat exchanger, Aht = 1M ² , S.St., shell and tube type.	1
9.	Receiver, cap. 100 lts., S.St-316 bottom outlet, with level indicator.	1
10.	Air-conditioning equipment.	1

Sl. No.	Description of the Item	Qty. (Nos.)
<u>VI. HYDROGENATION UNIT:</u>		
1.	Autoclave, cap. 100 lts., S.St-316 jacket, pressure 10 kgs/cm ² , inside pressure 100 kgs/cm ² , suction type stirrer, blow over pipe, explosion proof motor, with mechanical seal (Imported.)	1
<u>VII. MULTIPURPOSE REACTION UNITS (S.S.):</u>		
1.	Reactor, S.St-316, cap. 100 lts., jacketed bottom outlet, working pressure inside and jacket 6 kgs/cm ² , with the following agitators :	
	a) Anchor type agitator	1
	b) Propeller type agitator	1
	c) Turbine type agitator and each with explosion proof motor.	1
2.	Pressure filter, jacketed $\phi = 600$ mm S.St-316.	2
3.	Heat exchanger, Aht = 1M ² , shell & tube, S.St-316.	2
4.	Crystalliser, cap. 250 lts., St.Gl, Anchor type Agitator, bottom outlet, jacketed, explosion proof motor.	2
<u>VIII. MULTIPURPOSE REACTION UNIT (GLASS-LINED):</u>		
1.	Reactor, cap. 100 lts., jacketed, propeller Agitator, bottom discharge, explosion proof motor, jacket pressure 6 kgs/cm ² , St.Gl.	1
2.	Heat exchanger, bell type, Aht - 1M ² , St.Gl.	1
3.	Receiver, cap. 100 lts., St.Gl.with level indicator.	1
4.	Pressure filter, jacketed, $\phi = 800$ mm, St. Gl.	1
5.	Crystalliser, cap. 250 lts., Anchor type Agitator, bottom outlet, jacketed with explosion proof motor.	1
6.	Vacuum pump, water ring, cap. = 3M ³ / min. explosion proof motor.	2

Sl. No.	Description of the Item	Qty. (Nos.)
7.	Deep vaccum pump, cap. 200 M ³ /Hr. explosion proof motor.	1
8.	Ejector, four-stage, 1) cap. 10 kg/Hr., 2) 5 kg/Hr., Steel.	2
9.	Air circulation drier, material of construction S.St., cap 4 M ² .	1
10.	Fludised bed drier, cap. 10 kg/Hr., material of construction 3.St.	1
11.	Vaccum Tray drier, with internal coils of steam, cap. Aht = 4 M ² , S.St. Trays.	1
12.	Multi-mill, cap. 20 kg/Hr. material of construction S.St., explosion proof motor.	1
13.	Ball mill, porcelain, cap. 10 kgs., explosion proof motor.	1
14.	Nutsch filters, porcelain, cap. 50 lts.	2
15.	Open crystalliser, jacketed, cap. 250 lts., St. Gl., Anchor type Agitator, explosion proof motor, jacket pressure 3 kgs/cm ²	1
16.	Open crystalliser, jacketed, cap. 100 lts., S. St-316, explosion proof motor, jacket pressure 3 kgs/cm ² , Anchor type stirrer.	1

Equipment for Pilot Plant for Phytochemicals

S.No.	Description of the Item	Qty.(Nos.)
1.	Cutter/Chipper, cap. 20 kgs/Hr., Steel	1
2.	Disintegrator, cap. 20 kgs/Hr., steel	1
3.	Sieve shaker	1
4.	Digester, cap. 500 lts., S.St-316 bottom discharge, gate type stirrer	1
5.	Rotary filter, cap. $4M^2$, material construction steel	1
6.	Neutraliser, cap. 500 lts., S.St-316 Anchor type Agitator	1
7.	Extractor/Separator, conical with pumps, cap. 1000 lts., S.St-316, Anchor type stirrer	1
8.	Distillation unit, cap. 500 lts., S.St-316, jacketed, jacket pressure 6 kgs/cm^2 , including heat exchanger and receiver	1
9.	Forced circulation evaporator, cap. $4M^2$, S.St.-316.	1
10.	Plate and frame type pressure filter, cap. $4M^2$, S.St-316.	1
11.	Air circulation drier, Aht = $10M^2$, S.St-Trays	1
12.	Wiped-Film evaporator, Aht = $1M^2$, S.St.	1

