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ASSISTANCE IN DIVERSIFICATION AND EXPANSION OF MANUFACTURING FACILITIES FOR PHARMACEUTICALS IN ZAMBIA

SI/ZAM/86/905

ZAMBIA

Technical report: Manufacture of parenteral dosage forms and drops*

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

Based on the work of Mohammed Alauddin,
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United Nations Industrial Development Organization
Vienna

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I. EXPLANATORY NOTES AND ABBREVIATIONS

Explanatory Notes

1. Value of currency employed throughout this report are in United States Dollars.

   The economic evaluation has been carried out in Kwacha with following exchange rate:-

   1 U.S. Dollar : 8.00 Zambian Kwacha

2. All weights and measures are in metric system unless otherwise stated.
3. Main figures of quantities and values have been rounded off.
4. Drawings of the buildings and civil structures, though true to scale, require architectural details.
5. Measurement of equipment, fixtures and furniture are fairly close to actuals but subject to adjustments.
6. Costs of the equipment, raw materials and packaging materials are representative of the period April-June 1987.
7. Costs of civil work are latest professional estimates.
8. The text of the report has been kept brief by offering the details through tables, formats, and drawing.

Abbreviations

INDECO	:	Industrial Development Corporation.
G.P.L.	:	General Pharmaceuticals Limited
M.S.L.	:	Medical Stores Limited
ZIMCO	:	Zambia Industrial and Mining Corporation
M.O.H.	:	Ministry of Health
N.C.D.P.	:	National Commision for Development Planning
Z.N.P.F.	:	Zambia National Provident Fund
U.N.D.P.	:	United Nations Development Programme
U.N.I.D.O.	:	United Nations Industrial Development Organisation
G.M.P.	:	Good Manufacturing Practices
O.R.S.	:	Oral Rehydration Salt
I.V.F.	:	Intravenous Fluids
L.V.P.	:	Large Volume Parenterals
S.V.P.	:	Small Volume Parenterals

II ABSTRACT

Project Title

Assistance in Diversification and Expansion of Manufacturing Facilities for Pharmaceuticals in Zambia.

Project Number and Purpose

SI/ZAM/86/905

To establish indigenous facilities for manufacture of parenteral dosage forms and drops to satisfy the needs of national health delivery system.

Objective

To develop comprehensive plans covering all technical inputs, costs and implementation programme of the project.

Duration of the mission

Total	-	six months
Starting date	-	9 January 1987
Completion date	-	8 July 1987

As a result of successful accomplishment of the activities enumerated under the current preparatory assistance, a detailed package of recommendations backed by necessary inputs has been finalised. The project is now passing through pre-implementation phase of administrative formalities and approvals and has been scheduled to take off in the fourth quarter of 1987.

Salient features of the inputs are summarised below:-

- National requirements of small volume parenterals (SVP) and drops, based on the essential health needs, have been compiled.
- Plans have been finalised to redesign the factory building of GPL to include a facility for manufacture of SVP with capacity exceeding the national requirements by about 15 percent.

- Requirements of plant machinery and equipment have been tabulated including technical specifications, sources of supply and costs.
- Estimates of consumption of raw and packaging materials for the first year of production have been determined supported by sources of supply and costs.
- The cost of project has been estimated at $750,000 including $250,000 as working capital and contingencies.
- Sufficient fund for project financing have been secured through a loan from ZNPF.
- Preparatory work for floating tenders for civil work and import of equipment are in advanced stage of progress.
- Economic evaluation of the project has offered attractive results with 44.49 percent internal rate of return and a payback of 2 years and 4 months.
- Technical assistance for the implementation phase including an extensive training programme for the national staff has been requested from U.N.D.P. resources.

