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MANUFACTURE OF INTRAVENOUS FLUIDS AT PHILIPPINES GOVERNMENT HOSPITAL IN MANILA

SI/PHI/89/802

PHILIPPINES

Technical report: Individual work, findings and recommendations*

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

Based on the work of Dr. Lajos Aradi,
industrial pharmacist

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United Nations Industrial Development Organization
Vienna

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* This document has not been edited.

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I wish to acknowledge with thanks the wholehearted assistance and support extended to me by the D.O.H. and P.G.H.

I wish expecially express my thanks to Hon. R.M. Gamboa Undersecretary, Department of Health, Dr. L.H. Lazatin Ass. Director for Fiscal Services, PHG and Project Manager, Prof. W. Estacio Chairman, Industrial Pharmacy, College of Pharmacy U.P. Manila and Fillipino Counterpart expert, and last but not least Mrs Kathryn P. Sanbs Project Coordinator.

PREFACE

Part I. of this report covers the work which has been done in community by the two experts.

Mr . Lajos Aradi and Mr. Svend Bentholm

and which has been discussed with Prof. William Estacio who was nominated as counterpart to the mission.

Part II. covers the individual work and findings of the two experts.

RECOMMENDATION

1. We propose establishment of an I.V. Solution manufacturing plant in the Manila General Hospital.

   Our reasons are as follows:

   a./ the infusion consumption is the biggest in this hospital;
   b./ the hospital is equipped with the necessary basic utilities;
   c./ proper place is available for the I.V. plant;
   d./ establishment of an I.V. solution plant would assist University education too. Students could gain practical experiences in the production of steril large volumen parenterals;
   e./ cost of products will decrease to fifty percent of the current prices;

This is estimated to give a yearly saving of above 10 Million Pesos for the Manila Government Hospitals and M.G.H.

2. According to our current knowledge, we suggest for the planned production unit filling into plastic bottles as the most modern and safest solution.

3. We intend to use this unit as a pilot plant in the Philippines, because due to its medium capacity/1 million liter per year in one shift/ it could operate profitably, if set up in several parts of the country.

4. The possibility of planning small volume fluid (eye drops) plant which could be attached to the infusion plant occured during our work.
   We propose establishment of a production plant with a capacity of 1 - 1,2 Million units/year.

5. We propose for the reliable operation of the plant training of 2-3 persons abroad.

SUMMARY

We had to solve the following problems:

I. Examine the possibility of installing an infusion (i.v. fluids) plant.
At this point we also had to consider the standpoint of the Manilan experts. Here, the following details have to be listed:

a, information connected with the installation of a plant,

b, capital for running the project and demand for investment,

c, approximate costs of production.

II. Adjusting ourselves to above details we have to decide the technoloy to be applied in the plant. Furthermore the following points have to be determined: the exact place of the plant, list of equipments and machines, the source for obtaining the raw-material and primer packing-material, - short description of the technology and also a strategy for the realization of the plan.

III. Discussion of quality control, quality assurance and equipments needed for such.

IV. Application of GMP in production and quality control, aducation needed for this two points, requirement for training and also praeparation of complette documentation.

V. Determination of detailed cost estimation, raw-material demand on a one-year scale, and quality specification.

PART I.

INTRODUCTION

On arrival, the project was introduced to us via the document, "Terms of Reference for the Feasibility Study of the Hospital-based Production of I.V. Fluids Project" (Annex III.).

Besides, we gained more specific information to define the products to be made and the demand (Annex II.).

The steps of the manufacture and specific manufaturing practice was worked out and presented to our counterpart and the project coordinator.

Further, time was spent on screening offers from various companies to set up complete production units and evaluate quality.

In the "Terms of Reference", it was initially stated that the financial evaluation and economic analysis would be taken care of by UNIDO, but it was decided that this aspect would be handled by a financial expert to be assigned to the working team.

The main objectives was defined to be:

- To turn the feasibility studies already made to a great extent into a real implementation status.

- To advice the persons involved on qualitative and quantitative practice related to the manufacture of the selected I.V. fluid products.

Evaluation of offers received:

Documents and material from the following companies have been studied:

1. Bioluz, Saint Jean de Luz, in France (June 1989)

   Offers modules to be attached to customers buildings of laboratories warehouse, etc. They use P.V.C. containers and offer container assemblage.

2. Lab. AGUETTANT/OCGR, Lyon, France (Sept.1989)

   Offers a complete factory and container assemblage. They use own design of P.V.C. bags to be overwrapped.

3. ALFA-LAVAL ZETA, Roedevre, Denmark (April 1989)
   via DANASIA, Manila (today non-existing)

4. SCHUBERT SYSTEMS Ltd., Hampshire, England (April 1989)

   Offers complete equipment in customers building. It is a very detailed plan. (Production in Polypropylene containers.)

5. Pharmadule, Nacka, Sweden (June 1990)

   A very detailed program to deliver modules and all possible service. (Production in Polypropylene containers.)

6. KEMITERM ENG. Lynge Copenhagen, Denmark (June 1990)

   They give a firm offer for the equipment covering the process up to filling. Presently installing for EURO-MED in the Philippines.

AD I - II.

1.) The technique for making I.V.-fluids actually is not very complicated. It is a matter of dissolving the substances in Water for Injection, pass the solution through a filter, fill into proper containers and sterilize these in an autoclave.

This is also the method we find in the offer of all interested parties, in their offer to establish a manufacturing unit at the PGH.

In all the offers there are three pieces of heavy and expensive equipment: water treatment system a water distiller and an autoclave. Apparatuses of various manufacturers which are also widely used in other industries.

Only the machine for filling the solution into the final container is an I.V.-fluid specific piece of equipment.

At this point the product container becomes the decisive factor, (reasoning is given in detailes in the Technology chapter page 10.). Based is on this we recomend used the Polypropylene collapsible container .

The container comes sterile and completely sealed, and will be cut open by the filling machine immediately before being filled and resealed before leaving the machine - untouched by hand.

This crucial step of the production is secured in the SCHUBERT and the Pharmadule offers.

SCHUBERT offers to deliver all equipments and take the engineering responsibility for installing it in a building made ready by the customer. They propose two parallel lines, each producing 1 Million containers of one liter per year, using a factory floor area of 1645 m^2. There is a detailed list of equipment but no prices are available.

Pharmadule offers to deliver a complete set of equipments pre-fabricated in modules and trial run before dispatch. Pharmadule offers KEMITERM EQUIPMENTS. Such unit can be put into operation about 10 month after signing the agreement.

The use of prefabricated modules appears to be a quick and problemfree solution, but the disadvantage is that everything is so functionally set up that no room is left for modifications or changes at a later stage, and extensions can only be achived by purchasing new additional modules.

2./ Products to be made

After studiing the statistical figures available it was found that the total amount of I.V.-fluid units demanded is the following:

23 Million bottles for the whole country, it is projected to be 54 Million in the year 2000

12 Million for Metro Manila, projection is 24 Million in the year 2000

±1 Million for the OCH and PGH, projection is ± 1.5 Million in the year 2000

When limiting our concern to the most essential products of highest demands and those ones most simple to produce it was decided to start with the following products:

Dextrose 5% in Water

each 100 ml contains

Dextrose, anhydrous	5 g

Dextrose 5% in 0.9% Saline

each 100 ml contains

Dextrose, anhydrous	5 g
Sodium Chloride	900 mg

Dextrose 5% in 0.3% Saline

each 100 ml contains

Dextrose, anhydrous	5 g
Sodium Chloride	300 mg

Dextrose 5% in Lactated Ringers

each 100 ml contains

Dextrose, anhydrous	5 g
Sodium Chloride	600 mg
Sodium Lactate anhydr.	310 mg
Potassium Chloride	30 mg
Calcium Chloride	20 mg

Normal Saline

each 100 ml contains

Sodium Chloride	900 mg

Lactated Ringer Solution

each 100 ml contains

Sodium Chloride	600 mg
Sodium Lactate anhydr.	310 mg
Potassium Chloride	30 mg
Calcium Chloride	20 mg

Dextrose 10% in Water

each 100 ml contains

Dextrose, anhydrous	10 g

3./ Technology

3.1. Choise of system

Generally there is not much difference in the basic technology for making infusion products.

The choice of the final presentation of the product however is of great importance for the choice of some of the equipment.

Final product in glass bottles

In such case the following equipments are needed:

a bottle washing machine

rubber stopper-washing and sterilizing equipment,

capping machine for aluminium caps,

set-up for inspection of every single bottle,

Disadvantages of this system are the followings:

high-rate of rejects due to particulate matter

risk of breakage in handling (explosion in autoclave)

more space consuming,

heavy in transport,

price of Philippine made bottles is high.

In plastic containers

There are 3 types of plastic containers:

Polypropylene (P.P.)

Poly Vinyl Chloride (P.V.C.)

Poly-Ethylene (P.E.)

The P.P. can be incinerated without harm to the environment.

The P.V.C. is threatened to be banned of ecological reasons.

The P.E. is water vapor transmittable and need overwrapping.

Characteristics of the plastic containers are:

No washing or other pre-treatment needed,

container closure already inserted,

filling by automatic machines,

contamination risk is almost nil.

no risk of breakare during handling,

empty and filled containers are lower in weight,

price is competitive to glass,

the containers are not produced in the Philippines

In addition the use of plasticcontainers would decrease the costs of equipment by 300.000 U.S.D.

The working and storage areas could be 25-30% smaller, manpower requirement is less by 2-3 workers.

3.2. Site

4 different possibilities have been locked upon. (Annex IV.)

Plot no. I - The old Pharmacy - is situated in a two story building, 80 years old.

Ground floor is 273.6 m^2

Second floor 202.8 m^2

Total 476.4 m^2

The adjacent Dispensary building is very shaccy and the restoration is not feasible most probably.

Suggestion for renovating the old Pharmacy building would not only be an expensive and time consuming operation but it would be difficult and complicated also to make modern installations needed for a modern production unit, with up to date strict requirements for an adequate GMP (Good Manufacturing Practices).

Plot no. II.

A plot of 40 x 20 m 800 m^2 is currently occupied by an intermediate Canteen barak, surrounded by solid brick buildings leaves no possibility for future extension.

Plot no. III.

Situated next to a tennis court and presently used for storing technical scrap, etc. The area is approximately 2000 m^2. It is centrally situated; easily accessible and suitable for possible extension.

Plot no. IV.

An empty corner plot - $\pm$ 2000 m^2 - with two very busy streets and two sides. It was earlier proposed to be used for a PGH commercial center. Furthermore, it is situated in an outer corner of the PGH compound.

We would advise to select plot no. I. Pull down the old buildings and use the site for setting up a completely new production factory.

The set up of a hospital based production at the same time should be looked upon as a model production unit, which can serve further development of in house produced infusion products, under the auspices of the UP Industrial Pharmacy faculty and also be the pilot unit to

be reproduced at other government hospitals throughout the country.

No doubt - the optimal functioning of such units will contribute to a high standard of the pharmaceutical profession and at the same time provide the government hospital(s) with the most possible low priced I.V.'s for the benefit of the poor people.

It was estimated that about 30% of the PGH expenditures on medicines is used for infusion products, and 70% of this consumed through the Free Ward for the benefit of charity patients.

3.3. Flow of Process (Annex V.)

3.3.1. Water

City water will be taken from a buffer tank of 10.000 l. and pumped through a pre-treatment system to withhold particles and dissolved impurities. From this water a distiller will produce the Water for Injection, which will be used for making the fluids.

There will also be a need for water to go into the steam-generator (this water may not have to be deionized, this will depend on quality control results of the water analyses) for heating the distiller and two storage tanks; and for sanitizing the product holding tanks and their piping system, etc.

3.3.2. Clean Room

This area will have a special air treatment system which will keep the atmosphere free from dust, and the person will enter the room through a dust-free change room where special work-clothing is put on.

There will be a compounding tank of 500 l. used to dissolve the raw material, which have been weighed under control of the responsible pharmacist.

The solution will be pumped over into the bulk product tank and Water for Injection added through the compounding tank up to the correct volume.

This bulk product tank must keep the solution at a temperature of 80^{0}, in order to avoid any growth of micro-organism and development of pyrogens.

3.3.3. Aseptic Area

This is the heart of the process and the most critical step for obtaining highest possible quality.

This Room will be kept free of airborn bacteria by an air ultrafiltration system, and the operator will wear aseptic clothing and must be well trained for aseptic technics.

The warm bulk solution will pass through a heat- exchanger to bring the temperature down to the optimal filling temperature which is $+50^{0}$.

