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14766

DP/ID/SER.A/600 5 June 1985 English

Iran. Pharmacoutical chemicals.

TRANSFER OF TECHNOLOGY THROUGH THE ESTABLISHMENT OF A MULTI-PURPOSE PILOT PLANT.

DP/IRA/83/014

IRAN

Technical report: transfer of technology*.

Prepared for the Government of Iran

by the United Nations Industrial Development Organization,

acting as executing agency for the United Nations Development Programme

Based on the work of M.B. Bhate, pharmaceutical industry adviser

United Nations Industrial Development Organization
Vienna

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EXPLANATORY NOTES

General:

Value of currency: 1 US\$ - Rials 86.5 (April, 1984)

Organizations:

Alhavi A Government owned Pharmaceutical Formulation Unit under
The Ministry of Industries, Iran

Darupakhsh A Government owned Pharmaceutical Formulation Unit under

The Ministry of Health, Iran

N.I.O. National Industries Organization under the Ministry of Industries, Iran

Toobi A Government owned manufacturing unit for Inorganic Chemicals under the Ministry of Industries, Iran

U.N.D.P. United Nations Development Programme

 $\underline{\text{U.N.I.D.O.}}$ United Nations Industrial Development Organization

W.H.O. World Health Organization

Acknowledgements:

The writer wishes to express his deep appreciation for the assistance and information received from the concerned organizations, especially from Darupakhsh, N.I.O., Toobi, U... D.P., and U.N.I.D.O., which is hereby gratefully acknowledged.

Summary:

In accordance with the decision of the Government of the Islamic Republic of Iran, to achieve self-sufficiency with respect to pharmaceutical chemicals and since there are no facilities for the manufacture of pharmaceutical chemicals in the country, the only choice to achieve the Government objectives is to establish a pharmaceutical chemical pilot plant for the following reasons.

- Technologies for the production of pharmaceutical chemicals are not available in the country,
- 2. No facilities are available within the country to adopt technologies even if they are acquired.
- Skilled manpower to undertake manufacture of pharmaceutical chemicals is not available.
- 4. The present policy of the Government does not permit the setting up of subsidiaries by foreign companies.
- 5. The production of the pharmaceutical chemicals has to be undertaken by the State.

The only way to achieve the objective is, therefore, to acquire the missing links with UNDP assistance.

For this purpose a scheme for establishing a multipurpose pilot plant is being proposed. Such a scheme will provide:

- a) The necessary equipment to produce pharmaceutical chemicals needed for the formulations.
- b) Acquisition of suitable manufacturing technologies from the leading contractors in the world.
- c) A full fledged training programme off the job outside the country and on the job in the pilot plant.
- d) Experience, skill and confidence required for such manufacturing activities.

Introduction:

The Government of the Islamic Republic of Iran in their efforts to become self-sufficient in the pharmaceutical industries sector approached UNDP for assistance in the establishment of a pilot plant for the production of pharmaceutical chemicals. However, it was found necessary to investigate the pilot nature of the above project to introduce new technologies in terms of products, techno-economic feasibility with reference to qualified staff, raw materials and market. For this purpose, Mr. M. Bhate, UNIDO consultant, had been delegated to Iran.

Simplification and rationalization of production of pharmaceutical products is an absolute necessity for a public health programme. This calls for the production of generic drugs. In response to this the Government has already adopted a totally generic base approach. It is now the intention of the Government to produce, in the long run, as many pharmaceutical chemicals, listed, within the country as would be possible. With this intention the Government hopes to achieve:

- 1. Self-sufficiency with respect to the pharmaceutical chemicals required for their pharmaceutical industries.
- 2. To give a philip to their intended manufacturing activities in the country.

Pharmaceutical formulation is the only prevailing activity in the field of drugs. All raw materials in terms of bulk drugs are imported at present.

The lack of manufacturing activity for the production of pharmaceutical chemicals is, therefore, the principal bottleneck to self-sufficiency. There is also a critical shortage of trained manpower in managerial, administration, production engineering, etc.

According to the Government policy it is not possible to start these activities by:

- 1. Setting up turn-key ventures by foreign companies, and
- 2. Establishing joint ventures with such companies.

It is also not possible to start a manufacturing programme because of lack of technologies, experience and expertise needed by such a programme. The only way, therefore, is to acquire the above-mentioned requirements with UNDP assistance.

Justifications and Recommendations

As mentioned in the body of the report, Iran, like any other developing country, depends heavily on the imports of pharmaceutical chemicals required by the formulating industries. In order to be self-sufficient in this respect, the country has to set up manufacturing activities for the pharmaceutical chemicals, but this cannot be done because of lack of technology.

There are manufacturing activities on a large-scale for the production of some heavy chemicals and petroleum products. However, there is absolutely no manufacturing programme for pharmaceutical chemicals. It cannot be argued that because manufacturing experience and ability to produce these heavy chemicals is available, the same experience and skill is sufficient to start manufacturing activities for pharmaceutical chemicals. There is a basic difference in the manufacturing activities of heavy chemicals and pharmaceutical chemicals. This lies in the fact that whereas the pharmaceutical chemical industries have to deal with the manufacture of basic drugs, which are ultimately used by pharmaceutical formulation industries, where strict norms and standards have got to be followed, the other chemical industries do not have to deal with these conditions and thus do not have the required experience.

It cannot also be argued that because there are pharmaceutical formulation industries in the country, the necessary skill and experience exists for starting manufacturing activities for pharmaceutical chemicals. This is because the personnel involved in the pharmaceutical formulations only deal with the raw materials that have been produced according to strict manufacturing standards and norms. They do not have to follow these norms, whereas during the production of pharmaceutical chemicals such norms have to be adhered to with full determination and devotion. This sort of training is totally absent in any other manufacturing set—up and so it definitely does not exist in this country. Such experience and skill will, therefore, have to be developed in the country. In order to achieve this goal the country must acquire the following basic requirements, which are not available locally.

- i) The know-how for the manufacturing of pharmaceutical chemicals,
- ii) The experience, the skill and the rigid standards and devotion to follow the same,
- iii) A massive training programme off the job outside the country and on the job in the plant itself.

The only way to achieve this is to establish a multipurpose pilit plant and acquire the process know-how.

In view of the above-mentioned facts, a multipurpose plant to introduce manufacturing technologies and provide facilities for a massive training programme is highly recommended.

Analysis of the present status

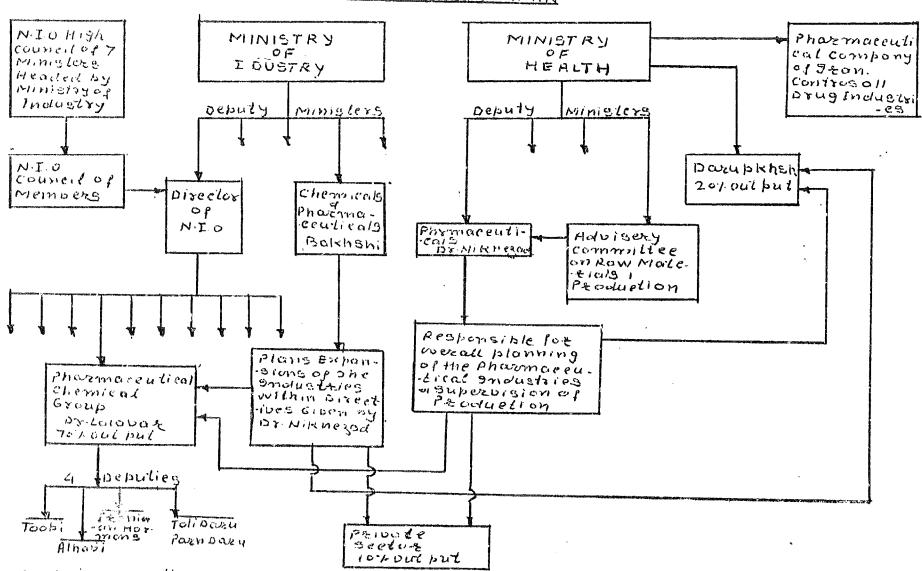
As mentioned above, to simplify and rationalize pharmaceutical chemicals the Government has already adopted afull fledged generic system for the production of pharmaceutical formulations. Such a generic list appears in Annex 1. Prior to the Revolution, there were about 4,000 different drug products on the Iranian market and they were mostly imported. These different drugs were sold under their proprietary names.

After the Revolution, the Government undertook preparation and promulgation of a generic name pharmacopea, comprising over 500 items. As a result of this and other measures, the number of different drug items have been reduced from over 4,000 to about 1,000, of which almost 600 are produced locally. The remaining ones have to be imported. These drugs are now sold in their generic names only.

National requirement of some specific pharmaceutical products have been tabulated in Annex $^2\cdot$

After the Revolution, the Government has nationalized most of the major industries, including of course the pharmaceutical industries. Accordingly, all the nationalized industries are directed by different ministries. An overall picture of the pharmaceutical industries in Iran is attached herewith.

STRUCTURE OF THE PHARMACEUTICAL



De Lolavar is the Chartonon of the Board of Directors for all firms in the country, in addition to appointing other Board Members.

The contribution of the private and Government undertakings towards the manufacture of pharmaceutical products is as follows:

National consumption (100%)

•		6	•
Immediate	past	Present	Forecast
Imported	60-65%	35-40%	20-25%
Formulations	35-40%	60-65%	75-80%

The contributions by N.I.O., Darupkhsh and the private sector towards production of pharmaceutical products is thus:

N.I.O.	70%
Darupakhsh	20%
Private	10%

Present Manufacturing Activities

The only manufacturing activities in the field of chemicals are:

- 1. Heavy chemicals such as sulfuric acid, caustic soda, ammonia, urea.
- 2. Petroleum products such as benzene, toluene, xylene, phenol.
- 3. Pharmaceutical formulations.

Not a single pharmaceutical chemical is being manufactured in the country.

Future Programme

Some of the organizations are preparing schemes in the field of pharmaceutical products production.

Mention may be made about the following activities under consideration.

Darupakhsh

Darupakhsh is a Government undertaking under the Ministry of Health and their activities are: a) Formulations and, b) Manufacture of bulk raw materials. The formulation activities are carried out by Darupakhsh while the bulk raw materials are manufactured by their subsidiary concern called Temad. Temad have recently started a pilot plant for the production of morphine and cocaine.

Alhavi Pharmaceutical Co.

This is also another Government undertaking. They have formulation units. They are now planning to cultivate herbs that normally grow in Iran and start the production of herbal medicines and plant extracts.

Toobi

This is yet another Government undertaking. Their main activities are production of inorganic raw materials. At present they are putting up a plant for the production of precipitated magnesia. The equipment is under erection and they expect to start the plant in a few months. They also have a research laboratory and are at present engaged in the recovery of caffeine from tea waste since Iran is producing sufficient quantities of tea.

Need for a Pilot Plant

As discussed earlier, the country has no technologies and manufacturing skills for producing pharmaceutical chemicals and must, therefore, acquire the same via transfer of technologies. Demonstration and training are parts of technologies. A laboratory demonstration on a work bench is not the way of imparting training because laboratory scale models just cannot simulate the operation conditions that are present on a large-scale plant. The operating personnel will have to be taught how to handle different equipment and different chemicals having different chemical and physical properties. To establish such a training programme, certain minimum production levels will have to be followed, which is just not possible on a work bench only. Again, a laboratory scale demonstration will not expose the personnel, undergoing training, to the sequence of operations and the sequence in which different equipments are used. This is possible only on a pilot plant or an actual large scale manufacturing plant.

The Pilot Plant

Selection of Product Mix

A study on the requirement of pharmaceutical chemicals and the possibilities of availability of technologies indicate a product mix that is presented in Annex 3. As mentioned earlier, certain minimum production levels have to be adopted for proper training programmes. Since the purpose of this plant is not to start a full manufacturing programme, the production level is so chosen that it will be within the minimum production level. The product mix spells out such production levels for different pharmaceutical chemicals. Another alternate product mix is also suggested in Annex 4. It will be noticed that the annual combined production of the product mix will be just 112.5 tons and that the percentage of each item produced varies from about 8 per cent of the national requirement, in the case of Paracetamol, to as much as 70 % of the national requirement for Chlordiazepoxide.

Selection of Equipment

Having selected the required product mix the next job is to provide suitable equipment to produce them. Lists of equipment and estimated cost, cost of civil construction and working capital requirements are given in Annex 5.

A multipurpose pilot plant can do many other functions. Also manufacturing processes of pharmaceutical chemicals are purely batch type operations, so once one product mix is tried out, the same plant can be used over again for trying another product mix. So the function of a pilot plant does not end when certain objectives for which it is set up are fulfilled. That is why it is called a multipurpose pilot plant. Thus a multipurpose pilot plant becomes a very handy tool at the hands of a receiving body to acquire various manufacturing programmes for not only pharmaceutical chemicals but for that purpose a host of other organic chemicals. The main objective of a pilot plant is the transfer of technologies the easy way. Working on a pilot plant by its very nature offers the body enough data that are required for a feasibility study. Such data are just not possible on a bench scale model.

The foregoing discussions lead to only one conclusion, that is that for a smooth transfer of technologies and for an on the job training programme, a multipurpose pilot plant is a must.

A look at the list of equipment will show that it includes glass lined and stainless steel equipment, some of which could be used in semi-commercial plants.

The following argument will justify the inclusion of the recommended equipment.

a) Material of construction

Glass lined and stainless steel reactors have been included in the project. An examination of the different processes of manufacture indicate that there are certain reactions, that are to be carried out under acidic conditions using acids such as sulfuric acid at critical concentrations and hydrochloric acid at any concentration, and with the use of various solvents such as benzene, toluene, acetone, methanol. No normal material of construction except glass lining can be used for carrying out such reaction.

Production of pharmaceutical products is a special job where strict adherence to manufacturing standards has to be followed. One of these conditions is to avoid iron contamination so stainless steel and rubber lined carbon steel reactors have been included to minimize iron contamination.

Size of the reactors

The size of any reaction vessel is a function of the batch volume. When there are a number of batch operations that have to be carried out in one type of equipment then the capacity of that equipment must be consistent with the maximum volume that has to be handled. Again, as mentioned earlier, for successful personnel training programmes, on the job and for smooth transfer of manufacturing technology, certain minimum production levels have to be followed. The capacities of all the reactors and the down stream equipment have been fixed after giving full consideration to the above-mentioned facts.

Number of Equipment

During the production programme one batch has to be transferred from one reaction vessel to the other having the same capacity and material of construction. Such transfers are necessary from the operation point of view. The reason for inclusion of two glass lined reactors of 1,000 lt is in accordance with the above discussion. The same argument holds good for stainless equipment also. Even though all equipment

may not be in use at any particular moment. The sequence of operations and facilities for intermediate storage of semi processed batches require the inclusion of that number of equipment. As far as dryers are concerned, some products can be dried under moderately high temperatures of up to 80-90°C, however some of the products are temperature-sensitive and are required to be dried at lower temperatures, which means under vacuum. This justifies the inclusion of vacuum dryer and forced draught dryers. Again, as far as possible no two products must be dried at the same time in a single dryer. Many times two or more products get ready for drying at the same time. Naturally, more than two forced draught dryers have to be included in the list. Chilled water plant and chilled brine plants have been included since the same reactions have to be carried out at temperatures beyond the reach of cooling water systems.

Two small boilers are two small (in half the required capacity) chilled water plants have been included instead of one big unit for both. The reason for this is that if there is only one big boiler and one big chilled water unit, then in the case of failure of any one of the units, the total production programme will come to a halt, whereas with two half capacity equipment, the production programme can still be carried out at a reduced level in cases of failure of any one of the smaller units.

Capacities of Bulk Storage Tanks

A close scrutiny of the raw materials requirement indicates large volumes of some of the solvents that have to be used. So is the case with acids. As such the inclusion of high capacity storage tanks is a necessity.

Raw Materials

Amexes 6, 7, 8 and 9 give the present-wise requirement of raw materials. These lists will facilitate the maintenance of inventory of raw materials at the required levels. Likewise the total requirements of raw materials has been divided in two groups, a) imported, and b) locally available raw materials. The requirement of these two groups has been listed separately in Annexes 10 and 11 respectively with the market price whereever possible prevailing in Teheran during March 1984.

Laboratory Equipment

Besides normal laboratory ware are included some sophisticated instruments such as:

- 1. High pressure liquid chromatograph,
- 2. Polarimeter,
- 3. Infrared spectrometer.

These instruments are required for precise analysis of pharmaceutical chemicals.

Since the purpose of the pilot plant is rigorous planning in every field, this addition will provide better experience to the quality control personnel.

Similarly, are also included in this list of laboratory instruments, one piece of equipment, i.e the Erwek a unit for formulation. This equipment will be useful in product development exercises.