III CONCLUSIONS AND RECOMMENDATIONS

a. Conclusions

- The current studies have confirmed the technical soundness as well as economic viability for establishment of a facility for manufacture of SVP and drops within the existing premises of GPL.
- Redesigning of the buildings will permit to accommodate a suitable size unit for production of SVP and drops. It will also allow expansion of other vital plant functions, centralization and enlargement of plant and engineering services and streamlining of the production lines.
- The technology for production of SVP is identical to that of I.V. Fluids except that of subdivision and as such the available experties will allow smooth adaptation of the techniques for the production of SVP and drops.
- An exercise has confirmed that the product unit costs would be fairly competetive with the imported products and would also result in about 55 percent saving in foreign exchange.
- The cost of the project is estimated at $750,000 including foreign exchange component of $355,000. Sufficient loan has been secured for this purpose.
- The payback period of the investment would be 2 years 4 months and offering 44.49 percent internal rate of return on the investment. (COMFAR)

b. Recommendations

1. Benefitting from the prevailing favourable exchange rate of K8.00 to $1.0, the project should be implemented expediently, specially the import of machinery should be formalised in order to open the letters of credit as soon as possible.

   Efforts should be made to obtain a blanket approval to cover the import cost of the entire machinery. At the same time exemption from the imports duty and other taxes on the machinery and material should be obtained.

2. Resources should be mobilised to build up stocks of I.V. Fluids and ORS to ensure uninterrupted supply of these products during the commissioning period of the plant.

3. Preparation should be commenced to arrange training of the national staff so as to make them available in the plant at the time of commissioning.

4. Expert technical assistance must be secured to ensure on the spot supervision and advisory services during the project implementation followed by trial runs, start-ups and commercial production.

IV INTRODUCTION

A. Project Background

According to sensible estimates the annual consumption of pharmaceuticals in Zambia is in the range of 22-23 million, about 50 percent of which is consumed in the public health sector and ZCCM health service combined. Out of this consumption, only about 10 percent is currently being manufactured locally, largely shared by National Drug Company Limited and General Pharmaceuticals Limited in the public sector and two privately owned companies.

Ever since the independence in 1964 and following the Rhodesian U.D.I. in 1965, the Government of the Republic of Zambia is eagerly pursuing development of indigenous pharmaceutical industry as most important means to ensure adequate health delivery programme for the nation. The need for provision of essential drugs from indigenous sources became more intense and preferable after the closure of Rhodesian border in 1973 while the route of South Africa, the traditionally main source of supply, became more and more unacceptable.

General Pharmaceuticals Limited, on the recommendations of UNIDO, was originally established for production of intravenous fluids in 1979 and since then is successfully meeting the national requirements. Through further assistance from UNIDO, an ORS production unit was added to the activities of GPL in 1985 and is in full operation since 1986.

As an outcome of the investigatory assessment carried out during the UNIDO mission in 1985 (US/ZAM/82/137), when it was suggested that by suitable redesigning of the existing building, sufficient floor space can be spared for establishing two reasonable sized units for production of diversified ranges of pharmaceuticals, the government showed keenness for setting up a facility for manufacture of SVP and drops at GPL, drawing benefit of utilization of several of the already installed plant services.

Pursuing the efforts in this direction, the GPL succeeded in securing a loan of 6.0 million kwacha ($750,000) in 1986 with simultaneous request to UNIDO to provide the services of a pharmaceutical industry expert in order to draw-up detailed technical plans with necessary inputs and a work programme for project implementation.

B. Official Arrangements

- Request for assistance through the Office of the President, Republic of Zambia (N.C.D.P.)	2 September 1986
- Approval by the Programme Development and Evaluation Branch, UNIDO, Vienna	13 November 1986
- Date of Project becoming operational	9 January 1987
- Duration of project	Six months
- Start of the mission (fielding of the expert)	9 January 1987
- Completion of the mission	8 July 1987

C. Contributions

1.	UNIDO Contribution	US $ 36,600
2.	Government Contribution	In kind

- Secretarial, clerical and other services essential for the UNIDO expert for the duration of the mission.
- Official transport to enable the UNIDO expert to carry out his duties.