A candle type prefilter will take care of the visible-size particles, and will at the same time function as a pressure-equalizer and be protective to the membrane-filter.

A Millipore Membrane filter placed at the filling machine will render the product solution particle free. Filter to be used should be of either 0.45u or 0.22u depending on the quality standards

to be set. These membranes should be protected by a prefilter membrane in order also not to overburden the filtration system.

The filling machine should operate fully automatic from the point where the container is inserted into the machine until they are sealed. There should not be more than one operator for the machine.

The PLM containers will come in cartons from which the are taken out still in a sterile sealed pack to be opened aseptically immediately before use.

3.3.4. Autoclaving

The filled and sealed containers will slide in a chute on to a turning table from where the autoclaving operator will hang them on especially designed frames mounted on a trolley and roll them into the autoclave. The autoclave will be fully automated and provided with recording instruments for the record of the batch. There should be a temperature measuring probe in the autoclave. This probe could be a permanently placed filled bottle so that the inner temperature of a container can be assured.

The autoclave will hold a minimum of 1000 one 1. containers. Normally the autoclaving cycle is set to 1 3/4 hour. After 2 hours the content has cooled down and its content can be taken out and has to be placed in cool-down area awaiting inspection for "floating particles" and labeling and packaging in cartons. These cartons will be placed in quarantine warehouse awaiting final release by Q.C.

Q.C. in the flow sheet is marked where the Quality Control department will execute "in process control".

A detailed list of equipment shown in Annex VI.

4./ Quality Assurance (Q.A.) and Quality Control (Q.C.)

Q.A. is a high level organization which will be concerned with the standards and the requirements which the production must meet, to be sure that the highest possible product safety and quality is guarantied for the patients and for the prescribing doctors.

Q.C. leader - A pharmacist who is responsible for the correct performance of the analytical work and the "in process control" connected with the product quality. The Q.C. will have the authority to release or reject products.

To carry out these activities there should be laboratories where the following work can be carried out:

- release of raw material incl. water for injection
- release of packaging material and labels
- release of bulk solution before filling
- release of the final product
- control of memorane filter integrity
- control of visual inspection performance
- validation of equipment performance and cleanliness
- validation of clean room and aseptic area compliance
- inspect for cleanliness and hygiene throughout the premises
- stability control

Two fully equipped laboratories, each ± 20 m^2 is needed.

A total area of ± 40 m^2

and a retention room for samples ± [illegible] m^2

5./ Proposed Organizational Chart and Personnel Requirements

Director

1. Production 2. Quality Control 3. Maintenance 4. Storage 5. Administrative

1. Production:

1 pharmacist
2 skilled assistants
2 assistants
6 skilled workers
7 workers

Total prs. 18

2. Quality Control:

2 pharmacist
2 skilled assistants

Total prs. 4

3. Maintenance:

1 engineer
1 technician
1 mechanic
1 utility worker

Total prs. 4

4. Storage:

1 storekeeper
2 workers

Total prs. 3

5. Administration:

1 bookkeeper
1 secretary

Total prs. 2

31 persons

Space requirement and material movement diagram is shown on Annex V.

PART II.

Ad III. Quality control and quality assurance system

1., The quality control department has to be under the supervision of a person completly independent from the process of manufacturing.

2., The quality control department has to have at its disposal all those correctly equipped permises with all the device, chemicals, which ensure the control of each and every raw material introduced into the infusion plant, ensure the control of the intervallic production, the classification of the finished product and also the stability tests.

Specification of the device and equipment used for control are to be found in Annex XI.

3., All examinations must be done according to the detailed and written instructions and must be documentated.

4., The task of this system is the so-called "release" or "rejection" of the finished product.

5., The sampling for the everage and control samples needed for the analysis are done by the quality control experts and also the storing of the samples is their task.

The control samples should be stored for 5 years.

6., Any kind of changes effectuated in the production must be previously enforced by performing the stability tests which should give the required results.

Ad IV. Application of GMP in the production and quality control, qualification needed for practice of GMP training and security regulations

.1. Regulations concerning the staff

1.a. The direction of the plant should be entrusted to an expert in possession of scientific education and previous experience.

b. The production and control of infusions should be done by well qualified experts and there are also needed a suitable number of people who form the staff who are well coached regarding the employed procedure.

c. The personal movement in the production area have be regulated in writing.

2. Regulations concerning the building of the infusion plant

2. a. The windows and doors of the building should close securely.

b. Individual phases of the production should be performed on premises well separated from each other. The passage of the material and staff to the aseptic premises has to be done by employment of a sluice system.

c. For the air-supply of the production area filtered air has to be ensured, and also flow of the air must be coming from the direction of the cleaner area towards the less clean area.

d. Separate storehouses must be available for:

- raw material,
- products waiting for qualification,
- qualified product and the product found satisfactory,
- raw material and products which have not been found santisfactory.

3. Stipulations concerning the equipment

3.a. Installation of equipment should be done according to logical order. This way big part of the mistakes can be avoided.

3.b. The equipment and device used in production have to be de-mounted and cleaned according to plans and should be registered in the control diary.

3.c. Working conditions of the device used for sterilizing has to be equipped with a register and must be documentated. The device should not be put into use without validity tests.

3.d. Recordings should be kept for the compressed air, inert gas. ion-changed water, distilled water used in the technology and also for the cleaning of the filters used in the "Laminar flow box" and air filtrator and also the maintenance of above should be recorded.

3.e. The piping used for the gases connected directly of the infusions must be made of stainless steel or appropriate plastic.

3.f. The distilled and ion-changed water should be circulated only in piping made of either stainless steel or appropriate plastic.

3.g. Sterilization of the piping and tanks should be done by steam gained from distilled water.

4. Hygienic stipulations

In recent times these stipulations are summarized in the so-called hygienic program of the production department, and are obligatory to each and every member of the staff. I would like to sum up the most important points of these programs:

4.a. Technological areas must be cleaned only after production hours and should be done so as not to stir up the settled dust. This can be achieved either by the use of a vacuum-cleaner or wet cloth.

At the start of each shift the floor of the production area must be wetted with water containing 1% phenol and the sluices must also be filled with this solution.

At the beginning and the end of each shift antiseptic solution has to be poured into all the drain and vaist collector pipes of the aseptic production area.

All the bathrooms, showers, toilets, corridors, dressing--rooms, and also the floors, furnitures, doors and tiles of the office found on the premises of the production area must be washed daily, with detergent, then with antiseptic solution.

The piping and windows should be washed once a week with detergent then with antiseptic solution.

At least once a year the inflating and deflating ends of the air-conditioner should be cleaned with a vacuum-cleaner. When restarting the air-pipes must be antisepticated with steam containing formaline.

The floors and tiles and also those walls which can be washed must be cleaned with solution of 2% detergent, while for disinfection, solution of 5% sodium hypochlorite must be used, these two solutions alternating weekly.

4.b. Hygienic stipulations concerning the staff

At least twice a week but on the aseptic area daily. we have to ensure clean cloths for the staff.

In the production area the hair has to be tied down, that is the wearing of a hat is obligatory.

Before starting work and after lunch, blowing nose or going to the toilet, hands should be washed each time. After washing hands disinfecting should be done with antiseptic solution.

For wiping hands either one-use paper towels or an appliance blowing warm air should be used.

Aseptic area can be approached only after use of the shower where the whole body has to be soaped and also clean garments should be put on. Hands - even after shower - have to be disinfected.

It is forbidded to take any kind of personal belongings to the aseptic area.

The following hand disinfectants can be used alternating monthly:

- Ritosept 0,5%,
- Ultrasol,
- Neomagnol 2%,
- Bradosan solution,
- Bradosept solution,
- Tego 51 2% solution.

5. Stipulations concerning the material used

All those materials must be registered which are used in either phase of the infusion production.
Recordings should be kept of the shipper, of the date of arrival, data concerning their analysis and qualification, and also about their use in the production.

These materials must be identified, well stored, sampled according to stipulations and can be released and used only upon receipt of written order from the quality control department.

Material waiting for release should be stored separately.

The material which is proved to be satisfactory should be labelled properly and can be taken to the premises only afterwards.

Unsatisfactory material should be stored seperately in the warehouse and should either be destroyed or re-sent to shipper.

Material imperfectly labelled or packed should not be used.

6. Stipulations concerning the process of production

6.a. Production of infusions can be started only in the possession of proper technological instructions. The plant cannot deter from these technological instructions, only if previously discussed with the head of the plant who should also put the alterations into writing.

6.b. Before any kind of production starts, the device used in the procedure should be checked whether their cleaning has been done.

6.c. The equipment and dishes used in the production should be labelled clearly. The label must show the name of the material and its indentification number.

6.d. The checking and verifications of the measuring device should be done at least one in every six months.

7. Recording of the finished products

7.a. The recording should show the detailed history of production, which certifies that the production was done according to the technological instructions.

It has to show:

- the name and number of the product,
- date of manufacture,
- the quantity and analytical serial number of the used material,
- the characteristic data of the filters used,
- the characteristics of the sterilizing procedure,
- output in the different phases of production which cannot exceed certain given limits,
- control data taken during the process of production.
- the minimal and maximal output permitted,
- the signature of the person(s) responsible for the production,
- the serial numbers of the analitical, sterility and pyrogenity control protocols, which certify that the products adhere to the given requirements.

This provision has to be signed by the persons responsible for the quality control.

NOTE: The protocols have to be kept for at least five years.

Naturally a lot more could be said in connection with GMP requirements of an infusion plant, but my opinion is, that the specifications have to be revised point by point adhering to local production and accoring to this revised specifications will have to be the workers trained, partly abroad, partly in Manila.

Ad V. Important estimates regarding the products of choos::

Decision of the most frequently used products had been made by the consuption of the biggest hospital. See Annex XII.

The products are the following:

Dextrose 5 % in Water

Each 100 ml contains	
Dextrose, anhydrous	5 g

Dextrose 5 % in Saline 0.9 %

Each 100 ml contains	
Dextrose, anhydrous	5 g
Sodium Chloride	900 mg

Dextrose 5 % in 0.3 % Saline

Each 100 ml contains	
Dextrose, andhydrous	5 g
Sodium Chloride	300 mg

Dextrose 5 % in Lactated Ringers

Each 100 ml contains	
Dextrose, andhydrous	5 g
Sodium Chloride	600 mg
Sodium Lactate anhydr.	310 mg
Potassium Chloride	30 mg
Calcium Chloride	20 mg

Normal Saline

Each 100 ml contains	
Sodium Chloride	900 mg

Lactated Ringer Solution

Each 100 ml contains	
Sodium Chloride	600 mg
Sodium Lactate anhydr.	310 mg
Potassium Chloride	30 mg
Calcium Chloride	20 mg

Dextrose 10 % in Water

Each 100 ml contains	
Dextrose, andhydrous	10 g

Or estimate is based on a based production of one million liters a yaer.

This production is filled in containers of 1000 ml, 500 ml and 250 ml.

	1000 ml	500 ml	250 ml
Total/year 1,000,000 lit.	46.5 %	38,5 %	15 %
	465.000 units/y	770.000 u/y	600.000 u/y
Total units /year	1.835.000		

This calculations were made inaccordance with Anne XII.

It is clear from the above that the daily filling capacity should be clear 7.140 units.

Total costs

It has been established from feasibility studies prepared earlier, the 70 % of the total cost is represented by the packaging materials.

Production cost of the product chosen by as is maximum 10-12 Pesos.

Yearly demand and value of the required raw materials and prices:

Yearly Production

			Dextrose	Sodium Chloride	Sodium Lactate cm	Potassium Chloride	Calcium Chloride
D_5 in w.	150.0001	150.000x50g	7500 kg				
D_5 in 0.9 Saline	300.0001	300.000x50g	15.000 kg				
		300.000x0,9g		2700 kg			
D_5 in 0.3 Saline	150.0001	150.000x50g	7500 kg				
		150.000x3,0g		450 kg			
D_5 in Lactated Ringers	150.0001	150.000x50g	7500 kg				
		150.000x6.0g		900 kg			
		150.000x3.1g			465 kg		
		150.000x0.3g				45 kg	
		150.000x0.2g					30 kg
Normal saline	100.0001	100.00 x9.0g		900 kg			
Lactate Ringers Sol.	100.0001	100.000x6.0g		600 kg			
		100.000x3.1g			310 kg		
		100.000x0.3g				30 kg	
		100.000x0.2g					20 kg
D 10 % in w.	50.0001	50.000x10g	5000 kg				

Total 1.000.000 liters

Dextrose Anhydrous	42.500 kg
Sodium Chloride	5.500 kg
Sodium Lactate anhydr.	775 kg
Potassium Chloride	75 kg
Calcium Chloride	50 kg

Yearly demand for raw-materials:

Yearly consumptions:

Dextrose anhydrous	42.500 kg		49,725.00 $
Sodium chlorocide	5.500 kg		1,665.00 $
Sodium Lactate a nh.	775 kg	-686.5 kg Lactic.acid.	16,476.00 $
Potassium chloride	75 kg		
Calcium chloride	50 kg		

At the present prices:

Dextrose anhydrous

USD 117/kg FOT Linz LAEVOSAN

Quality: BP. or USP -Pyrogen free-.