Infrastructure

Necessary information regarding services, availabilities of construction materials, and all other additional information required appears in the following Annexes:

Annex 12 - Availability of construction materials, facilities for storage and transport

Annex 13 - Availability of Utilities

Annex 14 - Additional information

Training Programme

Intensive on the plant training has to be given to personnel at all levels. In the first place a team of higher level personnel will have to be sent outside the country and the contractors offering manufacturing technologies will give very intensive training programmes to the selected team. A training programme for a period of 10 months has been envisaged. Annex 15 presents a list of such a team that will have to be sent for training. Similarly, Annex 16 presents the total requirement of the operating and administrative personnel.

Work Schedule

A tentative study of all the operations indicate that the total project will be completed in about 36 months after the approval of the project. A probable bar chart showing the timings for various activities is attached herewith.

Feasibility Study

A feasibility study has been made even though such a study is generally not required for pilot plant study. Market value of proposed mixes of pharmaceutical chemicals is given in Annexes 17 and 18. Cost of labour overheads is given in Annex 19.

As can be seen from Annexes 20 - 30, the cost of production for every single item works out higher than the respective prevailing market price. Results of only a few pharmaceutical chemicals such as Procaine Hydrochloride, Lignocaine Hydrochloride Oxyphenbutazone and Clotrimazole are somewhat interesting.

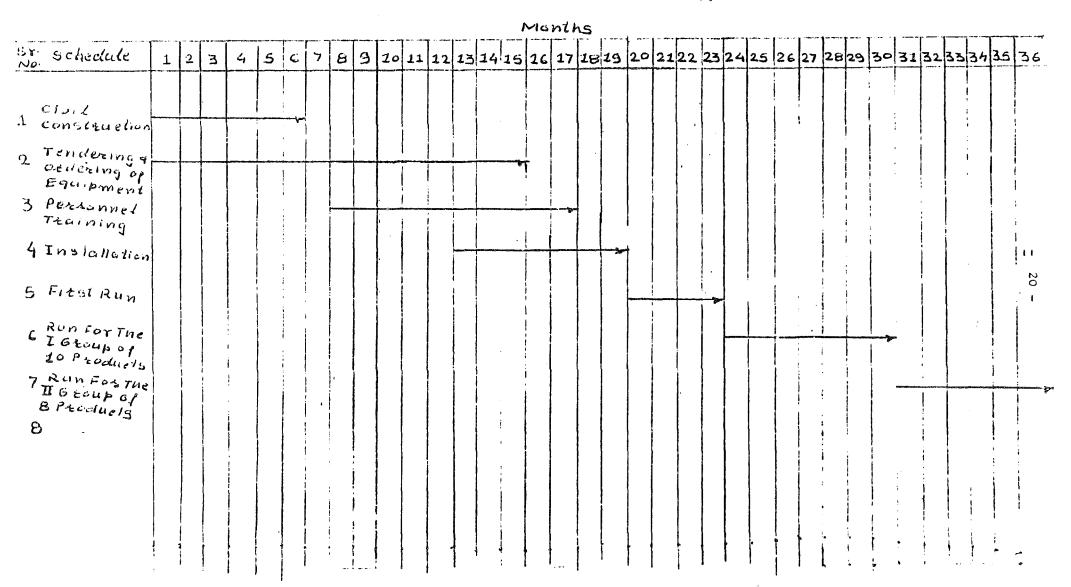
It therefore becomes very clear that the proposed multi purpose pilot plant will only fulfil the main objective of the project which is to make available the technologies and skills for the production of pharmaceutical chemicals and prepare

background for the manufacturing activities for such products. It also becomes very clear from the cost analysis that this plant is not meant for commercial production. Even the products produced will not be on sale, since in the first attempt they may not conf rm to the quality control standards. However, in case they do conform to the quality standards then they will be made available to the formulation industries.

Layout of Proposed Pilot Plant

Site plan for proposed pilot plant os shown in Annex 31. The layout of existing plant of Daru Paksh is indicated in Annex 32. The plant building of Daru Paksh is shown in Annex 33. The equipment layout for proposed pilot plant is indicated in Annex 34.

WORK SCHEDULE FOR MILLETT PURPOSE PILOT PLANT



Annex 1

GENERIC NAMES OF PHARMACEUTICAL CHEMICALS

Δ

acenocoumarol
acetaminophen
acetazolamide
acetic acid
acteohexamide
acetylcholine Cl
ACTH

* AGENTS FOR ACTIVE IMMUNICATION (pg. 72)

* AGENTS FOR PASSIVE IMMUNICATION (pg. 72)
albumin normal serum
ALCOHOL 38B (pg. 74)
allantoin
allopurinol
alprenolol
ALLERGIC EXTRACTS (pg. 73)
aluminium acetate
aluminium hydroxide
aluminium subacetate

amantadine HCl - ambenonium chloride

+ amikacin sulfate
aminacrine HCl
aminophylline
amiodarone
amitrptyline HCl
ammonium cbloride
ammonium hydroxide inhalant
amobarbital Na

amobarbital Na amoxicillin amphotericin B ampicillin

ampicillin Na

+ amyl nitrite
antihemophilic factor
ANTIVENINES (pg. 73)
apomorphine HCl
aprotinin

+ asparaginase
aspirin
atropine sulfate
azathioprine
azathioprine Na

В

bacitracin
barium sulfate
beclomethasone dipropionate
belladonna alkaloids (total)
benzalkonium chloride
benzethonium chloride
benzocaine
benzoin
benzoyl peroxide

benztropine mesylate
benzyl benzoate
bephenium hydroxynaphthoate
berberine HCl
beta caroten
betamethasone
betamethasone acetate
betamethasone disodium phosphate

+ bethanechol chloride
 bile extract
 biotin
 biperiden HCl
 biperiden lactate
 biacodyl
 bismuth subgallate

betamethasone valerate

+ bleomycin sulfate borax boric acid bromhexine Hcl bromocriptine mesylate buclosamide

buclosamide + bupivacaine HCl busuflan butalbital Na

C

caffeine
calamine
calcium gluconate
calcium pantothanate
candicidin
capreomycin sulfate

carbachol
carbamazepine
carbamide peroxide
carbenicillin disoidum
carbenicullin indanyl sodium
carbidopa
carbimazole
carbogen
carbon dioxide

C

t carmustine (BCNU)
cascara sagrada
castor oil
CDP-choline
cefazolin Na
cephalexin monohydrate
cephalothin soidum
cephradine
cetrimide
cetylpyridinium chloride

charcoal

chloral hydrate
chlorambucil
chloramphenicol
chormaphenicol palmitate
chloramphenicol sodium succinate
chlordiazepoxide

chlorguanide HCl chlorhexidine gluconate

chloroprocaine HCl
chlorpheniramine maleate
chloroquine phosphate
chlorpromazine
chlorpromazine HCl
chlorpropamide
chlorthalidone HCl

cholestyramine chorionic gonadotropin (human) chymotrypsin cimetidine cimetidine HCl

++ clemastine fumarate clidinium Br clindamycin HCl

+ clindamycin palmitate HCl

+ clindamycin phosphate clobetasol propionate clobutinol HCl clofibrate clomiphene citrate

clonazepam
clinidine HCl
clotrimazone
cloxacillin Na monohydrate
coal tar
codeine phosphate
colchicine
colistin sulfate
conjugated estrogens
cromolyn Na
crotamiton
cyclizine HCl

+ cyclopentolate HCl cyclophosphamide cyproheptadine HCl

++ cyproterone acetate cytarabine

D

+ dacabazine

+ dactinomycin dantrolene Na

+ dapsone (DDS)
daunorubicin HCl
deferoxamine mesylate
demeclocycline HCl

desmopressin
desoxycorticosterone acetate
dexamethasone
dexamethasone acetate
dexamethasone sodium phosphate
dexchlorpheniramine maleate
dexpanthenol

dextran

dextranomer

dextromethorphan HBr

diatrizoate meglumine

diazepam

diazoxide

dicloxacillin Na monohydrate

dicyclomine HCl

dienestrol

diethylstilbestrol

digitoxin

digoxin

dihydroergotamine mesylate

dihydrogenated ergot alkaloids
t dihydrotachysterol
dimenhydrinate

dimercaprol

+ dioctyl sodium sulfosuccinate diphenhydramine HCl diphenoxylate HCl dipyridamole dipyrone (injectable only)

+ disopyramide phosphate

+ disulfiram

+ dobutamine HCl
dopamine HCl
doxapram HCl
doxorubicin
doxycycline hyclate

doxycycline momohydrate ++ droperidol drarogesterone

Annex 1 (cont.)

Ε

edrophonium chloride

* ELECTROLYTES (pg. 74)

emetine HCl enflurane

ephedrine sulfate

epinephrine (HCl, bitartrate)

ergotamine tartrate

erythromycin ethylsuccinate

erythromycin lactobionate

* ESSENTIAL AMINO ACIDS (Pg. 69)

+ estradiol dipropionate estradiol valerate ethacrynic acid ethambutol

ether

ethinyl estradiol ethiodized oil

ethosuximide

+ ethoxazene HCl ethylstibamine ethylestrenol

eucalyptus Tr.

F

* FATS (Pg. 74)
felypressin
fenfluramine HCl

++ fentanyl citrate ferrous sulfate fibrinogen

+ flucytosine

+ fludrocortisone acetate

+ fluocinolone acetonide fluorescein Na fluorouracil fluphenazine (HC1)² flurandrenolide

+ flurazepam HCl

+ fluroxene

folic acid

+ folinic acid
 fosfestrol disodium
 furazolidone
 furosemide

G

gallamine triethiodide

+ gamma benzene hexachloride (lindane)
gelatin
gentamicin sulfate
gentian violet
glibenclamide

+ glucagon

G

glycerin glycopyrrolate

+ gold sodium thiomalate

gramicidin

griseofulvin (microcrystals)

guaifenesin

guanethidine sulfate

Η

haloperidol
halothane
hamaelis
hemicellulase
heparin Na
hexachlorophene

+ histoplasmin homotropine HBr

human plasma protein fraction

+ hydralazine HCl hydrastine HCl hydrochlorothiazide hydrocortisone acetate hydrocortisone Na succinate hydrogen peroxide

+ hydroquinone

hydroxychloroquine sulfate

hydroxypropylmethylcellulose (HPMC)

hydroxyurea
 hydroxyzine HCl
 hyoscine HBr
 hyoscyamine sulfate

Ι

ibuprofen
idoxuridine
imipramine HCl
indocyanine green
indomethacin

+ INFANT MILKS (pg. 74) insulin isophane (NPH)

insulin regular ultralente insulin Zn suspension - lente

intrinsic factor

semilente

iodine

iodipamide meglumine iodochlorhydroxyquin iopanoic acid

iopanoic acid

+ ipecac syrup

iron-dextran complex isocarboxazid

+ isoetharine mesylate

+ isoflurophate isoniazid

isoproterenol HCl isosorbide dinitrate isoxsuprine HCl

Annex 1 (cont.)

K

kanamcyin sulfate kaolin ketamine HCl

L

+ lactulose
levamisole HCl
levodopa
levothyroxine Na
lidocaine HCl
lincomycin HCl
liothyronine Na
lithium carbonate
lomustine

M

mafenide acetate megnesium hydroxide magnesium sulfate magnesium trisilicate mannitol mebendazole meclizine HCl medroxyprogesterone acetate mefenamic acid meglumine antimonate meglumine iothalamate melphalan menadione Na bisulfate menadione menotropins metnhol meperidine HCl mephenlermine sulfate mepivacaine HCl meprobamate merbromin mercaptopurine mestranol metaproterenol sulfate methadone HCl

- + methadone nor methamine mandelate methimazole methocarbamol methotrexate
- + methoxamine HCl
 methyldopa
 methyldopate HCl
 methylene blue
 methylergonovine maleate
- + methylphenidate HCl methylprednisolone acetate
- + methyltestosterone
 methyl salicylate
 metoclopramide HCl
 metrizamide
 metronidazole

- + metyrapone
- + miconazole nitrate
 mineral oil
 minocycline HCl
- + mithramycin
 mitomycin
 morphine sulfate
- + mumps skin test antigen myrtillus anthocyanosides

N

nalidixic acid nalorphine HCl naloxone HCl nandrolone decanoate nandrolone phenpropionate naphazoline HCl naphazoline nitrate neomycin sulfate neostigmine Br neostigmine methylsulfate niacin niacinamide niclosamide nifedipine niridazole nitrofurantoin nitrofurazone

- + nitrogen mustard nitroglycerin
- + nitroprusside Na nitrous oxide nitrous oxide
- * NONESSENTIAL AMINO ACIDS
 nonoxynol g
 norepinephrine bitartate
 norethindrone
 norethindrone acetate
 norgestrel (or levonorgestrel)
 nystatin

0

- + old tuberculin (mantoux)
 opium
 oxazepam
 oxethazaine
- + oxybutynin chloride oxygen oxymetholone oxyphenbutazone oxytetracycline HCl oxytocin

Annex l (cont.)

procaine HCl

progesterone

propanidid

procarbazine HCl

promethazine HCl

propantheline BR

Ρ proparacaine HCl pancreatin pancuronium Br propranolol HCl propyliodone pantothenic acid para aminobenzoic acid + propylthiouracil para aminosalicylic acid (PAS) protamine sulfate prothionamide paramycin sulfate protirelin paregoric pectin pseudoephedrine HCl psyllium penicillamine penicillin G, benzathine pyrazinamide penicillin G, potassium _ pyrethrins penicillin G, procaine pyridostigmine Br penicillin G, sodium pyrilamine maleate penicillin V, potassium pyrimethamine pentagastrin pyrvinium pamoate pentazocine HCl pentazocine lactate peppermint oil perphenazine quinacrine HCl phenazopyridine HCl quinidine sulfate phenobarbital phenobarbital Na phenolsulfonphtalein phentermine HCl reserpine resorcinol phentolamine mesylate phenylephrine HCl rifampin phenylpropanolamine HCl phenytoin phenytoin Na salbutamol physostigmine sulfate phytanodione (K1) salbutamol sulfate pilocarpine nitrate, HCl salicyclic acid piperazine citrate scopalamine N butyl bromide secobarbital Na pipotiazine palmnitate platinum diamino dichloride (cisplatin) secretin selenium sulfide polymyxin B sulfate polysorbate 80 silver nitrate polyvinyl alcohol silver sulfadiazine potassium chloride simethicane potassium iodide simfibrate povidone (polyvinylpyriolidone) sodium diatrizoate povidone iodine sodium EDTA sodium fluoride pralidoxine chloride (PAM) prazosin Hcl sodium ipodate prednisolone sodium nitrite prilocaine HCl sodium polystyrene sulfonate primaquine phosphate sodium salicyclate primidone sodium tetradecyl sulfate sodium thiosulfate probenecid procainamide HCl somatropin

+ spectinomycin HCl spironolactone

+ streptodornase streptokinase

sorbitol

Annex 1 (cont.)

streptomycin sulfate succinylcholine chloride sulfacetamide sodium sulfamethoxazole sulfamethoxypyridazine sulfapyridine

+ sulfapyridine sulfasalazine sulfisoxazole

+ sulfisoxazole acetyl sulfoxone Na sulfur

T

tamoxifen citrate terbutaline sulfate

testolactone
testosterone
testosterone propionate
testosterone enanthate
testosterone HCl
theophylline
thiabendazole
thiethylperazine maleate
thimerosal

thioguannie
thiopental Na
thioridazine HCl
thiothixene
thrombin
thyroid

thyrotropin
timolol maleate
tobramycin sulfate
tolazoline HCl
tolnaftate

tranexamic acid
tranylcypromine sulfate
triacetin (glyceryl triacetate)
triamcinolone acetoniae
triamterene
triclofos sodium
triethylene thiophosphoramide (thio-TEPA)
trifluoperazine HCl
triflupromazine HCl

trihexyphenidyl HCl trimeprimine maleate

trimeprazine tartrate trimethoprim

+ trimethaphan camsylate
+ trioxsalen

- + tripelennazine citrate
- + tripelennamine HCI
- tromethamine
 + tuberculin PPD

tubocurarine chloride

U

undecylenic acid urea

V

valproate sodium
vancomycin HCl
vasopressin
verapamil HCl
vinblastine sulfate (VLB)
vinoristine sulfate (VCR)
vitamin A
vitamin Bl (thiamine HCl)
vitamin B2 (riboflavin)
vitamin B6 (pyridoxine HCl)
vitamin B12 (cyanocobalamin)
vitamin C (ascorbic acid)
vitamin D (D2,D3)
vitamin E