List of Equipment for Formulations

SI. No.	Description with specifications
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TABLET SECTION:

1. Laboratory Kneader
2. Wet granulator
3. Dry granulator
4. Tablet abrasion tester
5. Tablet friability tester
6. Granule flow tester
7. Accela cota Pan - with spray coating device
- 5 to 10 kg. capacity
8. Ball mill - with 3 kg. capacity

OINTMENTS SECTION:

1. Ointment filling machine - $\frac{1}{2}$ Lt.
2. Crimping and printing machine
3. Ointment diffusion testing equipment
4. Triple roller mill 5 kg/hr.

LIQUIDS SECTION:

1. Zetameter

INJECTABLES SECTION:

1. Membrane filters 14 cm.
2. Mettler Balance

PACKING AND PACKAGING:

1. Thickness tester (Dial guage)

List of Equipment for Formulations

Sl. No. Description with specifications

TABLET SECTION:

1. Twin-shell blender 3 to 10 kg. capacity
2. Double cone blender - do -
3. Tray drier - 12 Al. trays, electrically operated with temp. control - 20 to 30 kg. capacity
4. Fluid bed drier - 5 kg. capacity
5. Tableting machine - Single punch machine with different sizes of punches and dies
6. Rotary Tableting machine - 16 station with different sizes of punches and dies
7. I.P./B.P. Disintegration testing machine
8. Dissolution testing apparatus
9. Hardness tester
10. Sieve analysis equipment - with various sieve sizes 10 to 120 mounted on a motor driven vibrating disc.
11. Coating pans
12. Worster type air suspension coating equipment - 1 to 5 kg. capacity
13. S.S. jacketted syrup making pans with stirrer mounted - 5 to 10 Lts. capacity
14. Laboratory stirrer with variable speed
15. Homogenizer, Lab. type with variable speed - 5 Lts. capacity
16. Mixer-cum-Grinder
17. Planetary mixer - 5 to 20 kg capacity
18. Vacuum drier
19. Strippacking machine - Bench type
20. Tin seaming machine

Sl. No.	Description with specifications
21.	Portable platform scale balance - upto 100 kg.
22.	Dial scale - upto 5kg. 100 gm. divisions
23.	Double Pan Balance - to weigh upto 100 gm. with an accuracy of 10 mg.
24.	Spray drying equipment
25.	Freeze drying equipment
26.	Poly. bag sealer - 'Sparkman type' - single line sealing for poly. bags of 100 to 1000 guage both for HDP and LDP, to operate on 230 volts., single phase A.C. supply
27.	Hammer mill - pilot scale model
28.	Punch polishing kit

OINTMENTS SECTION:

1. Steam jacketted S.S. Vessels, - 5 Lts. Cap. with a mounted stirrer with Gate type impeller
2. Homogenizer with jacketted arrangement
3. Triple roller mill - 5 kg/hr.

CAPSULES SECTION:

1. Hand filling capsule machine with interchangeable parts for sizes, 00, 0, 1, 2, 3, 4, 5-200 holes
2. Planetary mixer of 5 kg. capacity
3. Vibrating sifter with 10, 20, 40, 60 and 80 meshes

LIQUIDS SECTION:

1. S.S. jacketted vessel - 15 lts. capacity with a mounted stirrer
2. S.S. vessels with hinged lids - 2 Lts., 5 lts., and 10 lts. capacities
3. Liquid filling machine - single stroke - volumetric filling, with 15 to 450 ml. capacity
4. Bottle PP Capping machine for various nock sizes - hand operated
5. Optical checking equipment

Sl. No.	Description with specifications
6.	Ultrasonic bottle washing machine
7.	Bottle drying oven
8.	Hoppler viscometer
9.	Mechanical Laboratory stirrer with variable speed.