Over two ton the price is USD 1,12/kg.

Sodium chloride

1. USD 300/1000 kg FOT Austria

Quality: BP. or USP -Pyrogen free-.

2. ATS 3600/1000/kg FOT Austria 1$ = 11.60 ATS

Quality: BP -pyrogen free-.

3. DEM 1.20/kg MERCK West Germany

Quality: U.S.P.XXI. -Pyrogen free-.

Lactic acid

1. USD 2.40/kg FOT Barcelona-Spain-Ajoso-Montelio

Quality: U.S.P. XXI.

2. NLG 4.90/kg FOT BIOCHEM Netherland 1$ = 1,904 NLG

Quality: U.S.P. XXI.

Ad.VI. Small volume solutions and eye drops

In course of our work we realized the possibility of planning a plant for the production of eye drops solutions with a relative small amount of investment costs.

We wish to emphasize the importance of it by the followings:

1.) There is a great demand on eye drops and only the very expensive import products are available. We have studied the consumption of M.G.H. in 1989 and we found that these eye drops were bought from different companies against 1/2 Million peso.
Earlier we have already stated that the Manila State Hospitals buy five fold more than that is the consumption of M.G.H. It means that the consumption of the eye drops in Manila needs approximately 3 Million peso pro year.

Unfortunately a more exact survey could not be done due to the shortage of time.

In our opinion even if the new ophtalmological plant which we propose to establish furnished half of the demand existing in Manila it would result in an essential save of money.

2.) Almost everything wich is necessary for the production of the ophtalmological solutions is already at disposal in the frame of the project.

It means that the establishment of an important laboratory, which would elevate the level of the health care significantly, could be realized at relatively small investment.

I prepared a list of the necessary instruments and equipments in Annex XIII.

I see three possibilities for the preparation of eye drops:

I. preparation of simple products according to the prescriptions of different pharmacopoeias;

II. preparation of eye drops of more components with difficult production process by the help of licence and know-how;

III. If there is no possibility for the realization written above, I suggest purchase of stock solution from the firm who sales the product(s) in question and the preparation of the relevant eye drops follows from the stock solution.

Applying this simple commercial work and method of production buyers usually might get the stock solution at 50 % of that of the original purchase price.

Finally, we have to mention that also the appropriate supply of the uniform glass bottles or plastic tanks needed for filling might cause some concerns.
Our proposal is BÜNDER GLAS PLASTFORM West Germany. See Annex XIII.
If our proposal will meet a favourable judgement and this part of the project will be realized we can put the validation test of these tanks at the disposal of the project.

LIST OF ANNEXES

ANNEX I.

People and organizations contacted

A. Philippine Agencies

Hon. Rhais M. Gamboa
Undersecretary, Department of Health

Dr. Ernesto O. Domingo
Chancellor, University of the Philippines Manila

Dr. Felipe A. Estrella, Jr.
Philipoines General Hospital
University of the Philippines Manila

Dr. Pacita L. Zara
Executive Director, Phil. Council for Health Research & Dev.

Dr. Leopoldo H. Lazatin
Assistant Director for Fiscal Services , PGH
and Project Manager, I.V. Fluids Project

Dr. Antonio A. Limson
Assistant Director for Health Operations
Philippine General Hospital, PGH

Prof. Leticia Barbara I. Gutierrez
Dean, College of Pharmacy, UP Manila

Prof. William Estacio
Chaiman, Industrial Pharmacy, College of Pharmacy UP Manila
and Filipino Counterpart Expert

Mrs. Glory Chanco
Director, Chemical Industries Department
Board of Invetments

Mrs. Ellen Yu
Department of Nursing, PGH

Mrs. Emma Halili
Supervising Pharmacist, Department of Pharmacy, PGH

Mrs. Kathryn P. Santos
Project Coordinator

Mrs. Nadia R.M. Castor
Chief Pharmacy Dept. UP-PGH Medical Centre

B. Foreign Agencies

Dr. Christian A. Newman
Director, UNIDO Manila

Mr. Michael Winther
Assistant to the Country Director, UNIDO Manila

Mr. Ole D. Nielsen
Commercial Secretary, Danish Legation Manila

Mr. Gunnar Blaehr
Charge d'Affaires, Danish Embassy Manila

Mr. Hinrich Schumacher
European Chamber of Commerce of the Philippines

A.M. De Ynchausti representation of "BIOLUZ"
H. Laumond representation of "O.C.D.R.-AGUTTANT"

C. Contact by telecommunication

E. Roenlev P.L.M. Haustrup Plastic, Denmark

Mr. G. Hermann, Kemiterm, Denmark

Mr. C. Wallenborg, Pharmadule, Denmark

Mr. J. Gobel, representation of Santasalo-Sohlberg Corp., Finland

Mr. E. Ligetvari, representation of Scholler-Bleckmann GmbH., Austria

ANNEX II

LIST OF LITERATURE

1. "Terms of Reference for the Feasibility Study of the Hospital based Production of I.V. Fluids". DOH and UP Manila.

2. "Feasibility Report". Organisation Conception Gestion Realisation. AGUETANT Lyon, France.

3. "Large Volume Parenteral Solutions, Compact Plant". Istituto Sierovaccionogeno Italiano I.S.I.S.P.A.

4. "Produce Your Own Intravenous Solutions". Schubert System (Overseas) LTD.

5. "Documentation Covering Pharma Lines Range of I.V. Membrane Containers". PLM-Haustrup.

6. "Feasibility of Commercial Production of Intravenous Fluids Using Locally Developed Technology". Fermin Castaneda Palileo, B.S. Chemical MBM, Philippine Council For Health Research and Development. March 1989.

7. "Hospital-based Production of I.V. Fluids". (Preliminary Proposal). Department of Health and the University of the Philippines Manila.

 ANNEX III

PHILIPPINE GENERAL HOSPITAL
U.P. Manila
University of the Philippines
Taft Avenue, Ermita, Mla.

14 June 1990 fn:RMG6-14

Hon. Rhais M. Gamboa
Undersecretary
Department of Health
Sta. Cruz, Manila

Dear Undersecretary Gamboa:

We are sending herewith a copy of the document, "Terms of Reference for the Feasibility Study of the Hospital-Based Production of I.V. Fluids Project".

After the initial consultation among the working group, the expectations from each agency are as follows:

Market Study	-	DOH / UPM-PGH,CP / UNIDO
Plant Capacity	-	UPM-PGH,CP / UNIDO
Raw Material	-	UPM-CP / UNIDO
Location and Site	-	UPM-PGH,CP / UNIDO
Technology and Project Engineering	-	UPM-CP / UNIDO
Plant Operation and Manpower Requirements	-	DOH / UPM-PGH,CP / UNIDO
Implementation Schedule	-	DOH / UP Manila
Financial Evaluation	-	DOH / UP Manila
Economic Analysis	-	DOH / UP Manila
Conclusions and Recommendations	-	UNIDO / DOH / UP Manila

At this time, the UNIDO experts, in consultation with the Filipino expert, are already drafting their initial report.

We are looking forward to discussing with you the progress of this project.

Very truly yours,

LEOPOLDO H. LAZATIN, M.D.
Assistant Director for Fiscal Services
and Project Manager, I.V. Fluids Project

TERMS OF REFERENCE
for the
FEASIBILITY STUDY
for the
HOSPITAL-BASED PRODUCTION OF INTRAVENOUS (IV) FLUIDS

I. BACKGROUND

The National Drug Policy

The National Drug Policy is set on four main pillars designed to eventually bring about the availability and affordability of safe, effective, and good-quality drugs for all sectors of the country, especially for the poor who need them most, but who can least afford them. These four pillars form an integral unit, mutually complementary and supportive of each other.
These are:

- Assurance of the safety, effectiveness and usefulness of pharmaceutical through quality control.
- Promotion of the rational use of drugs by both health professionals and the general public.
- Development of self sufficiency in the local pharmaceutical industry.
- Targetted procurement of drugs by government.

The third pillar seeks to strengthen local capabilities in government as well as the private sector for the manufacture of basic and intermediate ingredients for drugs and medicine. With increased self sufficiency, local industry will be in a better position to respond to the needs of the population for the most essential of drugs.

The fourth pillar underscores the strong position of the government to influence the market being the single largest purchaser of drugs in the country. This means that any venture for self sufficiency will have the full support of the government.

Intravenous (IV) Fluids: The DOH Concern

For the past several years IV fluid requirements are supplied by a lone pharmaceutical company.

The Department of Health has in several occasions aired its concern, among these concerns are:

- monopolies usually result to overpricing
- distribution especially in the outlying areas can not be projected.

- if the lone producer of IV fluids closes for some unforseen reasons, the Philippines does not have a rational alternative to fall back on

For these reasons , the Department of Health echoed the need to develop local capability for the production of simple but high quality IV fluids.

Subsequently, the Department of Science and Technology (NSTA) created technical and working committees to look into the feasibility of a hospital-based IV fluids plant. These committees are composed of representatives from the Department of Health; University of the Philippines Manila; National Science and Technology Administration, and the Philippine Council for Health Research and Development.

Hospital-Based IV Plant

Hospital based-production of IV fluids is centered on the concept of establishing a pilot IV manufacturing facility attached to the Philippine General Hospital (PGH) since it has the capability and expertise to conduct chemical and biological tests necessary for the production of IV fluids.

The production of this pilot plant is expected to meet the IV fluid requirements of PGH as well as the other government hospitals in Metro Manila and peripheral areas.

This IV Fluid plant will serve as a pilot model that can be replicated in other hospitals or areas to ensure availability of IV fluids.

Objectives of the Project

Immediate objectives

1. To supply the requirements for IV fluids of the PGH and other government hospitals.

2. To complement the present production of IV fluids by a lone commercial pharmaceutical firm

3. To pilot test the use of local technology on a hospital level of production of IV fluids

4. To provide a pilot plant that can be replicated in other areas

Long range objectives

1. To develop local capability to produce IV fluids essential to the delivery of basic health care

2. To develop and improve local technology to produce IV fluids

3. To provide alternative solution to the problem faced by most third world countries regarding the availability of basic medical supplies particulary IV fluids

4. To lessen the country's dependence on imported IV fluids and eventually make the country self reliant

The Need for a Feasibility Study

To date, three foreign companies have have submitted their proposals which include their own market study, plant set up (technology and corresponding machineries or equipment), and recommended manpower. At least two of these companies have signified their intention to assist the Project in getting grants from their government to finance this Project.

In the light of the above developments, the Project is in need of a definitive set of criteria on which to base the final decision as far as the Project's viability, appropriate technology, and reasonable grant terms are concerned.

II. OBJECTIVES

A. Identify alternative appropriate IV production processes/technology and evaluate each alternative in terms of (but not necessarily limited to) the following:

(1) Availability of process/technology, including conditions to obtain such

(2) Operational implications and/or requirements (e.g. plant site, water, space, raw materials and sources, packaging materials and sources, manpower, sterility conditions, storage conditions).

(3) Working capital and investment requirements

(4) Estimated cost of production of each type of IV fluid

B. Based on the evaluation of letter a above, to give a recommendation as to which production process/ technology to adopt. This recommendation should include among others:

(1) economic viability analysis to justify going into the project

(2) plant site

(3) list of equipment, cost and sources

(4) raw materials and major packaging materials sources including conditions to obtain such

(5) manpower requirement

(6) description of the production process

(7) organization

(8) strategy to implement the project

III. SCOPE OF WORK

The feasibility study will include the following:

1. Market Study

1.1 Determine the specific type of products to be produced and assess the current level of domestic demand for each product.

1.2 Make projection for the likely growth in the local demand for each product for the coming 15 years indicating clearly all the assumptions made and the sources of information used in forecasting the demand of each product.