W

warfarin Na

Ζ

zinc sulfate zinc oxide zinc undecylinate

ANNEX 2

National Requirement of Pharmaceutical Chemicals*
From 1980 to 1987

Figures in tons

	1980-81	1981-82	1982-83	1983-84	1984-85	1985-86	1986~87
Diphenyl Hydantoin and its Na. Salt	4.3	4.6	5	6	6.5	8	9
Nicotin-amide	26.3	28	30	33	37	40	45
Niacin	21.5	23	25	27	30	34	40
Metronidazole	8.6	9.2	10	11	13	14	15
Imidazole from Acetaldyde	4	4.5	5	5.5	6	6.5	8
Mebendazole	2.6	2.6	3	3.4	3.8 .	4	4.5
Methyl Imidazole	0.8	0.9	1	1.1	1.5	2	3
Clotrimazole	2	2.5	3	3.4	3.7	4.2	4.5
Procaine Hydrochloride	8.5	9.5	10	11.5	12.6	14	15
Lignocaine Hydrochloride	4.4	4.4	5	5.8	· 6	6.8	7.5
Oxyphen Butazone	12	13.8	15	17	19	20	24
Nikethamide	3	0.92	1	1.2	1.4	2	2.3
Clofibrate	5	6.4	. 7.	8.5	9	10	11.5
Ethambutol	12.9	13.8	15	17	19	20	22
Isoniazid	4	4.5	10	13.0	15.0	18	18.0
Propranolol	1.5	1.8	2	2.5	3	3.5	4.5
Trimethoprim	17.5	18.5	20	24	27	29	32
Nalidíxic Acid	6	6.5	7	7.4	8	9	11
Indometacine	8.5	9	10	11.5	12	13	14.5
Diazepam	1.5	1.5	2.0	2.3	2.8	3.0	3.5
Chlorodiazepoxide	1.0	1.2	1.5	1.7	1.9	2.0	2.2
Paracetamol		-	250.0	261.0	273.0	. 286.0	300.0
Totals	155.9	167.12	437.5	474.8	511.2	569.3	597

^{*} Source of information: Darupakhsh as of March 1984

 $\frac{\texttt{Annex 3}}{\texttt{NATICNAL}}$ REQUIREMENT AND PROPOSED PRODUCTION LEVEL FOR DIFFERENT PHARMACEUTICAL CHEMICALS

PROPOSED PRODUCT MIX:A

No.	Name of Pharmaceutical Chemical	Proposed Annual Production Tons	Per cent National Requirement	National Requirement Tons/Year
		•		
1.	Nicotinamide	15	33.3	45
2.	Procaine Hydrochloride	8	50.0	16
3.	Clofibrate	3	25	12
4.	Diphenyl Hydentoin	4	44	9
5.	Lignocaine Hydrochloride	2	25	8
6.	Indometacine	2	13	15
7.	Nalidixic Acid	7	63	11
8.	Oxyphen Butazone	10	41	24
9.	Paracetamol	20	6.0	300
10.	Chlorodiazepoxide	1.5	70.0	2
11.	Niacin	15	37.5	40
12.	Mebendazole	3	60.0	5
13.	Ethambutol	10	45	22
14.	Isoniazid	5	27	18
15.	Chlortriamazole	2	40.0	5
16.	Diazepam	2	56.6	3.5
17.	Nikethamide	1	40.0	2.5
18.	Propranolol	2	44	4.5

Total annual production

112.5

Annex 4

PROPOSED PRODUCT MIX:B

No.	Name of Pharmaceutical Chemical	Proposed Annual Production Tons	Per cent National Requirement	National Requirement Tons/Year
1.	Metronidazole	6	42.8	14
2.	Phenylbutazone	5	-	-
3.	Ferrous Fumarate	4	•	-
4.	Ibuprofen	6	·	
5.	Aspirin	30	300	100
6.	Methyl Salicilate	3	•	-
7.	Sulfamethaxazole	4	-	_
8.	Trimethoprim	10	40.0	25
9.	Pyrazinamide	2		
10.	Haloperidol	10		-
11.	Chloroquine Phosphate	12		-
12.	Sulfinpyrazone	5	-	شعد
13.	Tinidazole	4	-	-

Total annual production

ANNEX 5

List of equipment and estimated cost

Estimated cost Ser- . Capa-No. Unit cost Total cost US\$ ial cîty US\$ Item - Process Equipment No. 1 Jacketed glass-lined reactor with agitator 1,000 1 2 40,000 80,000 2 G.L. condenser 4 sq.m. 2 8,000 16,000 3 G.L. Receiver 600 1 1 12,000 12.000 Jacketed S.S. reactor with agitator 4 1,000 1 4 9,000 36,000 5 S.S. Condenser 4 sq.m. 4 3,000 12,000 6 S.S. Receiver 600 1 2 3,000 6,000 7 Jacketed s.s. reactor with agitator 600 1 . 4 7,000 28,000 8 S.S. condenser 3 sq.m. 4 2,000 8,000 9 S.S. Receiver 500 1 2 3,000 6,000 10 Jacketed S.S. flat top reactor with agitator 600 1 1 6,000 6,000 11 M.S.R.L. flat top reactor with agitator 600 1 3,000 2 6,000 12 Jacketed S.S. concentration pan with agitator 400 1 1 4,000 4,000 Jacketed S.S. vacuum still pot with 13 200 1 1 4,000 4,000 agitator 14 S.S. Condenser 1.5 sq.m. 1,000 1 1,000 - 5 Jacketed S.S. Receiver 200 1 1 2,000 2,000 16 12,000 S.S. basket centrifuge 2 8,000 16,000 17 10,000 S.S. basket centrifuge 1 6,000 6,000 18 M.S.R.L. filter box 600 1 2 4,000 8,000 19 S.S. filter box 600 1 1 8,000 8,000 20 S.S. sparkler filter 1 3,000 3,000 21 S.S. pressure leaf filter 1 1,000 1,000

Sub-total: 269,000

ANNEX 5

List of equipment and estimated cost

(Continued)

				Estimated Cost	
Ser- ial No.	Item - Process Equipment	Capa-	No.	Únit cost US\$	Total cost
	·				bgt. frd 269,000
22	Forced draft dryer	94 trays	3	4,000	12,000
23	Forced draft dryer	40 trays	1	3,000	3,000
24	Forced draft dryer	30 trays	1	2,000	2,000
25	Forced draft dryer	10 trays	1	1,000	1,000
26	Vacuum shelf dryer with condenser		1	9,000	9,000
27	Water ring vacuum pumps	7 h.p.	4	2,000	8,000
28	High vacuum pump	2 h.p.	1	1,000	1,000
29	S.S. centrifugal pump	50 1bm at 25 m	4	2,000	8,000
30	M.S.R.L. pump	50 1bm at 25 m	2	1,000	2,000
31	All glass reactor	100 1	2	2,000	4,000
32	S.S. pulveriser		1	2,000	2,000
33	S.S. mechanical sieve		1	2,000	4,000
34	S.S. resin column	0.6 mo 1.5 m high	. 2	2,000	4,000
35	S.S. blender		1	3,000	3,000
36	S.S. vent. condenser	1.5 sq.m.	5	1,000	5,000
37	Dial type balance	to weigh 50 kg.	2	1,500	3,000
38	Miscellaneous Equipment - lump sum				6,000
				Total	344,000

<u>ANNEX</u> 5

List of equipment and estimated cost

(Contined)

Estimated cost Unit cost Ser-Capa-No. Total cost Item ial USS USS city No. Tank Farm Equipment Tank for storing hydrochloric acid, high 1 density polythene 10,000 1 2,000 2,000 2 M.S. storage tank for sulfuric acid 10,000 1 5,000 5,000 3 M.S. storage tank for caustic soda 10,000 1 4,000 4,000 M.S. storage tank for benzene 10,000 1 4,000 4,000 5 M.S. storage tank for toluene 10,000 1 4,000 4,000 6 M.S. storage tank for acetone 10,000 1 4,000 4,000 7 M.S. storage tank for ethanol 10,000 1 ື4**ຸ**000 4,000 8 M.S. storage tank for methanol 10,000 1 4,000 4,000 9 M.S. storage tank for diesel 10,000 1 4,000 8,000 10 C.I. submersible pump for solvent 5 2,000 10,000 11 C.I. pump for sulfuric acid 1 1,000 1,000 12 C.I. pump for caustic soda 1 1,000 1,000 13 Polypropeline pump for hydrochloric acid 1 1,500 1,500 M.S. vent condensers 1 sq.m. 5 1,000 5,000 15 C.I. pump for diesel oil 1 1,000 1,000 Service equipment Sub-total 58,000 1 Steam generator to generate steam at 10 atm 500 kg/hr 2 30,000 60,000 2 Demineralized water unit $3 m^3/hr$ 15,000 15,000 3 $3 m^3/hr$ Soft water unit, dealkalizer 10,000 10,000 H.D.P. storage tank for D.M. water, 4 10,000 1 2,000 4,000 5 H.D.P. storage tank for soft water 10,000 1 2,000 4,000 6 S.S. pump for D.M. water 25 1pm at 25 m 1,500 1,500 7 C.I. pump for soft water 25 1pm at 25 m 1 500 500 8 Refrigeration unit for chilled water at SC 30 tr 2 30,000 60,000 9 Refrigeration unit for chilled brine 10 tr 10,000 10,000

Sub-total

ANNEX 5 List of equipment and estimated cost

(Continued)

Estimated cost

Ser- ial No.	Item - Service Equipment	Capa- city	No.	Unit cost US\$	Total cost US\$
10	Cocling tower	150 tr	*	15,000	15,000
11	C.I. cooling water pump	1,500 lpm at 25 m	i . 2.	3,000	6,000
÷	C.I. chilled water pump	500 lpm at 25 m	2	2,000	4,000
13	C.I. chilled brine pump	100 lbm at 25 m	2	1,500	3,000
14	Hot oil circulation unit	70,000 K.cal/hr	1	15,000	15,000
15	AIr compressor		2	3,000	3,000
16	Electric substation 50 KVA		1	25,000	25,000
17	Diesel generator 50 KVA		1	20,000	20,000
18	Incinerator		1	2,500	2,500
19	Battery operated fork lift truck		1	15,000	15,000
				Total	273,500

ANNEX 5

Cost of Installed Equipment

			US\$	US\$
ı.	Α.	Cost of Process Equipment	344,000	
	В.	Cost of Tank Farm Equipment	58,000	
	C.	Cost of Service Equupment	273,500	•
		Total of A, B and C*		675,000
	D.	Cost of Spare Parts for 3 years trouble-free service	67,500	67,500
	Tot	al Ex-works Cost of Equipment		743,000
	E.	Handling charges to convert to Ex-works cost to F.O.B. cost	74,000	
	F.	C.I.F. charges 25% F.O.B. charges	204,000	
	G.	Handling charges in Iran 10% of C.I.F.	100,000	
		Total landed cost of equipment		1,121,000
	Н.	Cost of Installation		
		i) Cost of installation labour	190,000	
		ii) Cost of installation material	380,000	•
		iii) 10% extra for explosion proofing	57,000	
		Total installation cost		627,000
		Total installed cost of equipment		1,748,000

^{*} These cost figures are as per writer's experience and information on prevailing cost of fabrication in India

ANNEX 5

(Continued)

II. A. Equ	ipment for Analytical Laboratory	Quantity
1.	a) Metler semimicro balance	1
	b) Single pan balance	1
	c) Rough balance (Avery type)	1
2.	Melting point apparatus	1
3.	Laboratory drying oven (0 to 250°C)	2 (one vac. oven)
4.	Muffle furnace	1
5.	Karl Fischer apparatus	1
6.	Refractometer	1
7.	Spectro Calorimeter	1
8.	T.L.C. equipment	1
9.	Vacuum pump	1
10.	Heating mantles	3
11.	Hot plates	3
12.	PH meter	1
13.	U.V viewing cabinet	1
B. <u>Gl</u> a	ass Ware and Other Laboratory Items	
1.	Burette (10,25 and 50 cc capacity)	1 doz. each
2.	Pipettes (1, 2, 5, 10, 25 and 50 cc)	20 each
	Lamda pipettes (5, 10 and 25)	3 each
	Graduated pipettes (1, 5 and 10)	10 each
3.	Beakers (25, 50, 100, 250 and 500)	2 doz. each
	1,00 cc	1 doz. each
4.	Conical flasks (25, 50, 100, 250, 500 and 1,000 cc) Erlenmeyer	r 1 doz.
	Iodometric flask (250 ml)	1 doz.
5.	Kjaldhal distillation units (Kjaldhal flasks)	2
	Kjaldhal distillation units 500 ml	6
	Kjaldhal distillation units 300 ml	6

ANNEX 5 (Continued)

	(Concinded)	Quantity
6.	Platinum crucibles and tongs with pt. tip	2
7.	Nickel crucibles	2
8.	Silica (Vitreosol) crucible	1 doz.
9.	Miscellaneous items (such as stand, clamps, etc.)	
10.	Round bottom flask with standard joints (D-24) (100, 250 and 500 ml)	l doz. each
11.	a) Thermometer (ordinary 0 to 250°C)	6 -
	b) Thermometer (Q.F.C. 250°C)	3
12.	Standard glass joints, adapters, glassenheeds, etc.	
13.	Separating funnel (50, 100, 250 and 500 cc)	6 each
	Ordinary funnels	1 doz
14.	Weighing bottles	1 doz
15.	Sintared glass crucibles	1 doz.
16.	Filteration flask (50, 100, 250, 500, 1 ltr.)	6 each
17.	Glass condenser for various types	1 doz.
	Coiled type	1 doz.
18.	Glass cylinders (10, 25 and 100)	l doz. each
19.	Nesler tubes (25, 50 and 100)	1 doz.
20.	Volumetric flasks (10, 25, 50 and 100)	1 doz. each
	25, 500 and 1 ltr.	6
21.	Test tubes - all sizes	2 dez.
22.	Desiccators ordinary	4
	Vacuum	2
23.	Specific gravity bottle and pyknometers	10) 25) 3 each 50)
	Pyknometers	4
24.	100 1 all-glass assembly	1

Total estimated cost of Laboratory Ware A and B $$\tt US\$50,000$$

ANNEX .5 (Continued)

			US\$
	c. 1.	Perkin-Elmer Series 4 high pressure liquid chromatograph complete with all spares and accessories c.i.f.	58,800
	2.	Perkin-Elmer Model 241 polarimeter complete with all spares and accessories c.i.f.	20,000
	3.	Beckman Acculab infrared spectrophotometer complete with all spares and accessories c.i.f.	33,600
	5.	Erweka unit for formulation complete with all spares and accessories c.i.f. Atomic absorption spectrometer) Gas chromatograph)	40,000 48.600
	0.	Total	251.000
III.		t of Civil Construction Cost of process building - Basement/Ground Floor each 630 sq. m.	550,000
		Mezzanine floor 300 sq. m building available	
	В.	Additional cost for modifications, alterations and reinforcing existing columns and foundations	55,000
	C.	Cost of office accommodation, 50 sq. m. available	45,000
	D.	Cost of warehouse for raw materials, 250 sq. m. new construction	130,000
	Ε.	Cost of warehouse for finished products, 75 sq. m. new construction	40,000
	F.	Cost of building for service equipment, 220 sq. m. new construction	130,000
	G.	Work shop, cafeteria, time office, etc. to be pooled, hence no cost has been considered	
		Total cost of Civil Construction	950,000

ANNEX 5

	Summary		US\$
ı.	Installed cost of equipment		1,748,000
II.	Cost of laboratory equipment		202,400
III.	Cost of civil construction		950,000
			·
IV.	Requirement of Working Capital	US\$	üS\$
Α.	Margin money for imported raw materials (4 months inventory)	330,000	
В.	Margin money for indigenous raw materials (1 month inventory)	5,000	
C.	Stock in process 15 days stock	88,000	
D.	Cost of finished product for 1 month (margin money)	65,000	
E.	Provision for 1 month labour cost	60,000	
F.	Provision for interest	322,000	
	Total working capital		873,000

Annex 6

Annual Cost of Raw Materials and Inventory required for Pharmaceutical Chemicals *