INJECTABLES SECTION:

1.	Pressure filtration vessel 5 Lts. capacity with a pressure gauge
2.	Membrans filter holder - 19 cm. dia.
3.	S.S. Seamless vessel with air tight cap and with an inlet and airvent 5Lts. capacity
4.	Semi automatic ampoule sealing machine (table model)
5.	Semi automatic ampoule filling machine (table model)
6.	Single stroke ampoule and vial washing machine
7.	Dry heat sterilizer, temperature range 50 to 300°C with regulator
8.	Autoclave horizontal with downward air displacement, electrically/steam operated - 10 Lts. capacity
9.	S.S. jacketted vessel - 10 Lts.
10.	Ampoule and vial holding trays
11.	Laboratory stirrer with variable speed
12.	pH meter digital
13.	Pyrogen free distillation unit 5 Lts./hour
14.	Deionizer
15.	Sintered glass funnels G2, G3, G4, and G5 filters of 500 ml. capacity
16.	Buchner flasks - 1 Lt, 2 Lts, 3 Lts, capacity
17.	Buchner porcelain funnels

<u>Sl. No.</u>	<u>Description with specification</u>
18.	Vial capping machine (table model)
19.	Vaccum pumps - Double stage rotary vane type with 100 Lts./mt. of air displacement capacity, with 1/2 HP motor
20.	Visual Inspection equipment
21.	Photo Electric colourimeter

PACKING AND PACKAGING:

1. Bursting Strength Tester - Hand operated
2. One pan Balance
3. Vernier Calipers
4. Puncture resistance tester
5. Substance indicator for paper and paper boards
6. Water vapour transmission testing equipment

GENERAL EQUIPMENT:

1. Ovens with temperature regulators
2. Humidity chamber with temperature control
3. Photosensitivity testing equipment

APPENDIX E

List of Equipment for Process Control Laboratory

Sl. No.	Description of the Item	Qty.(Nos)
1.	PH-Meter	2
2.	pH-Meter, digital, Accuracy 0-01 pH	1
3.	Hot air oven upto 200°C, size 16" x 18"	2
4.	Melting point and boiling point apparatus	1
5.	Water bath-Thermostatic	1
6.	Oil bath-Thermostatic	1
7.	Water bath, cap. 1 K.W.	4
8.	Lab. stirrer	6
9.	Rotary film evaporator	1
10.	Muffle Furnace	1
11.	Digital flame photometer	1
12.	IR Moisture Balance	1
13.	Vacuum drier, electrically heated	1
14.	High vacuum pumps, 0.5 mm Hg. residual pressure	2
15.	Refrigerator, cap. 250 lts.	1

List of Equipment for Process Control Laboratory

Sl.No.	Description of the Item	Qty.(Nos.)
1.	Gas chromatograph (Imported) with TCD, FID , and ECD	1
2.	IR Spectrophotometer (M/s. Perkin-Elmer)	1
3.	Mettler monopan balance, cap. 100 gms.	1
4.	Mettler top pan balance, cap. 1 kg.	1
5.	Mettler top pan balance, cap, 5 kgs.	1
6.	UV Spectrophotometer, Beckman, Scanning model	1
7.	Autoclave, cap. 5 lts., pressure 100 kgs/cm ² , S.St. electrically heated	1
8.	Autoclave, cap. 2 lts., pressure 100 kgs/cm ² , S.St., electrically heated	1
9.	UV-Visible Spectrophotometer, Spectronic - 20	1
10.	Beckman Aquameter, KF-4	1
11.	Automatic Titrators	1