1.3 Determine a competitive ex-factory price for each product, taking into account the existing international and domestic prices. Each product should determine two sets of prices, one for the external market and the other for internal transfer pricing. Each price set up should be justified by details of the price build up.

1.4 Investigate government incentives and protection measures/policies which will influence the pricing of the proposed products.

1.5 Determine the most appropriate distribution scheme

1.6 If the potential to produce for other hospitals aside from the PGH and DOH hospitals exist, (a) assess potential volume of selected products, (b) identify the markets, and (c) elaborate the marketing

strategy, procedures and policies.

2. Plant Capacity

On the basis of the demand projection, and expansion possibilities determine the plant capacity specifically:

2.1 Select optimum initial and full capacity for each of the IV fluids.

2.2 State possibilities and provisions for future expansion and product diversification.

2.3 Determine a feasible production program for each product, if necessary.

3. Raw Materials

3.1 Determine the annual requirement of the major raw materials to produce each product at each stage.

3.2 Indicate the quantities, specifications and sources of alternative raw materials.

3.3 Investigate source of raw materials if additional raw materials other than those produced internationally would have to be procured to maintain an optimum level of production and explain any particular nature of intermediates such as import duties, etc.

4. Location and Site

An appropriate location and site will be recommended taking into account different determinants.

4.1 List possible locations and describe them with respect to raw materials and labor availability, proximity to market, infrastructure services, environmental considerations and any other additional relevant factors

4.2 Make recommendations for the most suitable site within the recommended location indicating it on an appropriate map. State additional requirement for transportation, utilities and other services and facilities.

5. Technology and Project Engineering

5.1 Outline the process flow and describe the selected technology for each level of production as well as justifify the selection having adequately presented alternative technologies.

5.2 List and specify the types and sizes of major machinery and equipment to be installed at each stage of production.

5.3 Describe the functions performed by each major unit at each stage of production.

5.4 Specify auxiliary capital equipment and prepare a list of spareparts required for each production stage.

5.5 Specify the necessary maintenance and repair facilities in an integrated manner. This investigation may cover some cost saving from the common facilities used for different stages of production.

5.6 Select the most feasible plant physical layout, stating reasons for choice.

5.7 Prepare equipment layout drawings to scale for each production facility and auxiliary shops.

5.8 Prepare functional charts for process and material flow and draw energy balance diagram for each production stage.

5.9 Specify as much as possible building and other civil engineering work requirements for the project broken down into site preparation and development, building, storage facilities, etc.

5.10 Provide brief site plan, if the site is finally determined

5.11 Estimate the power, fuel and other utility requirements for each stage of production.

5.12 Specify transportation facilities for raw materials and finished products in each stage of production.

5.13 Indicate the type and volume of effluents and the necessary treatment facilities before disposal (if applicable).

6. Plant Organization and Manpower Requirements

6.1 Propose an organization structure showing all line and staff relationships. Specify duties and responsibilities of each function.

6.2 Estimate total manpower requirement with breakdown of each unit of production as well as functional breakdown such as skilled, semi skilled, un skilled, technical, managerial, etc.

6.3 Work out training requirement for each production unit and specify minimum qualification required on the part of the trainees.

6.4 Indicate how and where the training should take place as well as its duration.

6.5 Identify technical assistance requirements of foreign experts; areas of specialization, duties, duration of assignments, etc.

7. Implementation Schedule

7.1 Work out a detailed implementation schedule showing major activities of the project such detailed engineering, tendering, contracting, delivery, construction, erection, etc. with the aid of appropriate bar chart.

7.2 Draw up manning program for the project implementation period as well as for plant operation consistent with the implementation schedule.

8. Financial Evaluation

8.1 Provide all investment cost estimates broken down into foreign and local components on annual basis.

8.2 Estimate the amount of working capital requirements, state specifically the criteria for its estimation

8.3 Estimate production and operating cost. Provide also sales revenue for each year.

8.4 Prepare cash flow analysis for 15 years of project life

8.5 Calculate internal rate of return on total

capital and on equity, and net present value of project at 18% hurdle rate.

8.6 Prepare balance sheet, profit and loss account for 15 years

8.7 Prepare table for source and application of funds.

8.8 Make a break even analysis for production quality, prices

8.9 Undertake sensitivity and risk analysis

8.10 Present suitable financial ratios

9. Economic Analysis

9.1 Calculate the net present value using 15% discount rate as hurdle rate and the economic rate of return.

9.2 Estimate the total employment.

9.3 Assess the impact of the project on the utilization of domestic resources.

9.4 Analyze the stimulus effect of the project on other economic activities

9.5 Estimate foreign exchange saving/earnings

9.6 Estimate other economic or social benefits that will be generated by the project

9.7 Assess the effect of the project on the environment.

10. Conclusions and Recommendations

10.1 Prepare a summary of conclusions and recommendations thereof stating clearly the reasons.

IV. EXPECTATIONS FROM EACH AGENCY

The sub studies will be conducted by the following:

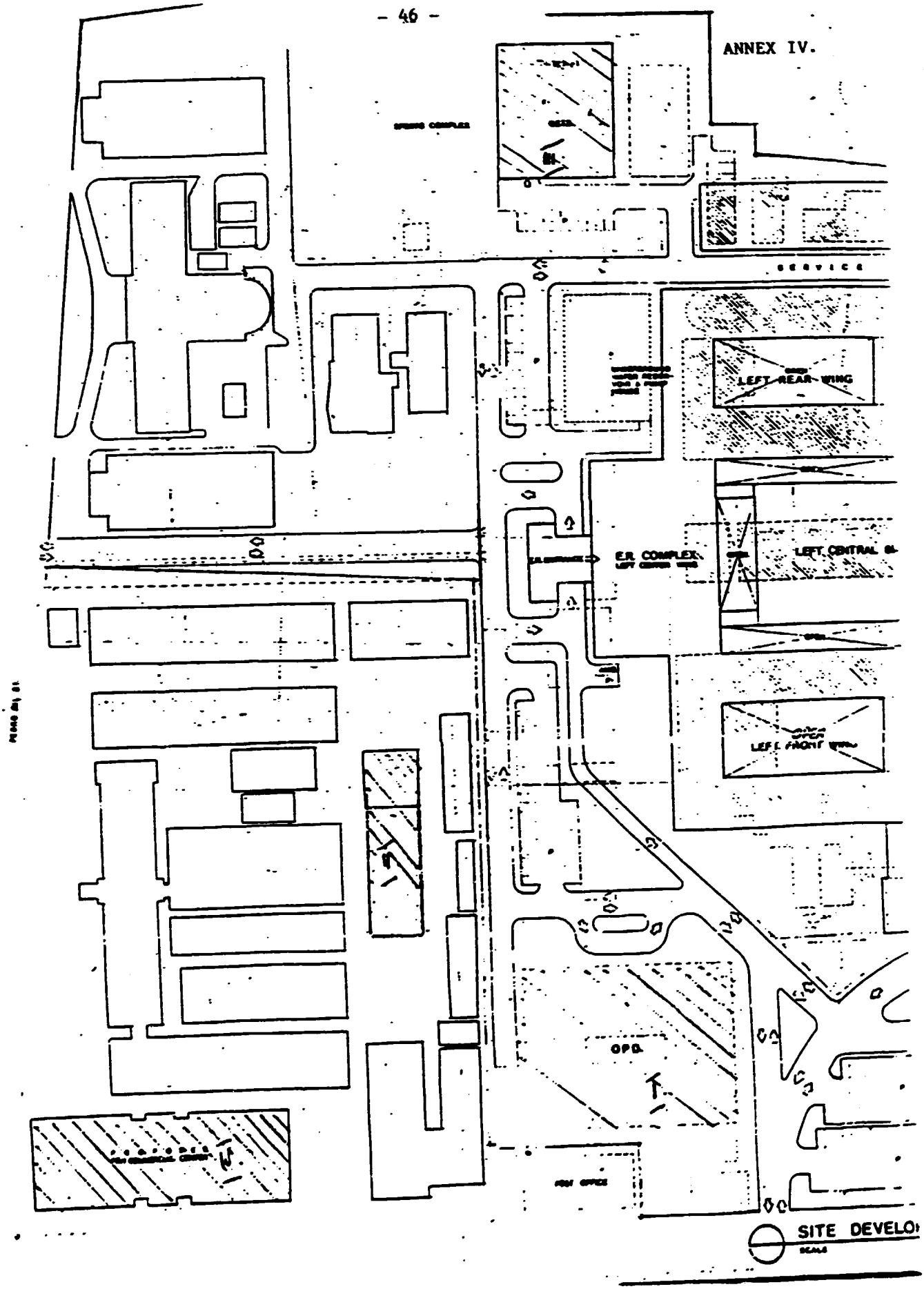
Market Study	-	DOH / UP Manila
Plant Capacity	-	UP Manila - PGH
Raw Materials	-	UPM College of Pharmacy

Location and Site	-	UP Manila - PGH
Technology and Project Engineering	-	UNIDO
Plant Organization and Manpower Requirements	-	DOH / UP Manila-PGH, CP
Implementation Schedule	-	DOH / UP Manila
Financial Evaluation	-	UNIDO
Economic Analysis	-	UNIDO
Conclusions and Recommendations	-	UNIDO / DOH / UP Manila

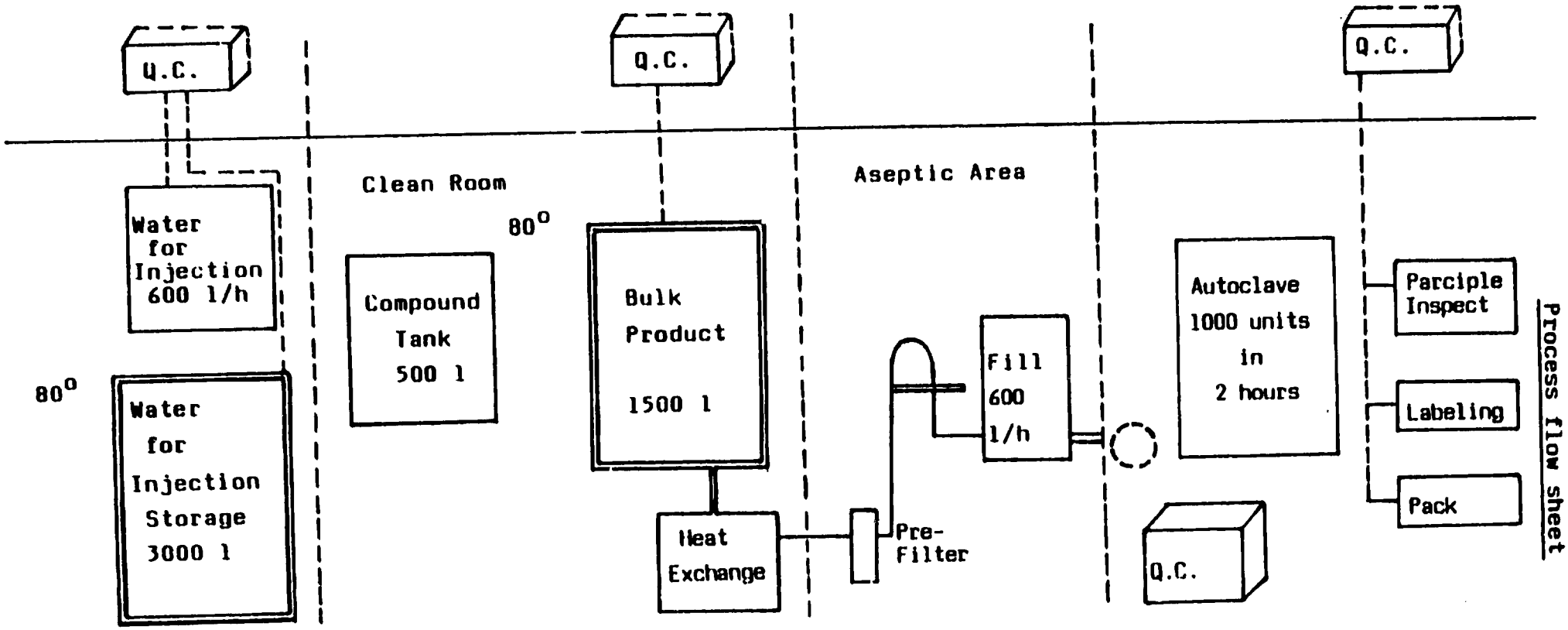
V. TARGET DATE OF COMPLETION

The feasibility study will be conducted within one (1) month to commence as soon as UNIDO has identified and assigned a technical expert. This time schedule already includes the preparation of the final report

ANNEX IV.