Product Mix - A

Chemical icotinamide rocaine Hydrochloride lofibrate iphenyl Hydantoin ignocaine Hydrochloride ndomethacin alidixic Acid	Imported US\$ 133,120 (44,000) 313,800 (104,000) 54,900 (18,000) 41,000 (14,000) 45,500 (15,000) 117,300 (39,000) 2,290,900	Local US\$ 2,200 14,000 (1,000) 48,300 (16,000) 4,600 (1,000) 5,600 (2,000) 40,600 (13,000)	Inventory US\$ 44,000 105,000 34,000 15,000 17,000 52,000
rocaine Hydrochloride lofibrate iphenyl Hydantoin ignocaine Hydrochloride ndomethacin alidixic Acid	(44,000) 313,800 (104,000) 54,900 (18,000) 41,000 (14,000) 45,500 (15,000) 117,300 (39,000) 2,290,900	14,000 (1,000) 48,300 (16,000) 4,600 (1,000) 5,600 (2,000) 40,600	105,000 34,000 15,000 17,000
lofibrate iphenyl Hydantoin ignocaine Hydrochloride ndomethacin	(104,000) 54,900 (18,000) 41,000 (14,000) 45,500 (15,000) 117,300 (39,000) 2,290,900	(1,000) 48,300 (16,000) 4,600 (1,000) 5,600 (2,000) 40,600	34,000 15,000 17,000
iphenyl Hydantoin ignocaine Hydrochloride ndomethacin	(18,000) 41,000 (14,000) 45,500 (15,000) 117,300 (39,000) 2,290,900	(16,000) 4,600 (1,000) 5,600 (2,000) 40,600	15,000 17,000
ignocaine Hydrochloride ndomethacin alidixic Acid	41,000 (14,000) 45,500 (15,000) 117,300 (39,000) 2,290,900	4,600 (1,000) 5,600 (2,000) 40,600	17,000
ndomethacin	45,500 (15,000) 117,300 (39,000) 2,290,900	5,600 (2,000) 40,600	
alidixic Acid	117,300 (39,000) 2,290,900	40,600	52 000
	1	· 1	J2,000
	763,000)	4,400 (1,000)	764,000
xyphen Butazone	287,700 (95,900)	209,200	165,600
aracetamol	300,400 (100,000)	-	100,000
hlorodiazepoxide	92,100 (31,000)	45,500 (15,000)	46,000
iacin	76,500 (25,500)	· 76,600 (25,500)	51,000
ebendazole	84,900 (28,399)	7,500 (2,500)	31,000
soniazid	30,000 (10,000)	88,700 (29,600)	40,000
Clotrimazole	165,000 (55,000)	-	40,000
iazepam	40,000 (13,000)	81,000 (27,000)	55,000
thambutol	215,200 (72,000)	6,800 (2,300)	74,000
ikethamide	26,000 (9,000)	3,000	10,000
	37,400 (12,000)	27,600	21,000
-		(13,000) thambutol 215,200 (72,000) ikethamide 26,000 (9,000) copranolol 37,400	(13,000) (27,000) thambutol 215,200 6,800 (72,000) (2,300) ikethamide 26,000 3,000 (9,000) (10,000) ropranolol 37,400 27,600

Annual Cost of Raw Material and Inventory Required for Pharmaceutical Chemicals

Product Mix - B

	Name of Pharmaceutical	Annual Co Raw Mate	rials	Annual Cost of	
No.	Chemical	Imported US\$	Local 'US\$	Inventory US\$	
1.	Metronidazole	372.700 (124.300)	49.500 (4.000)	128.300	
2.	Phenylbutazone	69.000 (23.000)	1.000	23.900	
3.	Ferrous Fumarate	9.000 (3.000)	21.000 (2.000)	5.000	
4.	Ibuprofen	204.350 (68.100)	49.300 (4.000)	72.100	
5.	Aspirin	147.000 (49.000)	900	49.000	
6.	Methyl Salicilate	160.000 (53.300)	6.230	53.300	
7.	Sulfamethaxazole	229.200 (76.400)	37.900 (3.000)	79.400	
8.	Trimethoprim	442.000 (147.300)	4.500	147.300	
9.	Pyrazinamide	103.200 (34.400)	18.300 (1.500)	36.000	
10.	Haloperidol	999.300 (333.100)	84.000 (7.000)	340.100	
11.	Chloroquine Phosphate	473.100 (124.400)	33.000 (3.000)	127.400	
12.	Sulfinpyrazone	387.500 (129.000)	61.900 (5.200)	134.200	
13.	Trínidazole	164.000 (55.000)	34.500 (3.000)	88.000	

No.	Home of Pharmaceutical	Raw materials required	Require- ment per	Unit cost of raw	.(aw material	Annual require-	Annual of raw ma	
	Chemical		100 kg product kg	materials US\$/kg	cost per 100 kg product US\$	ment of raw mate- rials tons	Imported US\$	Local US\$
1	Nicotinamide Annual proposed production 15 tons	1 3-cyanopyridine 2 Sodium Hydroxide 50% solution	138 26	6.15 0.50	848.70 13.00	20.7 3.9	127.300 -	- 1.950
		3 Active carbon 4 Liquor ammonia 5 Resin IRA-402	4 4 2	2.2 0.25 15.00	8.80 1.00 30.00 901.50	0.6 0.6 0.3	1.320 - 4.500 133.120	- 150 - 2.100
2	Procaine Hydrochtoride Annual proposed	l Benzocaine 2 Diethylamino ethanol 3 Sodium metal	117 108 0.7	20.00 11.55 16.00	2.340.00 1.247.40 11.20	9.36 8.64 56 kg	187.200 99.800 900	
	production 8 tons	4 Acetic acid 5 Toluene 6 Sodium chloride	1.8 36 21	1.00 0.60 0.70	1.80 21.60 14.70	144 kg 3.0 1.7	144 	1.800 1.200
,		7 Liquor ammonia 8 Hydrochloric acid 9 Sodium hydrosulfite	6 72 0.6	0.25 0.80 1.20	1.50 57.60 0.70	0.5 6.0 48 kg	- · - 60	0.200 4.800
		O Active carbon I Hyflowsupercel 2 Ammonium chloride	3 9 63	2.20 2.20 0.64	6.60 19.80 40.30	240 kg 720 kg 5	530 1.600 3.200	- - -
	1	3 Ethanol 4 Isopropranol 5 Acetone	30 68 27	2.50 3.00 1.80	75.00 204.00 48.60 4.090.80	2.4 5.5 2.2	16.500 3.900 313.834	6.000
3	Clofibrate Annual proposed	1 P. Chlorophenol 2 Acetone	100 480	6.00 1.80	600.00 864.00	3 15	18.000 27.000	-
	production 3 tons	3 Sodium Hydroxide 50% soln. 4 Chloroform 5 Hydrochloric acid 6 Sodium Bicarbonate	182 160 280 65	0.50 1.20 0.80 0.60	91.00 192.00 224.00 39.00	6 4.8 8.5 2.0	5.800 - 1.200	3.000 - 6.800
		7 Ethanol 8 Toluene 9 Sulfuric acid	480 40 26	2.50 0.60 0.12	1200.00 24.00 3.10	15 1.5 800 kg	-	37.500 900 90
	1 1 1	O Sodium sulfate anhydrous l Active carbon 2 Hyflow supercel	10 24 20	0.15 2.20 2.20	1.50 52.80 44.00 3335.40	300 kg 720 kg 600 kg	1.600 1.300 54.900	45 - - 48.300
e gode fo						- Christian Chri		

Annex 8

llo. Hame of Pharmacontical	Raw materials required	Require- ment per	Unit cost of raw	Maw material	Annual require-	Annual of raw ma	
Chemical		100 kg product kg	materials US\$/kg	cost per 100 kg product US\$	ment of raw mate- rials tons	Imported US\$	Local US\$
4 Diphenye Hydantoin Annual proposed production 4 tons	1 Benzil 2 Urea 3 Potassium hydroxide 4 Active carbon 5 Hydrochloric acid (33%)	117 53 93 1 144	6.40 1.60 2.00 2.20 0.80	748.80 84.80 186.00 2.20 115.20 1,137.00	4.48 2.11 3.72 40 kg 5.75	30.000 3.400 7.500 90 	- - - - 4.600 4.600
5 Lignocaine Hydrochloride Annual proposed production 2 tons	l M.Xylidene 2 Chloracetyl chloride 3 Sodium carbonate 4 Benzene 5 Diethylamine 6 Sulfuric acid 7 Active carbon 8 Sodium hydroxide \$0% soln 9 Acetone 10 Hydrochloric acid	64 60 40 420 80 35 4.5 28 400	2.40 12.18 0.50 0.50 8.30 0.12 2.20 0.50 1.80	153.60 730.10 20.00 210.00 664.00 4.20 9.90 14.00 720.00 28.00 2.554.50	1.28 1.20 800 kg 8.5 1.6 700 kg 90 kg 560 kg 8	3.000 14.600 - - 13.300 - 200 - 14.400	400 4,250 - 90 - 280 - 5,600
6 Indometacine Annual proposed production 2 tons	1 Para-anisidine 2 Sodium nitrite 3 Sodium hydroxide 4 Sod. sulfate anhydrous 5 Zinc dust 6 Sodium chloride 7 Hydrochloric acid 8 Acetic acid 9 Sodium bicarbonate 10 P. Chlorabenzoyl chloride 11 Ethanol 12 Active carbon 13 Hyflowsupercel 14 Levulinic acid 15 O.phosphoric acid 16 Toluene 17 Ethyl acetate 18 Petroleum ether	120 72 20 216 120 450 330 168 240 162 480 21 16.5 110 161 356 60 15	4.00 0.35 0.5 0.15 6.00 0.90 0.80 1.00 0.60 7.60 2.50 2.20 2.20 2.20 2.20 1.00 0.60 1.50 1.00	480.00 25.20 10.00 34.40 720.00 315.00 264.00 168.00 144.00 1.321.20 1.200.00 46.20 36.30 2.772.00 161.00 213.6 90.0 15.0 7.925.30	2.4 1.5 400 kg 4.32 2.4 9.0 6.6 3.36 4.8 3.25 9.6 420 kg 330 kg 2.2 3.22 7.0 1.2 300 kg	9.600 500 - 14.400 - 3.400 2.800 24.700 - 900 700 55.000 3.200 - 1.800 300 117.300	- 200 600 - 6.300 5.300 - - - - 4.200 - 40.600

Annex 8 (Continued)

No.	Name of Pharmacoutical	Raw materials required	Require- ment per	Unit cost of raw	Naw material	Annual require-	Annua of raw ma	l cost aterials
	Chemical		100 kg product kg	materials US\$/kg	cost per 100 kg product US\$	ment of raw mate- rials tons	Imported US\$	Local US\$
,	Nalidixic acid Annual proposed production 7 tons	1 2-Amino-6-Methyl pyridine 2 Diethyl ethoxl methylene malonate	160 320	12.00 [1.30	1.920. 3 3.616.00	11.1 22.4	134.500 253.100	-
		3 Petroleum ether 4 Sodium bicarbonate 5 Diphenyl ether 6 Dimethyl formamide	330 20 230 1,000	1.00 0.60 1.5 _1.2	330.00 12.00 345.00 1.200.00	23.0 1.4 16.1 70	23.000 800 24.500 84.000	
		7 Dimethyl sulfate 8 Sodium carbonate 9 Sodium hydroxide flakes 10 Hydrochloric acid	154 106 60 12	4.2 0.5 0.8 0.8	646.00 50.30 48.00 9.60	10.78 7.4 4.2 800	49.300 - 3.400	3.700 - 700
Addressed to a		ll Acetic acid 12 Active carbon	170 2.0	1.0	170.00 4.40 78.351.30	12 140	12.000 300 584.900	4.400
8	Oxyphen Butazone Annual proposed production 10 tons	1 Benzyl chloride 2 Parahydroxy azobenzene 3 Zinc dust 4 Sodium methoxide 5 Butylmalonic acid	133.5 200 87.2 47 179.5	1.70 3.0 6.00 4.00 7.00	226.95 600.00 523.00 188.00 1.256.50	13.35 20.00 8.7 4.7 18.0	22.695 60.000 53.200 18.800 126.000	-
		diethylester 6 Raney-Nickel 7 Hydrogen gas 8 Carbondioxide gas 9 Sulfurdioxide gas	45.5 0.9 85.0 96.0	4.0 1.0 1.0	182.00 0.90 85.00 96.00	4.6 90 kg 8.5 9.6	18.400 90 8.500 9.600	-
		10 Hydrochloric acid 11 Sodium hydroxide 12 Active carbon 13 Xylene	72.7 120.5 1.3	0.8 0.8 2.2 0.5	58.00 96.00 2.80 143.00	7.3 12.0 130 kg 28.6	9.600	5.800 - - 14.300
		14 / Benzene 15 Acetone 16 Ethanol 17 Sodium sulfate anhydrous	171 287 683 41	0.5 1.8 2.5 0.15	85.50 516.00 1.707.00 6.00	17.1 28.7 68.3 4.1	51.600 -	8.500 - 170.000 600
					5.772.65		378.785	199 .200

__43 _ Annex 8 (continued)

RAW MATERIAL REQUIREMENT FOR THE PRODUCTION OF PHARMACEUTICAL CHEMICALS

No.	Name of Pharmaceutical	Raw materials required	Require- ment per	Unit cost of raw	Raw material	Annual require-	Annual of raw ma	
	Chemical		100 kg product kg	materials US\$/kg	cost per 100 kg product US\$	ment of raw mate- rials tons	Imported US\$	Local US\$
9	Paracetamol Annual proposed production 20 tons	1 P.Aminophenol 2 Acetic anhydride 3 Sodium hydrosulfite 4 Active carbon	96 90 1.8 3	15 1.2 1.2 2.2	960.00 108.00 2.16 6.60 1.076.76	19.2 18.0 200 kg 300 kg	192 .000 21.600 400 600 214 .600	- - -
10	Chlordiazepoxide Annual proposed production 1.5 tons	1 Chloramino benzophenone 2 Ethanol 3 Hydroxymethyl sulfate 4 Chloracetaldehyde 5 Sodium bicarbonate 6 Chloroform 7 Acetic acid 8 Chromic acid 9 Sodium chloride 10 Sodium bisulfite 11 Acetone 12 Monomethylamine 13 Methanol 14 Active carbon 15 Hyflowsupercel	205 905 82.5 170 102.5 400 255 57.5 155 10 87.5 58 48 8	12.00 2.50 13.00 7.00 0.6 1.2 1.0 2.5 0.7 1.5 1.8 4.4 1.8 2.2 2.2	2.460.00 2.262.50 1.072.50 1.190.00 61.50 480.00 255.00 143.75 108.50 15.00 157.50 255.20 86.40 17.60 17.60 8.583.05	3 13.57 1.23 2.55 1.5 6.0 3.8 860 kg 2.32 200 kg 1.3 870 kg 720 kg 120 kg	36.000 - 16.000 17.800 900 7.200 3.800 2.200 - 300 2.300 3.800 1.300 300 92,200	33.900 1.600 35.500
11	Niacin Annual proposed production 15 tons	l 3-Cyanopyridine 2 Sodium Hydroxide Sol. 3 Active carbon 4 Sulfuric Acid	90 80 2 150	6.2 0.5 2.2 0.12	558.00 40.00 4.40 18.00 620.40	13.5 12.0 300 kg 22.5	83.700 600 - 84.300	6.000 - 2.700 8.700
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Annex 8 (Continued)

No.	Name of Pharmaceutical	Raw materials required	Require- ment per	Unit cost of raw	daw material	Annual require-	Annual of raw ma	
	Chemical	<u>-</u>	100 kg product kg	materials US\$/kg	cost per 100 kg product US\$	ment of raw mate- rials tons	Imported US\$	Local US\$
12	Mebendazole Annual proposed production 3 tons	1 Thiourea 2 Methylchlorformate 3 Dimethylsulfate 4 3-4-Diaminobenzophenone 5 Acetic acid 6 Active carbon 7 Ethanol 8 Methanol 9 Sodium hydroxide	50 95 50 110 20 20 100 500	1.4 11.20 4.20 3.11 1.00 2.2 2.5 1.8 0.8	70.00 1.064.00 210.00 343.10 20.00 44.00 250.00 900.00 80.00	1.5 2.85 1.5 3.3 600 kg 600 kg 3.0 15.0	2.000 31.900 6.300 10.300 600 1.300 - 27.000 2.400 81.800	- - - - - 7.500
13	Ethambutol Annual proposed production 10 tons	1 D-2 Aminobutanol 2 1-2 Dichloroethane 3 Isopropanol 4 Benzene 5 Hydrochloric acid 6 Sulfuric acid 7 Sodium hydroxide	128 60 450 10 60 120 60	3.20 2.40 3.00 0.50 0.8 0.12 0.8	409.60 144.00 1.350.00 5.00 48.00 14.40 48.00 2.019.00	12.8 6 45 1 6 12 6	41.000 14.400 135.000 - - 4.800	500 4.800 1.500
14	lsoniazid Annual proposed production 5 tons	1 4-Cyanopyridine 2 Sodium Hydroxide 3 Sulfuric Acid 4 Ethanol 5 Ammonia 6 Hydrazine Hydrate 7 Active Carbon	110 90 350 500 80 100 5	6.20 0.50 0.42 2.5' 1.0 2.0	682.00 45.00 42.00 1.250.00 80.00 200.00 11.00 2.310.00	8.5 4.5 17.5 25.0 4.0 5.0 250 kg	34.100 - - - - 10.000 600 44.700	2.300 2.100 62.500 4.000
	Chlortriamazole Annual proposed production 2 tons	1 O-Chlorobenzoic Acid 2 Imidazole 3 Acetonitrile 4 Triethylamine 5 Benzene 6 Thionylchloride 7 Aluminium Chloride 8 Acetone 9 Phosphorous Penta Chlorid	190 45 200 67 420 192 270 200 215 50	5.4 8.0 7.5 3.6 0.5 0.7 1.3 1.8 1.4	1.026.00 360.00 1.500.00 241.20 210.00 134.40 351.00 360.00 301.00 25.00	3.8 0.9 4.0 1.4 8.4 3.8 5.4 4.0 4.3	20.500 7.200 30.000 - 4.200 2.700 7.200 7.200 6.000	5.500 - - - - - - - 500