Site possibilities within the P.G.H. compound


Q.C.
Q.C.
Q.C.
Clean Room
Aseptic Area
Water for Injection 600 l/h
80°
Water for Injection Storage 3000 l
Compound Tank 500 l
80°
Bulk Product 1500 l
Heat Exchange
Pre-Filter
Fill 600 l/h
Q.C.
Autoclave 1000 units in 2 hours
Parciple Inspect
Labeling
Pack
Process flow sheet
raw material
in-process contr. incl.
clean room aseptic
finished product
product stability
Electric
Water
Air
Admin.
Pretreatment
dirt
chlorine
softener
de.ionizer
7140 units/day = 4000 l/day = 1,000.000 l/year

ANNEX VI.

List of Equipment

1 pc. city-water Buffertank 10,000 liters made localy

1 pc. Feed water pre-treatment installation cap. 1000 L/h.

Consist of: 1 pc. city water pump
1 pc. prefilter
1 pc. automatic deionizer unit
2 pcs. chemical container
1 pc. water softener
1 pc. fine filter

2 years spare parts cost ~ 105,000USD

1 pc. Finn-Aqua water still, Type 300-E-S
Cap. 600 L/h cost ~ 165,000USD

1 pc. Water for injections tank volume 3000 liter for storing of pyrogens-free distiller /WFi/ at 80° deg C.

1 pc. prefabricated piping cost ~ 58,200USD
Detailed offers from Santasalo-Sohlberg corp. Helsinki
Annex VII

1 pc. Cooler, to cool the water from 95°C - to 35-40°C
by Diesel Co. cost ~ 5,000USD

1 pc. Steam boyler Termo-Trading Dennmark 15,000USD

1 pc. Stainless steel vessel with stirner 500L ~ 15,000USD

1 pc. Stainless steel vessel with stirner 1500L ~ 20,000USD

2 pcs. Pumps cap. 1500L/h 5000USD ~ 10,000USD

1 pc. Filter combination cap. 1000L/h

consisting of:

1 filter housing, make Pall or Millipore, with atteched prefilter 1.2 um.

1 filter housing make Pall or Millipore, with sterile cartridge filter o.2 um. ~ 7,000USD

2 pcs. Stainless steel membrane filter holders for sterilizing filtration ~ 15,000USD

1 pc. Floor-scale 200 kg made localy

1 pc. Table scale 20 kg made localy

1 pc. heat exchanger made localy

1 pc. Filling equipment
Rotomatic PP/PE cap. 1000 units/h ~ 100,000USD
Detailed offers from Pax. Schubert co. Copenhagen Annex VIII

1 pc. Laminar flow 800 mm x 900 mm made localy

1 pc. Turne table 1500 mm diameter made localy

1 pc. Autoclave 2 door type
Cap. 1000 pcs. 1000 ml plastic container

12 pcs. Loading carriage with 8 shelves fully made of stainless steil ~ 320,000USD

1 pc. Steam sterilizer Type A.D.V. 669 ~ 50,000USD
Detailed offers from Scholler-Blechmouns Termite-AUSTRIA Annex IX.

1 pc. Conveyor belt made localy

3 pcs. Visual controll equipments localy ~ 20,000USD

1 pc. Labeling machine 800 units/h
Avery or Joham Weiss ~ 10,000USD

1 pc. Electric fork lift local production ~ 7,500USD

1 pc. Air handling system $100m^2$ x 3 x 20 cap.
Carrier Corp. ~ 35,000USD

1 pc. Generator, stand-by cap. 200 KWA
Eegholm Dennmark ~ 40,000USD

Total cost: ~ 1,000.000 USD
+ made localy ~ 150.000-200.000 USD

Detailed Offers from: Santasalo-Sohlberg Corp. Helsinki

06-07-90 12:03
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#0171 TROPTEL PH
12STC? SASC SF

TLX NO. 2 5 0 PNI/MSE
HOTEL TROPICANA. MANILA. PHILIPPINES

R O O M N O. 1 0 5
ATT: MR. DR. LASOS ARADI
UNIDO EXPERT
HOTEL TROPICANA
1630 LM
GUERERO STREET
MALATE: MANILA
PHILIPPINES

REF: PHILIPPINE GENERAL HOSPITAL
MANILA. PHILIPPINES

DEAR SIR.
WITH REFERENCE TO YOUR DISCUSSION WITH MR.J. GOEBEL FROM O.KOENIG AND COMP.. BUDAPEST. ON JUNE 4TH.1990. PLEASE FIND BELOW OUR BUDGET OFFER FOR FINN-AQUA WATER-FOR-INJECTION (WFI) PRODUCTION SYSTEM. THE SCOPE OF THIS OFFER COVERS THE FOLLOWING MAJOR SECTIONS:

A) FEED WATER PRETREATMENT
B) DISTILLATION
C) WFI - STORAGE TANK AND PUMP

SECTION (A) - PRETREATMENT
---

1 PCS RAW WATER PUMP AND EXPANSION TANK
1 PCS PREFILTER
1 PCS AUTOMATIC DEIONIZER UNIT
1 PCS MIXED-BED UNIT
2 PCS CHEMICAL CONTAINER
1 PCS WATER SOFTENER
1 PCS FINE FILTER
1 PCS SPARE PARTS SET
1 PCS SKID MOUNTING AND PIPING
1 PCS START-UP AND TRAINING AT SITE FOR DAYS

TOTAL PRICE FOR SECTION (A) IN USD 106.000.- .
==========

PLEASE NOTE THAT DIMENSIONING OF PRETREATMENT EQUIPMENT HAS BEEN DONE WITHOUT ANY INFORMATION OF THE RAW WATER QUALITY AT SITE. IN MANILA. FINAL CHOICE OF PRETREATMENT EQUIPMENT MUST BE BASED ON A PROPER WATER ANALYSE. RESULTS OF THIS ANALYSE MAY EFFECT THE SELECTION OF EQUIPMENT IN THIS SECTION.

SECTION (B) - DISTILLATION

1 PCS FINN-AQUA WATER STILL, TYPE 300-E-5
- WATER STILL FINN-AQUA 300-E-5 IS A MULTIPLE-EFFECT, ELECTRICALLY HEATED MODEL FOR DISTILLING OF DEIONIZED, DESALTED OR RO-WATER ACCORDING TO THE BELOW SPECIFICATION:
- FULLY AUTOMATIC OPERATION
- ELECTRICALLY HEATED MODEL
- CAPACITY 300 KG / H
- END PRODUCT IS DISTILLED WATER WHICH IS STERILE AND PYROGEN-FREE AND MEETS THE REQUIREMENTS OF THE USP XXI FOR WATER-FOR-INJECTIONS.
TEMPERATURE OF DISTILLATE 95-97 DEG CELCIUS
- CONDUCTIVITY OF DISTILLATE IS TYPICALLY 0.2-0.5 MICRO SIEMENS / CM
- DIMENSIONS OF UNIT 1995 X 850 X 2750 MM (W X D X H)
- WEIGHT 1020 KG
- POWER CONSUMPTION 90 KW. 380/220V /50HZ
- COOLING WATER CONSUMPTION 215 KG / H. AT 15 DEG CELCIUS (SOFTENED WATER MAX 7 DEG DH)
- FEED WATER CONSUMPTION 325 KG / H (DEMINERALIZED WATER MAX. 5 MICRO SIEMENS / CM. NO AMINES, NO CHLORIDES. MAX. SILICA CONTENT 1 PPM)
- COMPRESSED AIR FOR PNEUMATIC VALVES 6-8 BAR. QUALITY INSTRUMENT AIR
- MADE OF AISI 316 L STAINLESS STEEL
- PRESSURE VESSEL CONSTRUCTION IN ACCORDANCE WITH ASME STANDARD. INCLUDING OFFICIAL PRESSURE VESSEL DOCUMENTS.

OPTIONS:
1 PCS ELECTROPOLISHING
1 PCS PURE STEAM VALVE
1 PCS FEED WATER CONDUCTIVITY SYSTEM
1 PCS SECOND PEN IN RECORDER FOR FEED WATER
1 PCS FEED WATER PUMP SYSTEM
1 PCS COOLING WATER PUMP SYSTEM

SPARE PARTS:
1 PCS BASIC SPARES
1 PCS ELECTRONIC CARDS
1 PCS SPARE GASKETS

1 PCS START-UP AND TRAINING AT SITE FOR FIVE (5) DAYS IS INCLUDED IN THE BASIC PRICE.

TOTAL PRICE FOR SECTION (B) IN USD 115.000.- .

SECTION (C) - WFI TANK AND PUMPS

1 PCS WFI-STORAGE TANK. TYPE FINN-AQUA S-T2000/E VOLUME 2000 LITRES FOR STORING OF PYROGEN-FREE DISTILLATE (WFI) AT 80-DEG CELCIUS. CYLINDRICAL, UPRIGHT CONSTRUCTION. MAIN DIMENSIONS APPROXIMATELY DIAM. 1500 X 2200MM. TOTAL HEIGHT WITH FILTER ABOUT 2850MM. ELECTRICALLY HEATED WITH HEATING COIL IN THE TANK. MADE OF AISI 316 STAINLESS STEEL. INNER SURFACE FINISH 240 GRIT. COVERED WITH AISI 304 JACKET. INSULATED WITH 50MM ROCK WOOL. TANK CAN BE FLUSH STERILIZED WITH PURE STEAM. EQUIPPED WITH NECESSARY CONNECTIONS FOR:

- MANHOLE
- AIR FILTER
- LEVEL CONTROL
- LEVEL INDICATOR
- TEMPERATURE PROBE AND INDICATOR
- PRESSURE GAUGE
- SAFETY VALVE
- DISTILLATE INLET AND CLOSING VALVE
- DISTILLATE OUTLET AND CLOSING VAL
- DISTILLATE CIRCULATION INLET AND CLOSING VALVE
- PURE STEAM INLET AND CLOSING VALVE
- ELECTRICAL HEATING COILS

1 PCS DISTILLATE DISTRIBUTION PUMP

- CAPACITY 1500 L / H
- PRESSURE 2,0 BAR - ALL PARTS IN CONTACT WITH DISTILLATE MADE OF STAINLESS STEEL AISI 316. OTHER PARTS AISI 304.
- SANITARY CONSTRUCTION FOR PHARMACEUTICAL USE
- ELECTRIC MOTOR 2.0 KW. 3-PHASE 220/380V. 50 HZ. 2000 RPM.

1 PCS PREFABRICATED PIPING

THE SYSTEM CONSISTS OF PREFABRICATED PIPING FOR ONE (1) WFI-TANK / PUMP UNIT. THE PREFABRICATED PIPING CONSISTS OF THE INTER CONNECTING PIPING BETWEEN THE FINN-AQUA WATER STILL, THE WFI-TANK, AND THE WFI-PUMP, INCLUDING THE NECESSARY CLOSING VALVES, TYPE DISC, PRESSURE GAUGES, CLAMP CONNECTIONS, ETC. ALL PIPING AND COMPONENTS IN STAINLESS STEEL AISI 316.

TOTAL PRICE FOR SECTION (C) IN USD 50.200,- .

PRICES

THE PRICES ARE IN USD. INCLUDING SEAWORTHY EXPORT PACKING.

DELIVERY TERMS

FOB HELSINKI. FINLAND.

DELIVERY TIME

FIVE (5) WORKING MONTHS FROM FIRM ORDER AND OPENING OF LETTER OF CREDIT.

PAYMENT TERMS

IRREVOCABLE AND CONFIRMED LETTER OF CREDIT FOR 100 PERCENT OF THE CONTRACT VALUE WITH 30 PERCENT DOWN PAYMENT AGAINST BANK GUARANTEE AND 70 PERCENT PAYABLE AT SIGHT AGAINST SHIPPING DOCUMENTS.

CERTIFIED DRAWINGS

CERTIFIED DRAWINGS WILL BE SUBMITTED TEN (10) WEEKS AFTER ALL TECHNICAL MATTERS HAVE BEEN MUTUALLY AGREED UPON AND THE LETTER OF CREDIT HAS BEEN OPENED.

WARRANTY

TWELVE (12) MONTHS FROM START-UP. MAXIMUM EIGHTEEN (18) MONTHS FROM SHIPMENT.

VALIDITY OF OFFER

THIS OFFER IS VALID FOR SIXTY (60) DAYS.

WE HOPE THAT OUR OFFER MEETS YOUR REQUIREMENTS AND LOOK FORWARD TO FURTHER DISCUSSIONS WITH YOU AND YOUR ORDER. SHOULD THERE BE ANY QUESTIONS OR CONCERNS DO NOT HESITATE TO CONTACT US.

SINCERELY YOURS,
SANTASALO-SOHLBERG CORPORATION
PURE WATER SYSTEMS
PETER NIGEN
AREA SALES MANAGER

FINN-AQUA

ANNEX VIII

DETAILED OFFERS from: PAXALL SCHUBERT MACHINERY CO. A/S Copenhagen Denmark

REF: MR. MIKO
PROJECT.: ROTOMATIC FILLING EQUP.

DEAR SIR.

WITH KIND REFERANC E TO MR. MIKO WE HEREBY SEND YOU OUR BUDGET PRICES FOR ROTOMATIC FILLERS.
THE PRICES ARE ALL BUDGET PRICES. AND WE KIND LY ASK YOU TO CONTACT U S
WITH FURTHER INFORMATIONS. OR ORDER FOR US TO SEND YOU A COMPLETE QUOTATION WITH TECHNICAL DETAILS AND PRICES ETC.

ON THE BACKGROUND OF THE INFORMATION GIVEN BY MR. MIKO, WE INFORM YOU OF THE TWO BAG FILLING MACHINE WE MANUFACTURE. THESE ARE:

1) ROTOMATIC PP/PE

COMPLETE MACHINE AND CONTROL PANAL WITH SCHUCO 1000A FILLING EQUIPMENT. HEAT OR SEALING JAWS FOR CLOSING OF STEM.

CAPACITY: 1000-1200 FILLING PR./HOUR. DEPENDING ON VOLUME AND VISCOSITY

FILLING VOLUMES: 50-1000 ML +/- 0.5 PCT.

BUDGET PRICE: DKK 650.000

SPAREPART (2 YEARS) 40.000 DKK
FOB CHARGES 12.000 DKK

2) ROTOMATIC PVC. 1400

COMPLETE MACHINE W. 2 HF-WELDING STAIONS. CONTROL PANAL AND 6 PCS. SCHOCU 1000A FILLERS

CAPACITY: UP 1400 FILLING PR./HOUIR IN 1000 ML BAGS DEPENDING ON VOLUMES AND VISCOCITY.
VOLUMES: 100-1000 ML +/- 0.5 PCT

BUDGET PRICE: DKK 2.240.000

SPAREPARTS (2 YEARS) DKK 42.000
FOB CHARGES DKK 20.000

DELIVERY TIME: ACCORDING TO AGREEMENT

WE HOIPE THESE INFORMATION WILL HELP YOU AT THIS MOUMENT.
PLEASE INFORM FAX NUMBER ETC. FOR US TO SEND YOU A FULL AND DETAILED QUOTATION ONM THESE MACHINES.

WE CAN INFORM YOU THE TOGEATHER WITH THESE MACGINES WE ARE ABLE TO DELIVER LAF UNITS.
THESE UNITS WILL BE DESIGNED FOR THE MACHINES, AND NEDED WOPKING AREA . THE PRISES VARY FROM DKK45.000 TO80.000 DKK DEPENDING ON THE TYPE AND SIZE.

PLEASE DO NOT HESITATE TO CONTACT US FOR FURTHER INFORMATIONS. AND WE ARE LOKING VERY MUCH FORWARD TO HEARING FROM YOU.

KIND REGARDS

LYTZEN SCHUBERT MACHINERY A.D

LARS DRYCHANN

KONTACT ADDRESS:

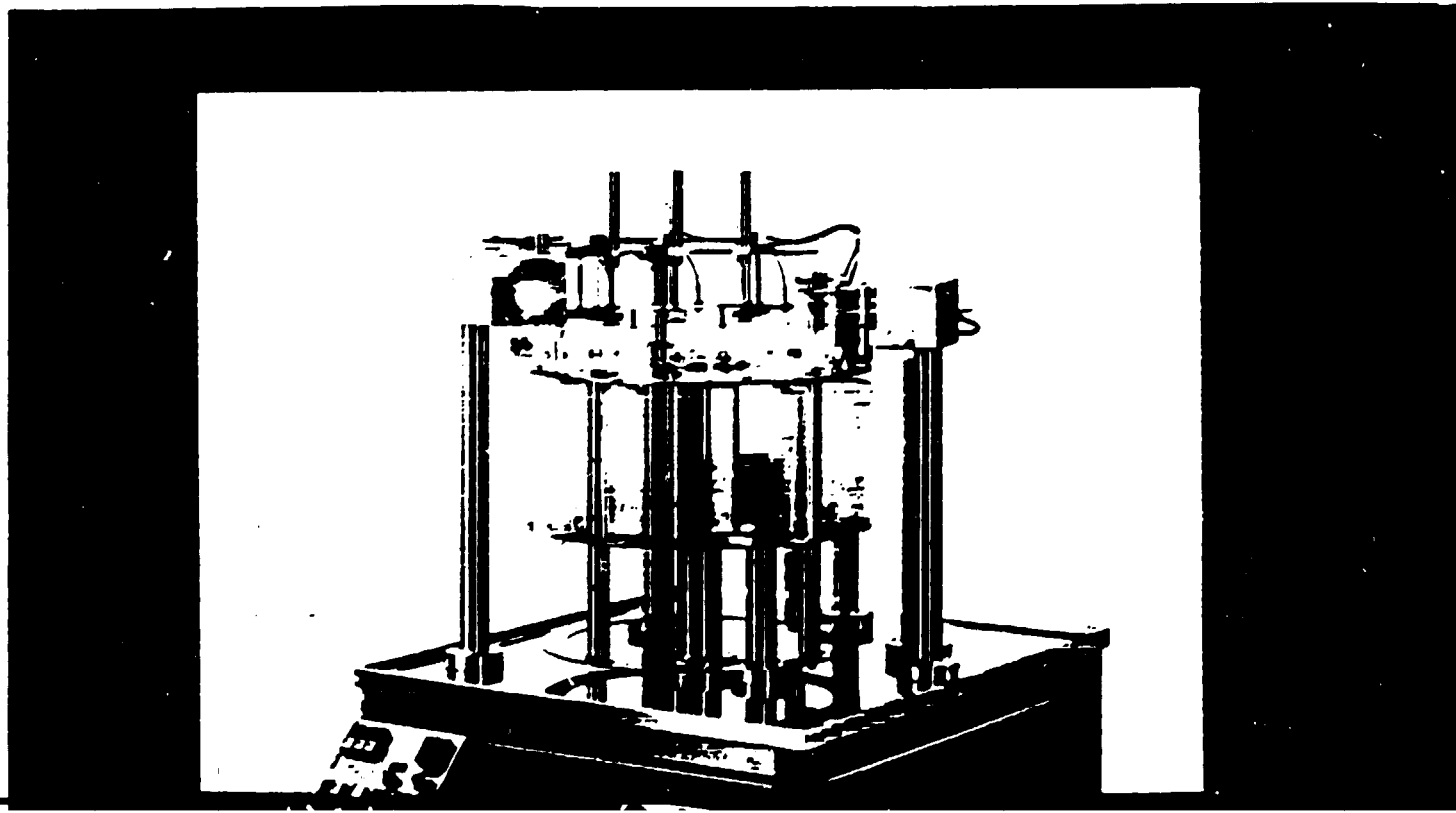
LYTZEN SCHUBERT MACHINERY A.S.
KANALHOLMEN 14 1C
DK-2650 HVIDOVRE
DENMARK

PHONE + 45 31409600
FAX + 45 36771020

TELEX
10720 LYSHV DK

VIA EASTERN TELECOMS

40171 TROPTEL PK.....



ANNEX IX.

Detailed Offers from: Schoeller-Bleckmann G.M.B.H. Ternitz Austria

1666OC SOT A+
40171 TROPTCL PM
COMPUTER TELEX - DO NOT INTERRUPT

FOR BEING AUTOMATICALLY PASSED ON TO THE COMPETENT DEPARTMENT
YOUR REPLY SHOULD BEGIN WITH "FAM

ID-NR: 900012005 00.06.90

FROM: SCHOELLER-BLECKMANN
TO: MR. DR. LAJOS ARADI. EXPERT OF UNIDO. ROOM NO 105

REF: BUDGET OFFER FOR STERILIZER

DEAR MR. ARADI.

PL FIND BELOW OUR OFFER

1. 1 PC ROTOTHERM STERILIZER SDR 12 12 48/2
CAPACITY APPROX 2000 BAGS/CYCLE
DETAILED CAPACITY DEPENDS ON THE FINAL SIZE OF BAG SAMPLES
BUDGET PRICE FOR COMPLETE STERILIZER INCL NON DRIVEN
ROLLER CONVEYOR IN THE CHAMBER EX WORKS. SEAWORTHY PACKED:
AUSTRIAN SHILLINGS 3.200.000.-

PRICE FOR ONE PC LOADING CARRIAGE WITH 8 SHELFES FULLY MADE
OF STAINLESS STEEL: ATS 70.000.

AS BASIC EQUIPMENT WE SUGGEST 12 CARRIAGES (=2 FULL LOADS)
SPARE PARTS. TRANSPORTING COSTS AND INSTALLATION ARE NOT
INCLUDED IN AM PRICE.

2. 1 PC STEAM STERILIZER TYPE ADV 669 FOR FILTERS AND
POROUS LOAD

PRICE FOR AM ADV WITH SINGLE DOOR AND EXTERNAL STEAM SUPPLY	ATS 650.000.-
ALTERNATIVELY 2 DOORS	ATS 690.000.-
ADD PRICE FOR BUILT IN STEAM GENERATOR	ATS 120.000.-
PRICE FOR 12 PCS STERILIZING CASSETTES (12 FULL LOADS)	ATS 19.200.-

DELIVERY: 9 MONTHS

WITH KIND REGARDS.
SB-MEDIZINTECHNIK
L. GRUBER J. BRUNNER

Firma
HUMAN
z.H.Hrn. Dr. L. Aradi

per Telefax

-
FAM1/Br/Hr
1990-06-25

Projekt Philippinen

Sehr geehrter Herr Dr. Aradi,

nachstehend unser Richtoffert über Sterilisator für Lösungen in PVC-Beutel:

1 Stk Rototherm Type SDR 12 12 48 / 2

Kapazität: ca. 3000 Stk 500 ml Beutel/Charge

Richtpreis ab Werk: öS 3,200.000,--

In diesem Preis ist ein nichtangetriebener Kollgang im Sterilisator enthalten.

Preis für 1 Stk Beschickungswagen mit 8 Lochblechtassen, komplett aus Edelstahl öS 70.000,--

Als Grundausstattung empfehlen wir 12 Wagen (= 3 volle Beschickungswagen)

Lieferzeit: 8 Monat nach Auftragserhalt

Angebotsgültigkeit: 4 Monate

Zu Ihrer Information: wir haben bereits 2 Stk Rototherm nach Philippinen geliefert (Montage in Kürze).
Heißwassersterilisatoren sind für PVC-Beutel nicht geeignet.

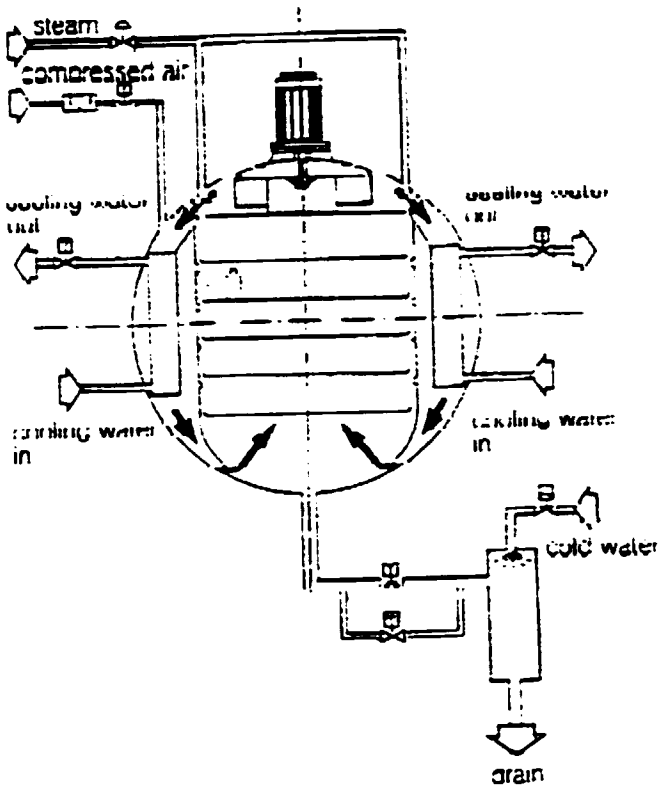
Für nähere Informationen stehen wir Ihnen jederzeit gerne zu Ihrer Verfügung.