Annex 8 (continued)

No.	Name of Pharmaceutical	Raw materials required	Require- ment per	Unit cost of raw	Raw material	Annual require-	Annual of raw me	
	Chemical		100 kg product kg	* materials US\$/kg	cost per 100 kg product US\$	ment of raw mate- rials tons	Imported US\$	Local US\$
16	Diazepam Annual proposed	1 Methyl chloramino benzophenone	180	5.60	1.008.00	3.6	20.200	-
	production 2 tons	2 Chloracetyl chloride	81	12.18	986.58	1.62	19.700	-
		3 Benzene	216	0.50	108.00	4.32	-	2.200
	ŀ	4 Acetone	43	1.80	77.40	860 kg	1.600	-
		5 Hexamine	133	4.50	598.50	2.66	-	_
		6 Ethanol	1.575	2.5	3.937.50	31.50	_	78.800
		7 Sodium bicarbonate	43	0.6	25.8	860 kg	500] -
		8 Active carbon	27	2.2	59.40	540 kg	1.200	-
	A Paragraphic Control of the Control	9 Hyflow supercel	4.5	2.2	9.90	90 kg	200	<u> </u>
					6.811.08		43.400	81.000
17	Nikethamide	1 Nicotinic acid	90	6.70	630.00	0.9	6.300	<u> </u>
	Annual proposed	2 Thionylchloride	179	0.8	14.3	1.8	1.200	_
	production 1 ton	3 Benzene	115	0.50	57.50	1.15	-	600
		4 Diethylamine hydrochloride	97	10.00	970.00	0.97	9.700	_
		5 Sodium hydroxide	54	0.80	43.20	0.54	400	_
		6 Toluene	290	0.60	174.00	2.90	_	1.800
		7 Hyflow supercel	18	2.20	39.60	180 kg	400	_
		8 Active carbon	7	2.20	15.40	70 kg	200	_
		9 Sodium sulfate	14	0.15	2.10	140 kg	-	200
		0 Sodium chloride	14	0.70	1.00	140 kg	_	200
		l Pot. Permanganate	1	5.46	5.46	10 kg	-	60
					1,952.60	_	18.200	2.860
18	Propranolol	1 L - Naphthol	121	8.96	1.075.20	2.42	21.700	
	Annual proposed	2 Epichlorhydrine	142	2.34	332.30	2.84	6.650	J
	production 2 tons	3 Sodium hydroxide	40	0.80	32.00	0.80	700] _
		4 Isopropylamine	135.5	2.10	284.60	2.70	5.000	
		5 Ethanol	520.0	2.50	1.300.00	10.40	-	26.000
		6 Benzene	140	0.50	70.00	2.80	-	1.400
		7 Active carbon	4.	2.2	8.80	80 kg	200	_
		8 Hydrochloric acid	14	0.7	1.00	280 kg	_	200
į		9 Isopropanol	60	3.0	180.00	. 1.2	3.600	-
		O Acetone	80	1.8	144.00	1.6	1.600	-
		l Hyflowsupercel	4	2.2	8.8	80 kg	200	
		2 Nitorogen gas	4 cm	-	<u> </u>	8 çm _		
				•	3.436.70		40.250	27.600

RAW MATERIAL REQUIREMENT FOR THE PRODUCTION OF PHARMACEUTICAL CHEMICALS - PRODUCT MIX - B

		MAN MAITHINI MEGATHERENT						
	g gapangapa kanal apadawakan kadapa sama membandan mangan magan milipin ng sagi mengadakan magaban s		Requirement	Unit cost	Raw	Annual	Annual cost	_
1	4 11		per 100 kg	of raw	material		of raw materi	als
No		Raw materials required	product kg	materials	cost per	of raw	Imported	Local
Ì	tical Chemical			us\$/kg	100 kg pro-	1	US\$	US\$
			L		duct US\$	tons	004	034
1			•					
1	Metronidazole	l 2-Methyl-5-Nitro Imidazole	190	10.0	1.900.00	11.4	114.000	
	proposed annual	2 Formic Acid	448	1.40	627.20	27.0	37.800	
- 1	production 6 tons	3 Ehtylene oxide	334	11.00	3.674.00	20.0	220.000	
- 1		4 Liq. Ammuonia	534	0.25	133.80	32.0	-	8.000
1		5 Sodium chloride	500	0.70	350.00	30.0		21.000
l l		6 Ethanol	156	2.50	390.00	10.0	-	20.500
- 1		7 Active carbon	7	2.2	15.4	420 kg _	900	
İ					7.090.40		372.700	49.500
- 2	Phenylbutazone	l Monochlorobenzene	188	1.20	225,60	9.9	11.400	
_]	proposed annual	2 Hydrazobenzene	87	3.00	261.00	4.4	13.200	
1	production 5 tons	3 Sodium Methoxide	28	4.00	112.00	1.4	5.600	
-		4 Diethyl-N-Butyl Malonate	102	7.00	714.00	5.0	35.000	
		5 Active carbon	10	2.20	22.00 .	.5	1.100	
		6 Hydrosulfite, sodium	1.3	1.20	1.56	65 kg	78	
1		7 Acetic acid	50	1.00	50.00	2.5	2.500	
1		8 Sulfuric Acid	50	0.12	6.00	2.5	•	. 300
1		9 Sodium carbonate	30	0.50	15.00	1.5		700
					1.407.16		68.878	1.000
	Ferrous Fumurate	l Ferrous sulfate	200	0.20	40.00	. 8	1.600	
		2 Fumaric acid	83	1.70	141.10	3.2	5.400	
	proposed annual production 4 tons	2 rumaric acid 3 Active carbon	3	2.2	6.60	120 kg	3.400	
	production 4 tons	4 Formalin	10.8 lt	0.4	4.30	120 kg	1.600	
			52	0.4	28.50	2	1.000	1.000
- 1		5 Sodium hydroxide 6 Ethanol	200	2.5	500.00	8		20.000
		о еснанот	200	۷۰٫۰ -	720.00	٥	8.900	21.000
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RAW MATERIAL REQUIREMENT FOR THE PRODUCTION OF PHARMAGEUTICAL CHEMICALS - PRODUCT MIX - B

	and the state of t	NAW PITTERIAL REQUIREMENT			1 1)	Annuál	Annual cost	
1	•		Requirement	Unit cost	Raw			: - 1 .
No.	Name of	Raw materials required	per 100 kg	of raw	material		of raw mater	1415
""]	Pharmaceutical	waw materials required	product kg	materials	cost per	of raw	Imported	Local
ļ	Chemica l			us\$/kg	100 kg pro-	materials	US\$	US\$
į				f	duct US\$	tons	054	
- 1			•					
4	Ibuprofen proposed	l Acetyl chloride	91	1.5	136.00	5.5	8.250	
- 1	annual production	2 Aluminium chloride	185	1.3	236.60	11.0	14.300	
1	6 tons	3 Dichloromethane	387	2.5	967.50	23.0	57.500	
1		4 Dimethyl sulfoxide	110.3	2.5	. 275.75	6.6	16.500	
1		5 Chloroform	50	1.2	60.00	3.0	3.600	}
a sa		6 Ethylene glyocol	448	0.8	358.40	30.0	24.000	
1		7 Hexane	132	0.9	118.80	8.0	7.200	
1		8 Hydrochloric acid	565	0.8	452.00	34.0		27.000
		9 Isobutyl benzene	151	5.0	755.00	9.0	45.000	27.000
		10 Methanol	120	1.8	216.00	7.2	45.000	12 000
		11 Potassium hydroxide	133	2.0	266.00	8.0	16.000	13.000
		12 Raney nickel	18					
ì		13 Sodium bicarbonate	1	4.0	72.00	1.0	4.000	
1			67	0.6	40.20	4.0	1	2.400
1		1	68	1.9	129.20	4.2	8.000	Ì
		15 Sodium chloride	125	0.7	87.50	7.5		5.300
		16 Sodium sulfate	100	0.15	15.00	6.0	}	900
1		17 Toluene	15	0.5	7.50	1.0		500
_					4.193.45		204.350	49.300
5	Aspirin proposed	l Salicilic acid	96	3.7	355.20	30	111.000	
1	annual production	2 Acetic anhydride	95	1.2	114.00	30	36.000	}
	30 tons	3 Sulfuric acid	4.5	0.12	8.40		30.000	000
- 1	30 20113	4 Sodium hydroxide	3.5			1.4	1	200
1	!	4 Southin Hydroxide).)	0.5	1.75	1.4	ļ	700
		<u>.</u>			497.35		147.000	900
6	Methyl salicitate	1 Salicilic acid	112	3.7	414.40	3.4	12.600	
- 1	proposed annual	2 Methanol	110	1:8	198.00	3.3		6.000
	production 3 tons	3 Sulfuric acid	17	0.12	2.04	0.5		10
- 1	•	4 Sodium carbonate	i2	0.5	6.00	0.4		200
- 1		5 Sodium sulfate	3	0.15	.45	0.1	}	1
		6 Potassium permanganate	oi	5.46	.95		•	10
1		o rocassium permanganare	0.	2.40		3 kg		10
-					621.84		12.600	6.230
- {								
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RAW MATERIAL REQUIREMENT FOR THE PRODUCTION OF PHARMACEUTICAL CHEMICALS - PRODUCT MIX - B

	Manager		Requirement	Unit cost of raw	Raw material	Annual	Annual cost of raw mater	(els
Nο	Name of Pharmaceutical Chemical	Raw materials required	per 100 kg product kg	materials us\$/kg	cost per 100 kg pro- duct US\$	of raw		Local US\$
7	.Sulfamethoxazole proposed annual production 4 tons	1 Acetone 2 Active carbon 3 Bacetylamino benzene	82	1.8	147.60 1.76	3.3 32 kg	5.900 100	
i		sulfonyl chloride 4 Liq ammonia 5 Benzene 6 Diethyl oxalate	195 737 33 205	4.5 0.25 0.5	877.50 184.25 16.50	8.0 . 30.0 1.3	36.000	7.500 700
		7 Hydroxylamine sulfate 8 Methanol 9 M.I.B.K	326 152	6.0 1.8 1.4	1.230.00 586.80 212.80	13.0 61.0	48.000 85.400	23.400
		O Pyridine Sodium Hydrosulfite Sodium hydroxide Sodium hypo chlorite 12%	97 6 133 64	5.5 1.2 0.5 0.20	533.50 7.20 66.50 12.80	4.0 0.3 5.3 2.6	22.000 400	2.600
		4 Sodium metal 5 Sulfuric acid 6 Toluene	34 252 94	16.0 0.12 0.5	544.00 30.24 47.00	1.4	22.400	1.200
	413				4.498.45		220.200	37.900
8	Trimethoprim proposed annual production 10 tons	2 Acrylonitrile 3 Active carbon 4 Liq ammonia 5 Aniline 6 Dimethyl Sulfoxide 7 Guanidine hydrochloride 8 Isopropanol 9 Morpholine 10 Sodium Hydroxide 11 Sodium methoxide 12 3.4.5 - trimethoxy	224 44 12 104 56 123 95 16 66 41	1.0 1.2 2.2 0.25 1.02 2.5 6.7 3.0 3.47 0.5 4.0	224.00 52.80 26.40 26.00 57.12 307.50 363.50 48.00 229.00 20.50 40.00	22.4 4.4 1.2 10.4 5.6 12.3 10.0 1.6 6.6 4.0	22.400 5.300 2.600 5.600 30.800 67.000 4.800 22.900 40.000	2.500
		benoza I dehyde	119	20.0	2.380.00	12.0	240.000	
		,			3.774.82		441.400	4.500
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RAW NATERIAL REQUIREMENT FOR THE PRODUCTION OF PHARMACEUTICAL CHEMICALS - PRODUCT MIX - B

, y - gyr gyrada media idan dan da dadarah Pritting - Mila capana niay ip Namely Mila er	and place and the second control of the second seco	Requirement per 100 kg	Unit cost of raw	Raw material	Annual rement	Annual cost of raw mater	ials
Name of Pharmaceu- tical Chemical	Raw materials required	product kg	materials us\$/kg	cost per 100 kg pro- duct US\$	of raw	Imported US\$	Local US\$
Pyrazinamide propose annual production 2	i l Pyrazine 2-3-dicarboxi- lic acid	180	25.0	4.500.00	03.6	90.000	
tons	2 Acetic anhydride	550	1.2	660.00	11.0	13.200	
	3 Methanol	472	1.8	849.60	9.5	13.200	17.100
	4 Toluene	90	0.5	45.00	1.8		900
	5 Liq ammonia	60	0.25	15.00	1.2	.]	300
and the species confirmment with the state of the state o				6.069.60		103.200	18.300
Haloperidol	l Aluminium chloride	100	1.3	130.00	10	13,000	
proposed annual	2 Fluoro benzene	60	8.00	480.00	6	48.000	
production 10 tons	3 Toluene	80	6.50	40.00	8		4.000
	4 Thionyl chloride	100	0.80	80.00	10	8.000	
	5 V-Chloro butyric acid	80	20.00	1.600.00	8	160.000	
	6 Benzene	300	0.5	150.00	30		15.000
	7 Petroleum Ether	300	1.00	300.00	30		30.000
	8 Potassium carbonate	40	0.33	13.20	4	1.300	I
	9 M.E.K	300	1.4	420.00	30	42.000	
	10 Potassium Iodide	50	20.4	1.000.00	5 ·	100.000	1
	11 P. Chloroaceto Phenone	250	5.00	1.250.00	25 .	125.000	
,	12 Methyl Iodide	240	8.00	1.920.00	24	192.000	1
1	13 Magnesium ribbon	4	12.00	4.80	40 kg	10	1
	14 Tetrahydrofuran	5	4.00	20.00	500 kg	2.000	1
	15 Ammonium chloride 16 Acetic acid	500	0.96	480.00	50	50.000	
	17 P. Formaldehyde	400	1.0	400.00	40	40.000	
	17 r. rormaldenyde 18 Acetic anhydride	50	0.86	43.00	5	4.000	
	19 Hydrogen Bromide	400	1.2	48.00	40	48.300	1
	20 Caustic soda	100	15.4	1.540.00	10	154.000	
į	21 Methanol	600	0.5	50.000	10		5.000
	22 Carbon-tetra-chloride	200	.62	360.00	60 20	10 000	30.000
	an outpoil certa-cliforing	200	.02	124.00	20	12.000	97 000
**** - *******************************				10.433.00	· · · · · · · · · · · · · · · · · · ·	999.310	84.000
				I		1	
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i			1	1	}		
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Annex 9 (continued

1	2 - 4 - 14 - 14 - 14 - 14 - 14 - 14 - 14		Requirement	Unit cost	l Raw	Annual	Annual cost	
				of raw	material	requirement		als
	Name of Pharmaceu-		per 100 kg		cost per	of raw	Of Edw macer.	
Nο	tical chemical	Raw materials required	product kg	materials			Imported	Local
				us\$/kg	100 kg pro-	l .	บร\$	US\$
				<u> </u>	duct US\$	tons	·	
		<u> </u>		ł		i		•
- 11	Chloriquine	l 4 Hydroxy-7chloro				1		
• • •	Phosphate proposed	quinoline	47	55	2.585.00	5.65	310.750	•
	annual production	2 Phosphorous oxychloride	94	1.5	141.00	11.3	9	
	12 tons	3 Dichloroethane	187	2.4	448.80	22.5	16.950 54.000	
	12 Lons	4 Novoldiamine	43.5	16.3	709.00			
		5 Ammonia	75	10.3	75.00	· 5.25	85.600	0.000
		6 Phosphoric acid	64.7	0.35	22.50	7.8	0.700	9.000
İ		7 Ethanol	58.8	2.5	147.00	8 .	2.700	17.500
		8 Carbon	5	2.3		7.0		17.500
		9 Phenol	23.5	0.8	11.00	0.6	1.300	
		10 Benzene	29		14.10	3.0	1.800	
		ll Caustic lye	73	0.5	14.50	4.0	•	2.000
1		ii Gaustic Tye	/3	0.5	36.50	9.0		4.500
			<u> </u>		4.203.60		473.100	33.000
12	Sulfin pyrazone	l Thiophenol	250	9.0	2.250.00	12.5	112.500	
	proposed annual	2 Dichloro ethane	340	2.4	816.00	17.0	40.800	
	production 5 tons	3 Caustic soda	108	0.5	54.000	5.0	10.000	2.500
	_	4 Diethyl malonate	283	5.0	1.415.00	14.0	70.000	2.300
		5 Sodium methoxide	137	2.4	139.40	6.9	16.600	
		6 Acetic acid	934	1.0	934.00	50.0	50.000	
		7 Chloro benzene	295	1.2	354.00	14.75	17.700	1
		8 Hydrazino bensene	258	6.0	1.548.00	12.9	77.400	
i		9 . Methanol	660	1.8	1.188.00	33	//.400	59.400
		10 Hydrogen perioxide	64	0.7	44.80	3.5	2.500	39.400
		,		•	8.743.20	, ,,,	387.500	61.900
			 					01.900
13	Trinidazole	l 2-Methyl-5-Nitro	190	10.0	1.900.00	7.6	76.000	
	proposed annual	imidazole			•	İ		
	production 4 tons	2 Triethylethanol	106	6.0	636.00	4.0	- 24.000	
		3 Sulfuric acid	57	0.12	6.84	2.5		3.000
i		4 Zinc chloride	204	1.17	238.68	8.0	9.400	
ł		5 Caustic soda	120	0.5	60.00	4.8		24.000
ı		6 Carbon	17	2.2	37.40	0.7	1.500	
Į		7 Acetic acid .	172	1.6	172.00	28.0	28.000	
I		8 Liq ammomia	750	0.25	187.50	30.0		7.500
1	·	9 llydrogen paroxide	320	0.8	256.00	13.0	10.400	
- 1	•	10 Hyflosupercel	16	2.2	35.20	0.7	1.500	Į
1	1	11 M.I.B.K	300	1.1	330.00	12	13.200	1
	ı		Į		3.859:62	Ļ	164.000	34.500
J	. [سو ، مردد د		104.000	1 34.500
- 1					•			
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nney 9 (continu