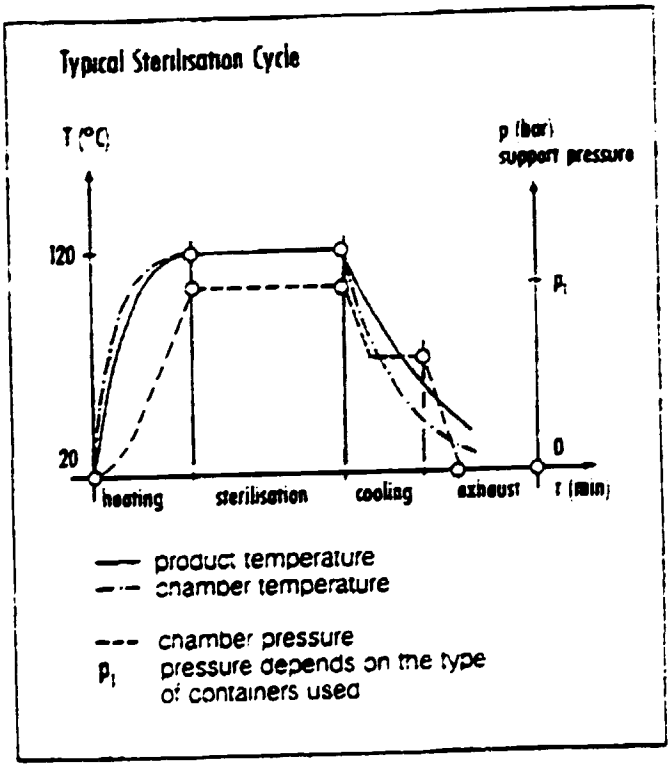
Mit freundlichen Grüßen

SCHOELLER BLECKMANN Ges.m.b.H.
MEDIZINTECHNIK

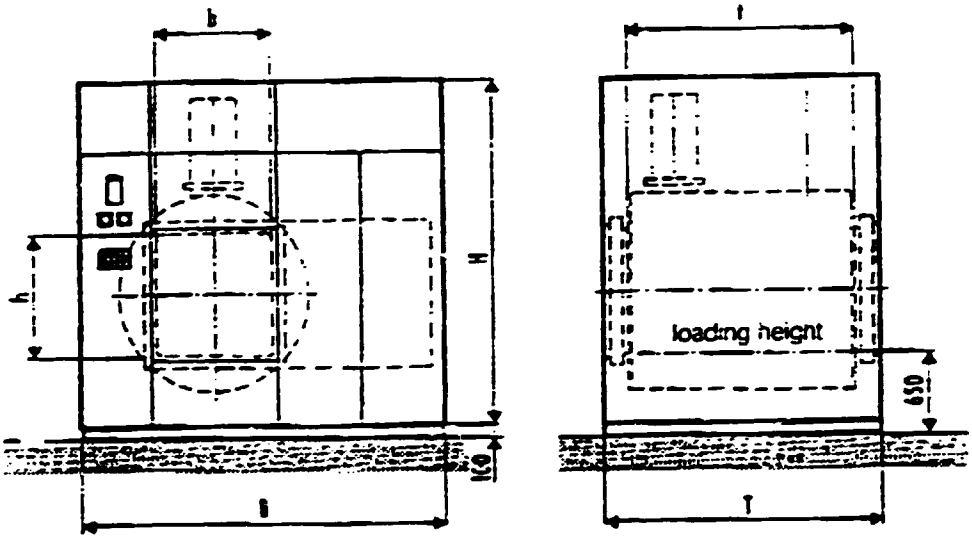
L. Graser J. Breyner

SCHEMATIC VIEW OF OPERATING PRINCIPLE





STANDARD SIZES



Plant type		Usable space h	w	d	Outside dimensions H	W	D
SDR 9 9	12	950	950	1250	3000	2900	1650
	15			1550			1950
SDR 12 9	12	1250	950	1250	3000	3200	1700
	18			1850			2300
	24			2450			2900
SDR 12 12	24	1250	1250	2450	3100	3000	2900
	30			3650			4100
	48			4850			5300
	60			6050			6500
	72			7250			7700

Dimensions in mm

* For special designs and additional equipment, please enquire.

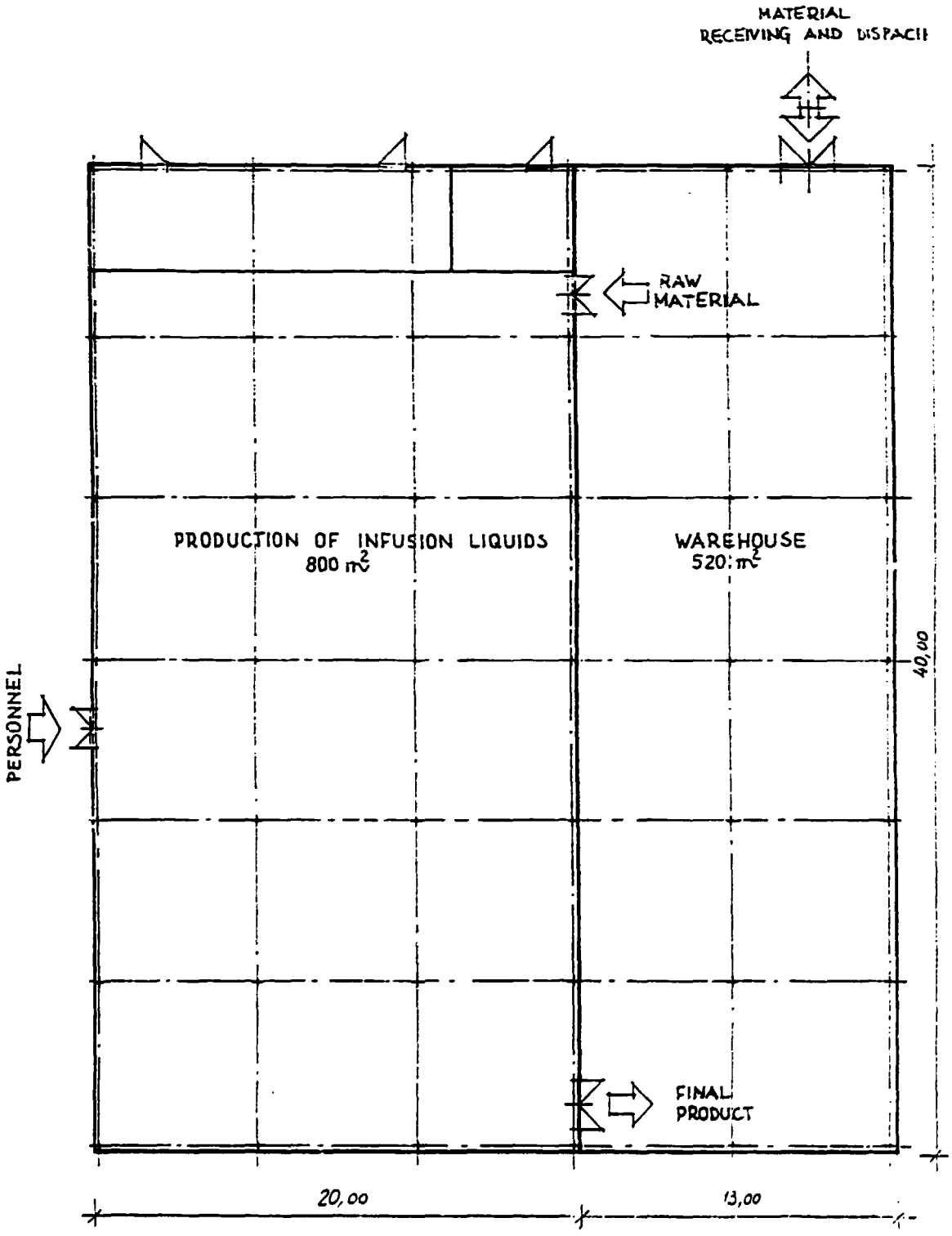
TECHNICAL DATA

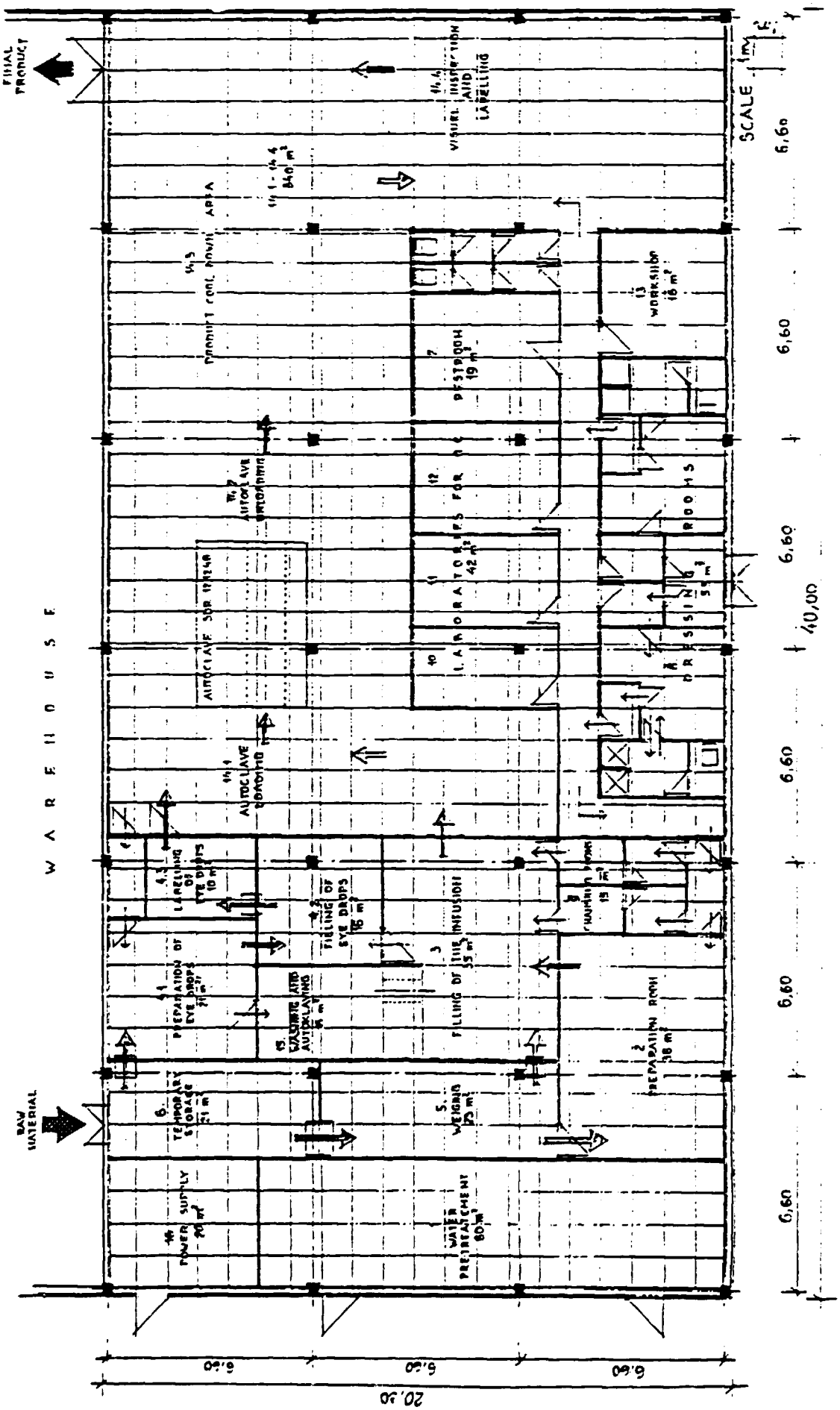
Technical Data		SDR	090912	090915	120912	120918	120924	121224	121236	121248	121260	121272
Usable chamber volume		m^3	0,97	1,22	1,30	1,94	2,59	3,46	5,18	6,91	8,64	10,37
Dimensions of usable chamber space	height	mm	950	950	1250	1250	1250	1250	1250	1250	1250	1250
	width	mm	950	950	950	950	950	1250	1250	1250	1250	1250
	depth	mm	1250	1550	1250	1850	2450	2450	3650	4850	6050	7250
Loading height		mm	650	650	650	650	650	650	650	650	650	650
Net weight		kg	3000	3300	4000	4700	5400	6500	8100	9800	11400	13000
Steam connection		DN	50	50	50	65	65	80	80	100	100	125
Peak consumption		kg/min	4,8	5,7	6,5	9,1	11,8	14,3	20,4	26,7	32,7	39
Rated capacity		kg/h	430	515	660	780	1180	1280	1840	2390	2950	3500
Consumption per cycle		kg	145	170	220	260	395	430	612	800	980	11700
Cooling water connection		DN	32	32	32	32	40	50	60	65	65	80
Peak consumption		l/min	52	58	71	130	130	152	205	269	350	392
Rated capacity		l/h	2300	2760	3540	4180	6350	7340	9360	12850	16800	18820
Consumption per cycle		l	1920	2300	2950	3480	5290	6110	8220	10710	14000	15680
Compressed air connection		DN	20	20	20	20	25	32	32	40	50	50
Peak consumption		m^3n/min	0,9	1,2	1,3	2	2,7	3,3	5,0	6,5	8,2	9,8
Rated capacity		m^3n/min	56	70	80	120	160	200	295	395	492	590
Consumption per cycle		m^3n	10	12	13,4	20	26,6	33	50	65	82	98
Power supply												
Rated capacity		kW	6,5	6,5	6,5	12	12	23	23	34	45	45
Consumption per cycle		kWh	7,3	7,3	7,3	13,5	13,5	26	26	38	50	50
Heat dissipation												
	heat side	W/m^2	350	350	350	12	350	350	350	350	350	350
	maintenance area	W	942	1170	1130	13,5	2200	2460	3370	4880	6080	7290
Cold water pressure		bar	gauge 2.0 min, 5.0 max.									
Water hardness		dH°	7 max.									
Steam pressure		bar	gauge 2.5 min, 8.0 max.									
Compressed air		bar	gauge 6.0 min, 8.0 max.									
Electric power rating			3 x 380 V, 50 Hz, permissible voltage variation ± 5%									