Annex 10

List of required imported raw materials

	Name of	Landed		Name of	Landed
No.		Price		Name of	Price:
**********	Raw Material	US\$	No.	Raw Material	US\$
1.	3-Cyanopryridine	6.19	51.	Thionylchloride	0.80
2.	Resin IRA-402	15.00	52.	Diethylamine hydrochloride	10.00
3.	Benzocaine	20.00	53.	Potassium permanganate	5.46
4.	Diethylamino Ethanol	11.55	54.	Alfa Naphthol	8.96
5.	Sodium Metal	16.00	55.	Epichlorhydrine	2.37
6.	Acetic Acid	1.00	56.	Isopropylamine	
7.	Sodium Hydrosulfite	1.20	57.	Thiourea	2.10
8.	Active Carbon	2.20	58.	Methylchlorformate	1.40
9.	Hyflosupercel	2.20	59.	Dimethylsulfate	4.20
10.	Isopropanol '	3.00	60.	3-4-Diaminobenzo phenone	
11.	Acetone	1.80	61.	D-2 Aminobutanol	3.11
12.	P.Chlorophenol	6.00	62.	4-Cyanopyridine	3.20
i3.	Chloroform	1.20	63.	Hydrazine hydrate	6.20
14.	Benzil	6.40	64.	O-Chlorobenzoic acid	2.00
15.	Potassium Hydroxide	2.00	65.	Imidazole	5.40
16.	M-Xylidine	2.40	66.	Acetonitrile	8.00
17.	Chloracetyl chloride	12.18	67.	Triethylamine .	7.50 3.60
18.	Diethylamine	8.30	68.	Aluminium chloride	0.70
19.	P-Anisidine	4.00	69.	Phosphorous pentachloride	1.40
20.	Sodium Nitrite	0.35	70.	2-Menthyl-5-Nitro imidazole	
21.	Zinc Dust	6.00	71.	Formic acid	
22.	P-Chlorobenzoyl Chloride	7.60	72.	Ethylene oxide	1.50
23.	Levulinic Acid	25.20	73.	Monochlorobenzene	11.00
24.	O-Phosphoric Acid	1.00	74.	Hydrazina	1.20
25.	Ethyl Acetate	1.50	75.	Sodium Methoxide	3.00
26.	2-Amino-6-Methyl Pyridine	12.00	76.	Diethyl-N-Butyl Malonate	4.00
27.	Petroleum Ether	1.00	77.	Ferrous sulfate	7.00
28.	Diethyl ethoxy methylene		78.	Fumaric acid	0.20
	malonate	11.30	79.	Formaldehyde	1.20
29.	Diphenyl ether	. 1.50	80.	Acetyl chloride	0.40
30.	Dimethyl formamide	1.20	81.	Dichloroethane	1.50
31	Dimethyl sulfate	4.20	82.	Dimethyl sulfoxide	2.50
32.	Caustic Soda flakes	0.80	83.	Ethylene glycol	2.50
34.	P-Hydroxy Azo benzene	3.30	85.		0.80
25	Codium mathorida	2 40	07.	Isobutylbenzene	5.00

Annex 10 (continued)

	No.	Name of Raw material	Landed Price US\$	
	99.	4-Hydroxy-7-chloro quinoline	55.00	
1	00.	Phosphorous Oxychloride	1.50	
1	01.	Novoldiamine	16.30	
1	02.	Phosphoric Acid	0.35	
1	03.	Thiophenol	9.00	
1	04.	Diethyl Malonate	5.00	
1	05.	Hydrogene Peroxide	0.70	
. 1	06.	Zinc Chloride	1.17	
1	07.	Fluorobenzene .	8.00	
1	08.	V-Chlorobutyric acid	20.00	
1	09.	Potassium carbonate	0.30	
1	10.	Methyl Ethyl Ketone	1.40	
1	11.	Potassium Iodide		
1	12.	P.Chloroaceto phenone	5.00	
1	13.	Methyl Iodide	8.00	
1	14.	Magnesium Ribbon	12.00	
1	15.	Tetra Hydrofuran	4.00	
1	16.	Ammonium chloride	0.96	
1	17.	P.Formaldehyde	0.86	
	18.	Hydrobromic acid	15.4	
	19.	Carbon Tetrachloride	0.62	

Source of Information: 1. Darupaksh

- 2. Chemical Market Reporter
- 3. Chemical Weekly (Bombay)
- 4. Sarabhai Research Centre

Annex [1]
List of Indigenously Available Raw Materials

No.	Name of Raw Material	Market* price US\$/kg	No.	Name of Raw Material	Market* price US\$/kg
1	Sulfuric Acid (98%)	0.12			
2	Hydrochloric Acid	0.80			
3	Nitric Acid (60%)	0.84 -			
14	Caustic Lye (50%)	0.50			
5	Sodium Bicarbonate	0.60		·	
_	Sodium Carbonate	0.50			
7	Sodium Chloride	0.70			
8	Sodium Sulfate	0.15			
ò	Ammonium Chloride	0.64	â		
10	Liquor Ammonia (24%)	0.25			
11	Ammonia Gas	1.00			
12	Ethanol	2.50			
13	Methanol	1.80			
14	Benzene	0.5			
	Toluene	0.5		•	Secretary Constraints
16	Kylene	0.5			
17	Urea	1.6			
	* Source of information: Darupakhsh as of March 1984				

Annex 12

Availability of Construction Materials, Facilities for Storage and Transport

All building construction materials are available. The price structure of the major construction materials is:

1. Cement US\$ 4.50/50 kg. bag

2. Bricks US\$60.00/1,000 bricks

3. Structural steel: US\$ 0.70/kg

Prevailing cost of building constructions:

For factory buildings - US\$ 814/m²

For godowns - US\$ 520/m²

Storage and transport facilities: There is a highway running across both the pilotplant building, which is existing and recommended for the multi-purpose pilot plant, and an available open piece of land. Transport facilities are available.

The existing storage facilities in the pilot plant building, considered for this project, will not be available because the basement is recommended for multi-purpose pilot plant. Storage facilities will have to be created by constructing a warehouse.

Annex 113

Availability of Utilities

Major utilities, such as steam, electricity, good quality and plentyful supply of water, are available during construction and erection periods.

Additional utilities for the multi-purpose pilot plant will have to be made available for which provision has been made in the project.

Required information:

Steam: Fuel charges for steam generation

US\$ 0.07/kg steam generated

Electricity: Supply, 440 V, 3 phase 50 \$\impreceps\$

Power failures do occur many times. To take care of this situation a 75 KVA diesel generator has been provided

Water: Good quality water is available either by sinking bore wells

or can be drawn from canal running along the highway

Quality: 250 p.p.m. Total hardness

550 p.p.m. Total dissolved solids

Cost of water: US\$ 0.21/1,000 lt

Cost of softing: US\$ 0.25/1,000 lt

Cost of dimineralization USS 0.46/1,000 lt

ANNEX 14

Additional Information

- 1. Customs duty in Iran on imported equipment 35%
- 2. Handling charges in freight and other charges required to be paid to bring equipment from the port to Teheran - US\$ 29 per ton
- 3. Rates of interest on borrowing:
 - a) From financial institutions 12%
 - b) From the Bank

- 12%
- 4. Rates for insurance permia R 19 per 1,000
- 5. Income tax rates, for pilot working only 20%
- 6. Sales tax if any nil
- 7. Testing charges for getting finished drugs nil
- 8. Rates for building constructions:
 - a) For factory purposes R1 70,000/sq.m
 - b) For godowns
- R1 45,000/sq.m.
- 9. Depreciation allowed on:
 - a) Equipment 10% st. line
 - b) Buildings 5%
- 10. Maintenance cost in per cent of:
 - a) Cost of equipment 5%
 - b) Cost of building constructions 2.5%

(1 US\$ = 86.5 Rials (R1).

Source of information: Darupakhsh as of March 1984

ANNEX 15

Training Requirement Outside the Country

	Number	Month
Production Director	1	6
Factory Chief	1	3
Financing Supervisor	1 .	1
Personnel (Quality Control) (Chemist, Toxilogist)	3	6
Production Manager, Chemist and Operator	5	10
Chemical Engineer (Designer)	1	3
Mechanical Engineer and Technicians	2	4
Total:	14	33

ANNEX .16

Personnel Requirement for the Plant

	Produc- tion	Labor- atory	Mainten- ance	Adminis- ration	Finance	Purchase	Services
Plant Manager, Chemist and high-level personnel	7	3	2	1	1	. 1	-
perators, Technicians, Clerk	4	3	3	3	3	2	1
Skilled workers	6	1	6	. 1	1	1	1
Unskilled workers	14	-	3	•	_	-	6
Total:	31	7	14	5	5	4	8

Total need: 74

Annex 17

Market Value of Pharmaceutical Chemicals

Product Mix

		
No.	Name of Pharmaceutical Chemical	Market Price* US\$/kg
1	Nicotanimide	8.00
2	Procaine Hydrochloride	46.30
3	Clofibrate	31.72
4	Diphenyl Hydantoin	12.58
5	Lignocaine Hydrochloride	46.30
6	Indomethacüb	37.03
7	Nalidixic Acid	69.45
8	Oxyphen Butazone	. 38.77
9	Paracetamol	14.77
10	Chlordiazepoxide	56.71
11	Niacín	9.26
12	Mebendazole	254.63
13	Ethambutol	393.52
14	Isoniazid	8.68
15	Clotriamazole	103.16
16	Diazepam	32.40
17	Nikethamide	13.88
18	Propranolol	23.15

^{*} These are the prevailing local purchase prices in Teheran as of March 1984. Information supplied by Darupakhsh

Annex 18 Market Value of Pharmaceutical Chemicals Product Mix B

No.	Name of Pharmaceutical Chemical	Market Value US\$/KG
1.	Metronidazole	23.00
2.	Phenylbutazone	13.94
3.	Ferrous Fumarate	2.80
4.	Ibuprofen	31.00
5.	Aspirin	2.80
6.	Methyl Salicilate	2.50
7.	Sulfamethaxozole	25.00
8.	Trimethoprim	45.00
9.	Pyrazinamide	64.40
10.	Haloperidol	340.00
11.	Chloroquine Phosphate	26.00
12.	Sulfinpyrazone	200.00
13.	Tinidazole	28.00

- Source of Information: 1. Chemical Weekly (Bombay)
 - 2. Sarabhai Research Centre
 - 3. Ambalal Sarabhai Enterprise

ANNEX 19
Cost of Labour and Overheads

·		
		Rls
Production		26,040,000
		, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Laboratory		7 900 000
2430144019		7,800,000
Waintana		
Maintenance		10,680,000
Administration		4,680,000
Finance		4,680,000
Purchase		3,360,000
Services		4,320,000
		7,320,000
Total		(1.5(0.000
10001		61,560,000
	=	711,600 US\$
		(1 US\$ = 86.5 Ris)

Source of information: Darupakhsh as of March 1984

COST OF PRODUCTION - PRODUCT MIX A

Name of Pharmaceutical Chemical

Figures in US\$

No.	Item	Nicoti- namide	Procaine NCl	Clofi- brate	Diphenyl Hydantoin		Indome- thacine	Nalidixic ^x Acid	Oxyphen- butazone	Paracetamo
					1					
1.	Coat of raw materials	9.02	40.90	33.35	11.37	25.57	79.32	206.71	57.72	10.76
2.	Cost of utilities	1.20	0.85	0.62	0.35	0.50	0.62	1.14	0.65	0.20
3.	Cost of labour & overheads	6.16	6.25	6.00	6.25	5.30	5.30	6.15	6.40	6.24
4.	Cost of depreciation and									
	maintenance	2.85	2.87	2.75	2.87	2.50	2.50	2.81	2.95	2.87
5.	Cost of interest	3.53	5.40	4.66	3.65	4.10	7.10	22.57	6.10	3.90
<u>5.</u>	Cost of insurance	0.26	0.38	0.37	0.28	0.30	0.55	1.70	0.46	0.29
	Cost of Production	23.02	56.65	47.75	24.61	38.24	95.09	241.08	74.28	24.36
	Market Prices per kg	8.00	46.30	31.72	12.58	46.30	47.03	69.45	38.77	14.77

No.		Chlordia- zepoxide	Niacin	Mebend- azole *	Ethambu- tol	Isonia- -zid	Clotri- mazole	Diazepam	Niketha- mide	Propran- olol
1.	Cost of raw material	85.83	6.20	29.81	21.20	23.10	45.00	68.71	20.80	34.36
2.	Cost of utilities	0.43	0.25	0.56	0.43	0.32	0.45	0.90	0.50	0.35
3.	Cost of labour and overheads	9.47	6.65	5.93	7.12	6.40	5.25	5.25	7.00	5.25
4.	Cost of depreciation and									
	maintenance	4.40	3.06	2.73	3.30	2.95	2.50	2.50	3.30	2.50
5.	Cost of interest	10.2	3.85	4.66	4.78	2.88	7.50	5.20	5.20	4.45
6.	Cost of insurance	0.73	0.28	0.33	0.36	0.34	0.55	0.45	0.40	0.35
	Cost of Production	111.06	20.29	44.02	37.29	35.99	61.25	84.01	37.20	47.26
EL 40eg en Well, in Silver, gleven sa	Market prices per kg	56.71	9.26	54.36	36.00	, 8.68	103.16	32.40	13.88	23.15

COST OF PRODUCTION - PRODUCT MIX - B

No.	Item	Metroni- dozole	Phenylbu- tazone	Ferrous Fumarate	Ibuprofen	Aspirin	Methyl Sali- cilate	Sulfame- thoxazole
1.	Cost of raw materials	70.90	14.7	7.20	41.92	4.76	6.11	47.20
2.	Cost of utilities	0.70	0.65	0.20	0.82	0.25	0.20	0.53
3.	Cost of labour and overheads	5.93	7.12	8.89	5.93	7.11	7.11	8.89
4.	Cost of depreciation and							
	maintenance	2.66	3.67	4.11	2.66	3.29	3.29	4.11
5.	Cost of interest	6.66	4.30	4.55	5.03	3.73	6.20	7.92
6.	Cost of insurance	0.42	0.30	0.32	0.33	0.28	0.43	0.50
	Cost of Production per kg	87.27	30.74	25.27	56.69	19.42	23.34	69.15
	Market Price per kg	23.00	13.94	2.80	31.00	2.80	2.50	25.00
No.	Item	Trimetho-	Pyrazina- mide	Haloperi- dol	Chloroquine Phosphate	Sulfin pyrazone	Tinidazole	****
		10.10	(0.00	100 00	10.01	0.7.50	20.50	
1.	Cost of raw materials	40.48	60.69	109.03	42.04	87.53	38.59	
2.	Cost of utilities	1.50	0.65	1.50	0.45	1.60	0.35	
3.	Cost of labour and overheads	7.12	7.12	7.12	7.12	7.12	7.12	
4.	Cost of depreciation and	2 20	2 20	2 00	0.75	2 (7	/ 11	
-	maintenance	3.29	3.29	3.29	2.75	3.67	4.11	
5.	Cost of interest	6.10	6.55	9.60	4.80	8.80	6.00	
6.	Cost of insurance	0.40	0.42	0.56	0.31	0.52	0.45	
a i ve i ttalka apa	Cost of production per kg	58.89	78.72	131.10	57.47	109.24	56.62	
	Market Price per kg	45.00	64.40	340.00	26.00	200.00	28.00	