The consumption figures refer to a sterilisation cycle at 121 °C, for solutions in 500 ml glass containers, to DIN 58 363/Part 5, loading temperature 20°C, cooling water temperature 15°C, unloading temperature 60°C.

ANNEX X.

SPACE REQUIREMENT AND MATERIAL MOVEMENT DIAGRAM IS SHOWN




FINAL PRODUCT
SCALE 1:
VISUAL INSPECTION AND LABELLING
PERSONNEL ROOMS
WORKSHOP
PASSING ROOMS
LABORATORIES FOR QC
AUTOCLAVE SOR INTER
AUTOCLAVE BOROSIL
LABELLING OF EYE DROPS
FILLING OF EYE DROPS
PREPARATION OF EYE DROPS
FILLING OF IRIS INFUSION
PREPARATION ROOM
TEMPORARY STORAGE
WEIGHING
POWER SUPPLY
WATER PRETREATMENT
RAW MATERIAL
WAREHOUSE
6,60
40,00
20,30

ANNEX XI

Equipments and instruments for the Quality Control and Quality Assurance

1.) For the chemical laboratory

- Laboratory furnitures, e.g. cupboards, central bench, wall benches, tables for balances.
- Fume cupboard.
- 2 pcs Analitical balances:
  Capacity: 300 grams
  Accuracy: 0,001 gram
- 1 pc Balance
  Capacity: 2,2 kg
  Accuracy: 0,01 gram
- 2 pcs Digital laboratory pH-mV meters incl. Glass electrodes and different standard buffer solutions for the calibration.
- 1 pc UV/Visible Spectrophotometer.
- 1 pc Flame-photometer for the determination of Na, K.
- 1 pc Polarimeter suitable for tubes with leught up to 200 mm, with single inclined focusable eyepiece, tube holder seat, polarizer, analizer and sodium lamp.
- 1 pc Conductivitimeter.
- 1 pc Viscosimeter with thermostat.
- Muffle oven with electric pyrometer for temperature regulation up to 1000°C.
  Chamber size: 250x170x120.
- Water bath with 3 independent baths.
- 2 pcs Eletromagnetic stirrers.

- 1 pc Melting point test tube incl. thermometer, max. 250°C.
- Various equipment and different materials, such as:

  conical flasks, funnels, beahers, filters, volumetric flasks, thermometers, evaparating diskes, porcelain crucibles, weighing bottles, stands, tripods, bunsen burness, vacuum desiccators, glass buretts and pipetts.

- Chemical reagents, reference standards.

2.) **For the Microbiological laboratory**

- Hot-air oven for depyrogenation, 250°C - 300°C capability.
  Chamber size approx: 600x600x600.
- Laboratory-autoclave, stainless steel.
  Chamber size approx: 600x600x600.
  Complete with two sets of sterilisation baskets.
- 2 pcs Water circulation incubator, one with refrigerating group.
  Capability: up to 40°C.
  Accuracy: ± 0,5°C.
  Chamber size approx: 300 lit.
- Refrigerator.
  Capacity approx: 250 lit.
- Laminar-Flow box -"Class 100"- board in stainless steel.
  Horizontal type.
  Filter size: 600x1200 mm.
- 2 pcs Stainless steel sinks, with wash basins and support shelves.
- 2 pcs tables with stainless steel shelv.
- Technical balance 5 kg capacity (0.1 g accuracy).
- Microscope, binocular clear field, magnification 4x, 10x, 40x, 100x.
- Sterility control system, complete with various accessories.
  Principle: MEMBRAN FILTER METHOD.

- Temperature-Block Module Heater 37°C ±1°C for L.A.L. test Vortex-Genie.
- Various glass equipment and different materials: filters, thermometers, bottles for reagents, pyrex funnels, microbiological pyrex test tubes, Petri-dishes.
- Different culture medias for the sterility testing. and hygenic control.

3.) **For the Quality Assurance**

- Particle counter for testing of the particulate matter contamination of the infusion solutions.
  Working principle: either by microscopic method (USP XXII.) or by electronic sensor.
- Particle counter for the validation of the clean-room facilities. HEPA filters and Laminar-Flows.
- Air-flow velocity meter.
- 6 or 12 channel Digital-Thermometer complete with thermocouples for validation of the autoclaves.

TOTAL CONSUMPTION OF I.V. FLUIDS BY THE PHILIPINE GENERAL HOSPITAL AND THE DOH METRO MANILA IN 1988

	U.P. - P.G.H.			D.O.H. - M.M.		
	1000 ml	500 ml	250 ml	1000 ml	500ml	250 ml
Dextrose 5% in water	4.560	4.200	18.000	38.699	125.202	7.667
D5 Lactated Ringers			3.600	139.162	36.402	15.248
D5 Normal Saline				61.101	7.751	3.967
D5 Normal Ringers	34.300	4.128				
D5 Normosol	18.000	2.400				
Dextrose 5 0.3 Saline					73.736	25.160
Dextrose 5 0.3 Normosol	2.380	5.100	5.040			
Dextrose 5 0.9 Normosol	5.148	1.704				
Dextrose 5 I.M.B.		5.472	9.600			
Dextrose 10% in water			2.004	3.735	20.717	
Tripied Distilled Water				747		100 ml 4.157 50 ml 44.468
Lactated Ringers	192	600		16.401	14.202	
Normal Saline				4.371	2.169	
Mannitol 20%		2.700	4.320			
Aminosin		600				
Aminosin 5%		540				
Dextrose 75%		360				
Total:	114.780	27.304	42.564	329.207	340.179	99.777

Overall Total = 954.311 Cost P 21.751.443

1000 ml	443.987 units	46.5%
500 ml	357.983 units	38.5%
250ml	142.394 units	15%

ANNEX XIII.

List of equipments for the production of eye drops (Minimum requirements)

I. For the compounding and filtration of the solutions

1.) Balance:

Type: SARTORIUS PT 1200 g/0.1 g.
Expected price: ca. 1.000 - 1.100 USD
Supplier: SARTORIUS GmbH
West Germany
GÖTTINGEN

2.) Vessel for making of the stock solution

Type: SARTORIUS SM 17531 (10 Litres)
Expected price: ca. 800 - 900 USD
Supplier: SARTORIUS GmbH
West Germany

3.) Vessel for compounding of the solution

Volume: btto. 125 Litres

Type: Stainless steel, inside polished, monoblock construction, jacketed vessel, provided with security group and 0.2 micron air filter.

The vessel is provided with agitator, and connections for:

- WFI inlet
- tube for gassing
- heigh adjustable level contr
- spraying device for cleaning
- thermometer
- product inlet
- vacuum valve

Product outlet: - by bottom valve
Sampling: by sampling valve
Expected price: ca. 20 - 22.000 USD
Supplier: DIESSEL GmbH.
West Germany
HILDESHEIM

4.) Filling vessel - for the collection of the sterile solution.

a.) Volume: 120 Litres
Type: single wall, stainless steel, polished, not pressure vessel, sterilizable by steam in an autoclave, provided with:
- product inlet,
- product outlet,
- sterile vent filter connection.

Expected price: ca. 1.800 - 2.000 USD

b.) Alternative:

2 pcs 60 Litres SARTORIUS SM 17534
Type: identical with the above 120 litre type
Expected price: ca. 900 - 1.000 USD
Supplier: SARTORIUS GmbH
West Germany
GÖTTINGEN

5.) Filters

- 1 pc. SARTORIUS SM 16276
142 mm Filter holder GMP type, incl. connectors for the sanitary flanges, clamp and gasket.
Furthermore 50 pcs./pack 0,2 micron filter membrane (PTFE or Nylon 66) and 50 pcs./pack prefilter sheets.

Expected price: ca. 2.000 - 2.200 USD

- 1 pc. SARTORIUS SM 16277
293 mm Filter holder, GMP type, incl. connector the sanitary flanges. clamp and gasket.
Furthermore 50 pcs/pack 0,2 micron filter memorane (PTFE or Nylon 66.) and 50 pcs/pack prefilter sheets.

Expected price: ca. 2.700 - 3.000 USD

Supplier: SARTORIUS GmbH.
West Germany
GÖTTINGEN

6.) Laminar - Flow hood

size: approx: 600 x 1200 mm net filter surface
Standing on legs.
Vertical air flow.

Quality: CLASS 100 acc. to Fed. st. 209 b.

Supplier: INTERKLIMA
Austria
Vienna

7.) Additional equipments:

- Memoran type compressor:

Type: SM 16617
Expected price: ca. 2.000 - 2.200 USD

- Memoran type vacuum pump

Type: SM 16697
Expected price: 1.000 - 1.100 USD

- Peristaltic pump:

Type VP 380
Expected price: ca. 1.800 - 2.000 USD

Supplier of the above equipments: SARTORIUS GmbH.
West Germany
GÖTTINGEN

II. For the filling and closeing of the eye drops

1.) Specification of the primary packaging materials:

- 10 ml plastic dropper bottle
  Type: 34032-00-1128
  Material: LUPOLEN 1810 E WHITE
- Dropper insert
  Type: 14166-00-1002
  Material: LUPOLEN 1800 H -natural
- Tamper - proof closure
  Type: 15190-00-2111
  Material: HOSTALEN GC 7260 White

Supplier: BÜNDER-GLAS PLASTOFORM
West Germany
BÜNDE 1 (Westfalen)

Expected price: Ex works, in case of purchase of 100.000 complete set of the aboves
approx: 15.000 DEM (ca. 9.000 - 10.000 USD 100.000 pcs.

Extra charges for the sterilization by etilen-oxic (ETOX)
approx: + 15 %

2.) Filling unit

Type: Semiautomatic, hand operated
FMS model Dispensor

Specification:
- 2 filling pistons for the filling of 10 ml
- product contacting parts should be sterilized by steam in an autoclave
- single stroke operation

Expected price: 10.000 USD

Supplier: J. WICK GmbH - Austria
Vienna

3.) 2 pcs. Laminar - Flow Bench

Size: approx: 600 x 1.800 mm net filter surface
Provided with stainless steel surface working table.
Quality: CLASS 100 acc. to the Fed.St. 209/B.

Supplier: INTERKLIMA - Austria
Vienna

III. Labelling and packaging

1.) Labelling by self-addhesive labels.
The process should be done manually.
The printing of Batch No. and Exp. date on the labels should be done manually by symple stamps usually used in offices.

2.) Cartooning

The process should be done manually .
The printing of Batch. No. and Exp. date on the cartoon boxes should be done manually by simple stamps usually used in offices.

Expected cost: ca. 200 - 300 USD