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Annex: 22
Allocation of costs of depreciation, maintenance, labour and overheads

Product Mix A

Pharmaceutical Chemical Cotinamide Cotinamid	productions tions 15 8 3	Weightage 13 7 2.5	Depreciation and Maintenance US\$ 42,700 (2.85) 23,000 (2.87) 8,200	US\$ 92,500 (6.16) 50,000 (6.25)
ocaine Hydrochloride ofibrate phenyl Hydentoin	8	7	42,700 (2.85) 23,000 (2.87)	92,500 (6.16) 50,000 (6.25)
ocaine Hydrochloride ofibrate phenyl Hydentoin	8	7	(2.85) 23,000 (2.87)	(6.16) 50,000 (6.25)
ofibrate phenyl Hydentoin	3		(2.87)	(6.25)
phenyl Hydentoin		2.5	8,200	
	4		(2.73),	18,000 (6.00)
gnocaine Hydrochloride		3.5	11,500 (2.87)	25,000 (6.25)
	2	1.5	5,000 (2.50)	10,600 (5.3)
domethacine	2	1.5	5,000 (2.50)	10.600 (5.3)
lidixic Acid	7	6	19,700 (2.81)	43,000 (6.15)
yphen Butazone	10	9	29,500 (2.95)	64,000 (6.4)
rzcetamol	20	17.5	57,500 (2.87)	1.24,500 (6.24)
lorodiazepoxide	1.5	2.0	6,600 (4.4)	14,200 (9.47)
acin	15	14	46,000 (3.06)	99,700 (6.65)
ben dazole	3	2.5	8,200 (2.73)	17,800 (5.93)
hambutol	10	10	33,000 (3.30)	11,200 (7.12)
oniazid	5	4.5	14,800 (2.95)	32,000 (6.40)
lortramazole	2	1.5	5,000 (2.50)	10,500 (5.25)
azepam	2	1.5	5,000 (2.50)	10,500 (5.25)
kethamide	1	1.0	3,300 (3.30)	7,000 (7.00)
copranolol	2	1.5	5,000 (2.50)	10,500 (5.25)
	oniazid lortramazole azepam kethamide opranolol	oniazid 5 lortramazole 2 azepam 2 kethamide 1	oniazid 5 4.5 lortramazole 2 1.5 azepam 2 1.5 kethamide 1 1.0 opranolol 2 1.5	hambutol. 10 10 33,000 (3.30) oniazid 5 4.5 14,800 (2.95) lortramazole 2 1.5 5,000 (2.50) azepam 2 1.5 5,000 (2.50) kethamide 1 1.0 3,300 (3.30) opranolol 2 1.5 5,000 (2.50)

 $\frac{\text{Annex 23}}{\text{Allocation of cost of depreciation, maintenance, labour and overheads}}$ Product Mix B

No.	Name of Pharmaceutical Chemical	Annual Froduction Tons	Percentage Weightage	Allocation of Depreciation & Maintenance	cost of Labour and Overheads
1.	Metrobidazole	6	5	16.450	35.580
2.	Phenylbutazone	5	5	(2.66) 16.450 (J.67)	(5.93) 35.580 (7.12)
3.	Ferrous Fumarate	4	5	16.450	35.580 (8.89)
4.	Ibuprofen	6	5	16.450 (2.66)	35.580 (5.93)
5.	Aspirin	30	30	98.700 (3.29)	213.480 (7.11)
6.	Methyl Salicilate	3	3	9.870 (3.29)	21.348 (7.11)
7.	Sulfamethoxazole	4	5	16.450 (4.11)	35.580 (8.89)
8.	Trimethoprim	10	10	32.900 (3.29)	71.160 (7.12)
9.	Pyrazinamide	2	2	6.580 (3.29)	14.232 (7.12)
10.	Haloperidol	10	10	32.900 (3.29)	71.160 (7.12)
11.	Chloroquine Phosphate	e 12	10	32.900 (2.75)	71.160 (7.12)
12.	Sulfinpyrazone	5	5	16.450 (4.11)	35.580 (7.12)
13.	Tinidazole	4	5	16.450 (4.11)	35.580 (7.12)
				329.000	711.600

Annex 24

Cost of Depreciation and Maintenance

Annual Depreciation and Maintenance

Α.	Cost of Equipment	US\$	1,940,000		
	Annual cost of depreciation at 15% since it is a chemical plant			US\$	291,000
	Annual cost of maintenance				29,000
В.	Cost of civil construction		1,000,000*		
	Annual depreciation of building at 5%				5,000
	Annual maintenance				4,000
	Total cost of depreciation and maintena	ınce			329,000
	* Refer to Annex 2				
	Cost of Labour				
	From Annex 15				•

Basis for allocation of cost of maintenance, depreciation and labour

Because more than one product will be produced in this plant the cost of depreciation, maintenance and direct labour have been allotted according to calculated weightage for every pharmaceutical chemical based on the usage of the equipment by that particular chemical.

711,600

Cost of Raw Materials

This cost has been taken vide Annex 6.

Total cost of direct labour and overheads

Cost of Services

Because of scanty process information, cost of utilities are given on ad hoc basis taking into consideration amount of solvents used and recovered by any particular pharmaceutical during the production

Annex 25
Allocation of the cost of Interest

Product Mix A

No.	Name of Pharmaceutical	Annual Produc- tion tons	Percentage Weightage	Allocation of cost of interest on fixed cost US\$	Cost of interest on invent- ories US\$	Total annual cost of interest US\$	Cost of interest per kg of product US\$
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Nicotinamide Procaine Hydrochloride Clofibrate Diphenyl Hydantoin Lignocaine Hydrochloride Indomethaeine Nalidixic Acid Oxyphen Butazone Paracetamol Chlordiazepoxide Niacin Mebendazole Ethambutol Isoniazid Chlortriamazole Diazepam Nikethamide Propranolol	15 8 3 4 2 7 10 20 1.5 15 3 10 5 2 2 2	13 7 2.5 3.5 1.5 1.5 6 9 17.5 2.0 14 2.5 10 4.5 1.5 1.5	45,000 24,200 8,500 12,000 5,200 20,500 31,200 60,000 7,000 48,500 34,500 17,200 5,200 5,200 3,400 5,200	8,000 19,000 6,000 2,600 3,000 9,400 137,500 29,700 18,000 8,300 9,300 5,500 13,300 7,200 9,800 7,200 1,800 3,200	53,000 43,200 14,000 14,600 8,200 14.600 158,000 61,000 78,000 15,300 57,800 14,000 47,800 14,400 15,000 12,400 5,200 8,900	3.53 5.40 4.66 3.65 4.10 7.1 22.57 6.10 3.90 10.20 3.85 4.66 4.78 2.88 7.50 6.20 5.20 4.45
	* Total fixed cost, vide Annual interest at 12%			O.	·		

600

Annex 26
Allocation of the cost of Interest

Product Mix B

No.	Name of Pharmaceutical Chemical	Annual Produc- tion Tons	Percen- tage Weight- age	Allocation of cost of interest on fixed cost US\$	Allocation of cost of interest on inven- tories US\$	Total annual Cost of interest US\$	Cost of interest per kg of Product US\$
ı.	Metronidazole	6	5 .	17.350	23.000	40.350	6.66
2.	Phenylbutazone	5	5	17.350	4.200	21.500	4.30
3.	Ferrous Fumarate	4	5	17.350	900	18.250	4.55
4.	Ibuprofen	6	5	17.350	13.000	30.350	5.06
5.	Aspirin	30	30	103.100	8.800	112.000	3.73
6.	Methyl Salicilate	3	3	103.310	8.300	18.600	6.20
7.	Sulfamethoxazole	4	5	17.350	14.300	31.650	7.90
8.	Trimethoprim	10	10	34.700	26.500	61.200	6.10
9.	Pyrazinamide	2	2	6.940	6.170	13.100	6.55
10.	Haloperidol	10	10	34.700	61.200	96.000	9.60
11.	Chloroquine Phosphate	12	10	34.700	23.000	57,700	4.80
12.	Sulfinpyrazone	5	5	17.350	24.440	41.500	8.30
13.	Tinidazole	4	5	17.350	6.960	24.000	6.00
				345.900			

Annual Interest on the Investment on Inventories of Raw Materials

Product Mix A

No.	Name of	Inventories		Total Inventory	'Annual Interest
	Pharmaceutical Chemical	Raw Materials	Others		at 12%
	,	U\$\$	US\$	บรรุ .	US\$
1	Nicotinamide	44,000	22,000	66,000	8,000
2	Procaine Hydrochloride	105,000	52,000	157,000	19,000
3	Clofibrate	34,000	17,000	51,000	6,000
4	Diphenyl Hydantoin	15,000	7,000	22,000	2,600
5	Lignocaine Hydrochloride	17,000	8,000	25,000	3,000
6	Indomethacine	52,000	26,000	78,000	9,400
7	Nalidíxic Acid	764,000	382,000	1,146,000	137,000
8	Oxyphen Butazone	165,000	83,000	248,000	29,700
9	Paracetamol	100,000	50,000	150,000	18,000
10	Chlordiazepoxide	46,000	23,000	69,000	8,300
11	Niacin	51,000	26,000	77,000	9,300
12	Mebendazole	31,000	15,000	46,000	5,500
13	Ethambutol	74,000	37,000	111,000	13,300
14	Isoniazid	40,000	20,000	60,000	7,200
15	Chlortiamazole	55,000	27,000	82,000	9,800
15	Diazepam	40,000	20,000	60,000	7,200
17	Nikethamide	10,000	5,000	15,000	1,800
18	Propranolol	21,000	10,000	31,000	3,700
despiration of the second second					
		1			

 $\frac{\text{Annex 28}}{\text{Annual Interest on Investment on Inventories of Raw Materials}}$ Product Mix B

Nc.	Name of Pharmaceutical	Inventori Raw Materials US\$	es Others US\$	Total Inventory US\$	Annual Interest @ 12% US\$	
1.	Metronidazole	128.000	64.000	192.000	23.000	
2.	Phenylbutazone	23.000	12.000	35.000	4.200	
3.	Ferrous Fumarate	5.000	2.500	7.500	900	
4.	Ibuprofen	72.000	36.000	108.000	13.000	
5.	Aspirin	49.000	24.500	73.500	8.800	
6.	Methyl Salicilate	53.000	26.500	69.500	8.300	
7.	Sulfamethoxazole	79.500 ⁻	39.500	119.000	14.300	
8.	Trimethoprim	147.300	73.600	221.000	26.500	
9.	Pyrazinamide	34.400	17.000	51.400	6.168	
10.	Raloperidol	340.100	170.000	510.000	61.200	
11.	Chloroquine Phosphate	127.400	63.600	191.000	23.000	
12.	Sulfinpyrazone	134.200	67.000	201.200	24.140	
13.	Tinidazole	55.000	3.000	58.000	6.960	

Annex 29

Allocation of Cost of Insurance

Product Mix A

Amount to be insured

								4	1
No.	Name of Pharmaceutical Chemical	Annual Product- ion Tons	Percentage Weightage	Alloca- tion of Fixed Cost US\$	Cost of Invento- ries US\$	Total Amount Insured US\$	Annual Premium at 9/1000	Cost of Insurance per kg US\$	
	Nicotinamide	15	13	375,000	66,000	441,700	4,000	0.26	
2	Procaine Hydrochloride	8	7	202,300	157,000	359.300	3,000	0.38	
3	Clofibrate	3	2.5	72,200	51,000	123,200	1,100	0.37	
	Diphenyl Hydantoin	4	3.5	101,200	22,000	123,200	1,100	0.28	
4	Lignocaine Hydrochloride	2	1.5	43,300	25,000	68,300	600	0.30	
5	Indomethacine	2	1.5	43,300	78,000	121,300	1,100	0.55	
6	Nalidixic Acid	7	6	173,400	1,146,000	1,319,400	11,900	1.70	
7 8	Oxyphen Butazone	10	9	260,100	248,000	508,100	4,600	0.46	
		20	17.5	505,750	150,000	655,750	5,900	0.29	
9	Paracetamol Chlordiazepoxide	1.5	2	57,800	69,000	126,800	1,100	0.73	
10		15	14	404,600	77,000	481,600	4,300	0.28	
11	Niacin .	3	2.5	72,200	46,000	118,200	1,000	0.33	
12	Mebendazole	10	10	289,000	111,000	400,000	3,600	0.36	
13	Ethambutol	5	4.5	130,000	60,000	190,000	1,700	0.34	
14	Isoniazid	2	1.5	43,300	82,000	125,000	1,100	0.55	
15	Clotriamazole	2	1.5	43,300	60,000	103,300	900	0.45	
16	Diazepam	1	1	28,900	15,000	43,000	400	0.40	
17	Nikethamide	2	1.5	43,300	31,000	74,300	700	0.35	l
18	Propranolol	&	+ • •		-				

2,890,000

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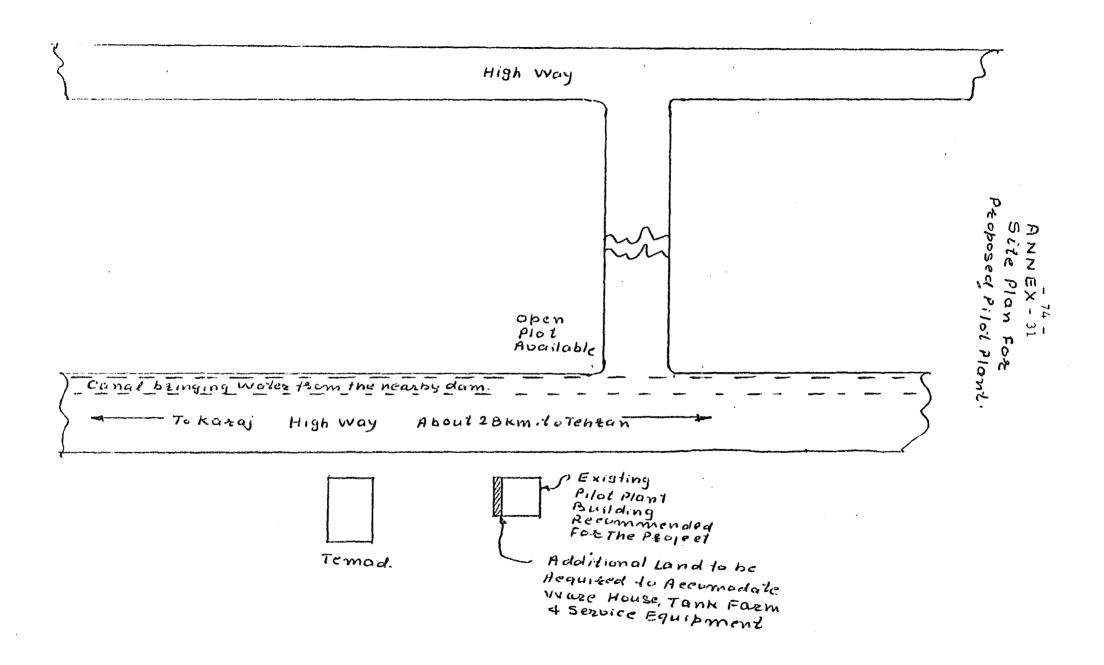
Annex 30

Allocation of Cost of Insurance
Amount to be Insured

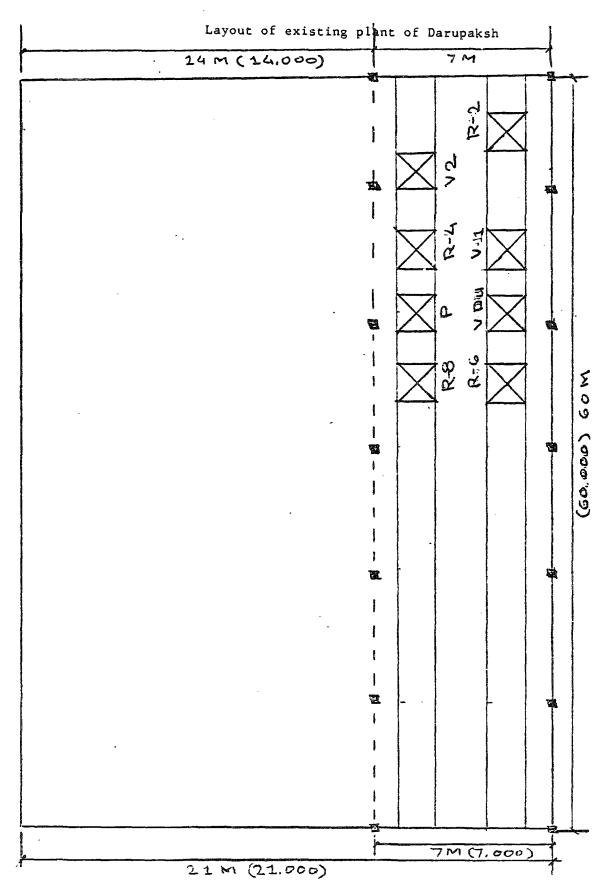
Product Mix B

No.	Name of Pharmaceutical 'Chemical	Annual Production Tons	Percentage Weightage	Allocation of Fixed Cost US\$	Cost of Invento- ries US\$	Total Amount Insured US\$	Annual Premium @ 9/1000	Cost of Insurance per kg US\$
1.	Metronidazole	6	5 .	144.500	128.300	273.000	2.500	0.42
2.	Pnen y l but az one	5	5	144.500	23.000	167.500	1.500	0.30
3.	Ferrous Fumarate	4	5	144.500	5.000	150.000	1.300	0.32
4.	1buprofen	6	5	144.000	72.000	216.500	2.000	0.33
5.	Aspirin	30	30	867.000	49.000	916.000	8.300	0.28
6.	Methyl Salicilate	3	3	86.700	53.300	140.000	1.300	0.43 🛶
7.	Sulfamethoxazole	4	5	144,500	79.400	224.000	2.000	თ 0.50
8.	Trimethoprim	10	10	289.000	147.300	436.000	4.000	0.40
9.	Pyrazinamide	2	2	57.800	34.000	92.200	830	0.42
0.	Haloperidol	10	10	289.000	340.000	629.000	5.660	0.58
1.	Chloroquine Phosphate	12	10	289.000	127.400	416.500	3.800	0.31
2.	Sufinpyrazone	5	5	144.500	134.200	278.700	2.510	0.52
3.	Tinidazole	4	5	144.500	55.000	199.500	1.800	0.45

2.890.000

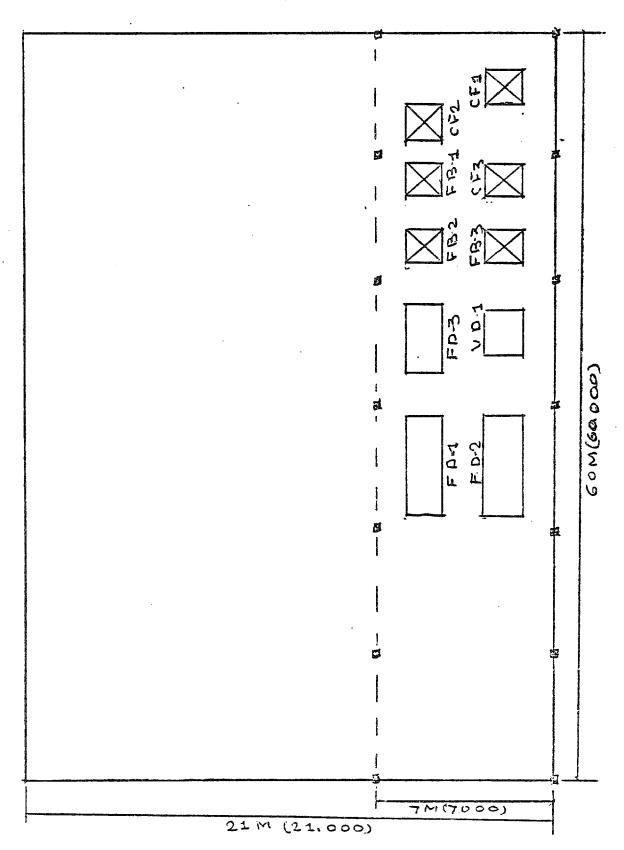


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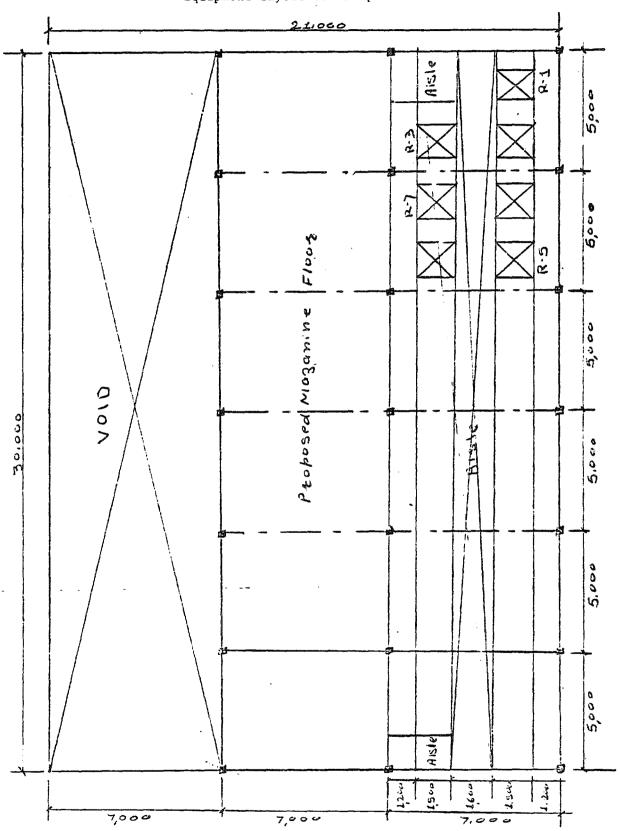
existing Ground Floce of Pilot Plant Buildgof Dazupakhsh

Plant Building of Darupaksh



Basement of Pilot Plant Buildsof Darupokhsh

Equipment Layout for Proposed Pilot Plant



Ptoposed Maganine Floor over Existing Geound Floor of Pilot Plant Buldge of Darupakhsh

Annex 35

List of the Visited Institutions

1. <u>Daruparksh</u>: A Government undertaking for the manufacture of pharmaceutical formulations

Dr. M. E. Zolfaghari Manager, Basic Pharmaceutical Production of Temad (a Division of Darupakhsh), Teheran

2. National Industries Organization:

Dr. P. Lolavar Group Manager of National Industries Organization, Teheran

3. Alhayi Pharmaceutical Co:

Dr. Gh. Akhavan Fazid Managing Director and Member of the Board of Alhavi Pharmaceutical Company, Teheran

Mr. M. Baloutehian Planning and Materials Manager of Alhavi Pharmaceutical Co.

4. Toobi:

Dr. Razaeyan, General Manager

Mr. Khazaet, Financial Manager

 $\mbox{Mr.}\xspace$ Esmailnezad, Chemical Engineer in Charge of Production and Development

Mr. Houssaini, Chemical Engineer

Dr. Morteza, Head of Research Laboratories

ANNEX:

Cost of Production

	and the second of the second o	Name of Pharmaceutical Chemical Figures in US\$							
No.	ltem	Niacin- amide	Procaine HCl	Clofi- brate	Diphenyl Nydantoin	Lignocaine HCl	Indome- thacine	Nalid Aci	
1	Cost of raw materials	9.02	40.90	33.35	11.37	25.57	79.32	327.	
2	Cost of utilities	1.20	0,85	0.62	0.35	0.50	0.62	1.	
3	Cost of labour and overheads	6.16	6.25	6.00	6.25	5.30	5.30	6.	
4	Cost of depreciation and maintenance	2.85	2.87	2.75	2.87	2.50	2.50	2.	
5	Cost of interest	3.53	5.40	4.66	3.65	4.10	7.10	22.	
6	Cost of insurance	0.26	0.38	0.37	0.28	0.30	0.55	1.	
r 18200000 agenyenyya 182000	Cost of production	23.02	56.65	47.75	24.61	38.24	95.09	362.	
	Market prices per kg	8.00	46.30	31.72	12.58	46.30	37.03	69.	
No.	Item	Chlordia- zepoxide	Niacin	Mebend-* azole	Etham-* butol	Isoniazid	Clotria- mazole	Diaze	
1	Cost of raw materiala	85.83	7.40	30.79	21.20	6.94	82.52	25.	
2	Cost of utilities	0.43	0.25	0.56	0.43	0.32	0.45	0.1	
3	Cost of labour and overheads	9.47	6.65	5.93	7.12	6.40	5.25	5.	
4	Cost of depreciation and maintenance	4.40	3.06	2.73	3.30	2.95	2.50	2.	
5	Cost of interest	10.2	3.85	4.66	4.78	2.88	7.50	6.	
6	Cost of insurance	0.73	0.28	0.33	0.36	0.34	0.55	0.4	
and the state of t	Cost of production	111.06	21,49	40.00	37.29	19.83	98.75	41.	
	Market prices per kg	56.71	9.26	254.63	393.52	8.68	109,16	32.4	

^{*} Market prices of these products seem to be exhorbitant

x Information available on raw material requirement appears doubtful

Annex:
Allocation of costs of depreciation, maintenance, labour and overheads

No.	Name of Pharmaceutical	Annual produc-	Percentage Weightage	Allocation	of costs of
Pharmaceutical Chemical		tions · tons	weightage	Deprecia- tion and Maintenance	Labour and Overheads
				US\$	US\$
1	Nicotinamide	15	13	42,700 (2.85)	92,500 (6.16)
2	Procaine Hydrochloride	8	7	23,000 (2.87)	50,000 (6.25)
3	Clofibrate	3	2.5	8,200 (2.73),	18,000 (6.00)
4	Diphenyl Hydentoin	4	3.5	11,500 (2.87)	25,000 (6.25)
5	Lignocaine Hydrochloride	2	1.5	5,000 (2.50)	10,600 (5.3)
6	Indomethacine	· 2	1.5	5,000 (2.50)	10.600 (5.3)
7	Nalidixic Acid	7	Ġ	19,700 (2.81)	43,000 (6.15)
8	Oxyphen Butazone	10	9	29,500 (2.95)	64,000 (6.4)
9	Paracetamol	20	17.5	5 ⁷ ,500 (2.87)	124,500 (6.24)
10	Chlorodiazepoxide	1.5	2.0	6,600 (4.4)	14,200 (9.47)
11	Niacin ,	15	14	46,000 (3.06)	99,700 (6.65)
12	Mebendazole	3	2.5	8,200 (2.73)	17,800 (5.93)
13	Ethambutol	10	. 10	33,000 (3.30)	11,200 (7.12)
14	Isoniazid	5	4.5	14,800 (2.95)	32,000 (6.40)
15	Chlortramazole	2	1.5	5,000 (2.50)	10,500 (5.25)
16	Diazepam	2	1.5	5,000 (2.50)	10,500 (5.25)
17	Nikethamide	1	1.0	3,300 (3.30)	7,000 (7.0 0)
18	Propranolol	2	1.5	5,000 (2.50)	10,500 (5.25)
	ures in brackets are respective pharmaceutical chemical	costs in US\$ p	er kg	329,000	711,600

Annex

Cost of Depreciation and Maintenance

Annual Depreciation and Maintenance

Α.	Cost of Equipment	US\$	1,940,000		
	Annual cost of depreciation at 15% since it is a chemical plant			US\$	291,000
	Annual cost of maintenance				29,000
В.	Cost of civil construction		1,000,000*		
	Annual depreciation of building at 5%				5,000
	Annual maintenance				4,000
	Total cost of depreciation and maintena	ince	•		329,000

* Refer to Annex 2

Cost of Labour

From Annex 15

Total cost of direct labour and overheads

711,600

Basis for allocation of cost of maintenance, depreciation and labour

Because more than one product will be produced in this plant the **co**st of depreciation, maintenance and direct labour have been allotted according to calculated weightage for every pharmaceutical chemical based on the usage of the equipment by that particular chemical.

Cost of Raw Materials

This cost has been taken vide Annex 6.

Cost of Services

Because of scanty process information, cost of utilities are given on ad hoc basis taking into consideration amount of solvents used and recovered by any particular pharmaceutical during the production

Annex
Allocation of the cost of Interest

No.	Name of Pharmaceutical	Annual Produc- tion tons	Percentage Weightage	Allocation of cost of interest on fixed cost US\$	Cost of interest on invent- ories
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Nicotinamide Procaine Hydrochloride Clofibrate Diphenyl Hydantoin Lignocaine Hydrochloride Indomethaeine Nalidixic Acid Oxyphen Butazone Paracetamol Chlordiazepoxide Niacin Mebendazole Ethambutol Isoniazid Chlortriamazole Diazepam Nikethamide Propranolol	15 8 3 4 2 2 7 10 20 1.5 15 3 10 5 2 2	13 7 2.5 3.5 1.5 1.5 6 9 17.5 2.0 14 2.5 10 4.5 1.5 1.5	45,000 24,200 8,500 12,000 5,200 20,500 31,200 60,000 7,000 48,500 8,500 34,500 17,200 5,200 5,200 3,400 5,200	8,000 19,000 6,000 2,600 3,000 9,400 137,500 29,700 18,000 8,300 9,300 5,500 13,300 7,200 9,800 7,200 1,800 3,200
	* Total fixed cost, vide Annual interest at 12%			347,000*	

- 83 - Annex

Annual Interest on the Investment on Inventories of Raw Materials

No.	Name of	Inventori		Total Inventory	Annual Interest at 12%	
	Pharmaceutical Chemical	Raw Materials	Others			
		US\$	US\$	US\$	US\$	
1	Nicotinamide	. 44,000	22,000 .	66,000	8,000	
2	Procaine Hydrochloride	105,000	52,000	157,000	19,000	
3	Clofibrate	34,000	17,000	51,000	6,000	
4	Diphenyl Hydantoin	15,000	7,000	- 22,000	2,600	
5	Lignocaine Hydrochloride	17,000	8,000	25,000	3,000	
6	Indomethacine	52,000	26,000	78,000	9,400	
7	Nalidixic Acid	764,000	382,000	1,146,000	137,000	
8	Oxyphen Butazone	165,000	83,000	248,000	29,700	
9	Paracetamol	100,000	50,000	150,000	18,000	
10	Chlordiazepoxide	46,000	23,000	69,000	8,300	
11	Niacin	51,000	26,000	77,000	9,300	
12	Mebendazole	31,000	15,000	46,000	5,500	
13	Ethambutol	74,000	37,000	111,000	13,300	
14	Isoniazid	40,000	20,000	60,000	7,200	
15	Chlortiamazole	55,000	27,000	82,000	9,800	
16	Diazepam	40,000	20,000	60,000	7,200	
17	Nikethamide	10,000	5,000	15,000	1,800	
18	Propranolol	21,000	10,000	31,000	3,700	
-						
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Amount to be insured

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No.	Name of Pharmaceutical Chemical	Annual Product- ion Tons	Percentage Weightage	Alloca- tion of Fixed Cost US\$	Cost of Invento- ries US\$	Total Amount Insured US\$	Annual Premium at 9/1000	Cost of Insurance per kg US\$
1	Nicotinamide	15	13	375,000	66,000	441,700	4,000	0.26
2	Procaine Hydrochloride	8	7	202,300	157,000	359.300	3,000	0.38
3	Clofibrate	3	2.5	72,200	51,000	123,200	1,100	0.37
4	Diphenyl Hydantoin	4	3.5	101,200	22,000	123,200	1,100	0.28
Ť	Lignocaine Hydrochloride	2	1.5	43,300	25,000	68,300	600	0.30
5		2	1.5	43,300	78,000	121,300	1,100	0.55
6	Indomethacine	7	6	* 173,400	1,146,000	1,319,400	11,900	1.70
7	Nalidixic Acid	10	9	260,100	248,000	508,100	4,600	0.46
8	Oxyphen Butazone		17.5	505,750	150,000	655,750	5,900	0.29
9	Paracetamol	20		·	69,000	126,800	1,100	0.73
10	Chlordiazepoxide	1.5	2	57,800		481,600	4,300	0,28
11	Niacin	15	14	404,600	77,000			•
12	Mebendazole	3	2.5	72,200	46,000	118,200	1,000	0.33
13	Ethambutol	10	10	289,000	111,000	400,000	3,600	0.36
14	Isoniazid	5	4.5	130,000	60,000	190,000	1,700	0.34
15	Clotriamazole	2	1.5	43,300	82,000	125,000	1,100	0.55
16	Diazepam	2	1.5	43,300	60,000	103,300	900	0.45
17	Nikethamide	1	1	28,900	15,000	43,000	. 400	0.40
18	Propranolol	2	1.5	43,300	31,000	74,300	700	0.35

2,890,000

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Annex .

List of the Visited Institutions

1. <u>Daruparksh</u>: A Government undertaking for the manufacture of pharmaceutical formulations

Dr. M. E. Zolfaghari Manager, Basic Pharmaceutical Production of Temad (a Division of Darupakhsh), Teheran

2. National Industries Organization:

Dr. P. Lolavar Group Manager of National Industries Organization, Teheran

3. Alhavi Fharmaceutical Co:

Dr. Gh. Akhavan Fazid Managing Director and Member of the Board of Alhavi Pharmaceutical Company, Teheran

Mr. M. Baloutehian
Planning and Materials Manager of Alhavi Pharmaceutical Co.

4. Toobi:

Dr. Razaeyan, General Manager

Mr. Khazaet, Financial Manager

Mr. Esmailnezad, Chemical Engineer in Charge of Production and Development

Mr. Houssaini, Chemical Engineer

Dr. Morteza, Head of Research Laboratories