D. Objective of the Mission

1. Development Objectives

- To manufacture essential drugs locally to achieve a steady supply and self sufficiency of pharmaceuticals for the national requirements.
- To promote import substitution and foreign exchange saving.
- To stimulate growth of related industries such as packaging materials and pharmaceutical chemicals.
- To provide development of technical and managerial manpower.

2. Immediate Objectives

To provide technical assistance for plant design, identification of new products, manufacturing technology, specifications of machinery and equipment and training of the local personnel.

V. ACTIVITIES

A. National Requirements

Detailed review of several compilations of the requirements of pharmaceuticals in the public sector carried out in the past ten years did not provide a sensible pattern of consumption in case of numerous essential dosage forms. In view of such anomalies it was deemed necessary to make totally fresh approach to compute the requirements of SVP and drops.

Recent work being carried out at MSL towards compilation of an up-to-date national directory of pharmaceuticals and to rationalise the procurement, stocking, distribution and consumption proved extremely helpful in compilation of national requirements.

Working in close collaboration with MSL and maintaining constant liasion with ZCCM and other agencies, it was possible to develop a quantified list of 23 SVP dosage forms in 37 different pack presentations (annex 1) and 13 ear, nose and eye drops dosage forms (annex 2) which represent almost 95 percent of the consumption of these two dosage form groups. The remaining 5 percent dosage forms are consumed in too small quantities to justify commercial production locally.

Requirements of these pharmaceuticals, which are tabulated according to the dosage form presentations in annex 3 represent the national consumption in the public health sector and ZCCM combined. During the current study no attempt was made to ascertain the consumption levels in the private sector.

As a result of this study the requirements of various group of SVP and drops dosage forms computes out as follows:

I.	STERILE LIQUIDS		
	a. Ampoules	(1,2,5,10 & 20ml)	2.40 million
	b. Vials	(10,20,50 & 100ml)	1.70 million
II.	DROPS	(all 10ml)	1.00 million
III.	STERILE DRY FILLS (antibiotics)		
	a. Single dose vials (10ml)		2.0 million
	b. Multiple dose vials(15 & 30ml)		1.4 million

B. Building, Redesigning and Expansion

1. Existing buildings and layout

The factory with all its service annexes and central administration offices is modern and built over a piece of land measuring 13,750m^2 (annex 4.). The centrally situated plant itself is spread over an area of 1,524m^2. It is built of R.C.C. columns and beams structure and as such internal modification can be carried out easily and economically.

The existing internal layout of the building (annex 5), however, does not offer rationale and efficient utilization of space:

- Area allocated to packaging of IVF and ORS are far larger than actually required.
- Raw material stores, quality control and the workshop have been allocated much smaller space as compared to the needs
- Water treatment plant is located at a large distance from the solution making room and linked through long supply line.
- Offices for the Production Manager and the Plant Engineer are not provided.
- The personnel changerooms are built on both end of the building.
- Compressor is housed in a room within the building.

In view of these considerations it became apparent that given due efforts towards relocations, expansions and redesigning, sufficient floor space could be made available for establishment of a medium size facility for production of SVP within the existing building alongwith expansion in other plant functions to meet the increased needs.

2. New plant design

a. General

In redesigning and expansion of the plant building, main aim was to keep the area of new buildings to a minimum due to cost considerations although the preliminary evaluation had indicated additional requirements of about 500m^2. As a consequence, certain hitherto unutilised cantilever conopies measuring 201m^2 have been incorporated into the plant at relatively small cost (annex 6).

These extensions will house the water treatment unit and the remaining will become parts of SVP and ORS production units and quality control with provision of about $40m^2$ for chlorohexidine manufacturing unit. Only the workshop and compressor would be housed in the new premises where all engineering services will be centralised

After relocation, the main production floor will be redesigned according to the plans shown in annex 6. Table 1 provides statistics towards the suggested adjustments, expansions and additions.

b. Main Features

- An overall increase of $483m^2$ useful floor space.
- Reclaimation of $405m^2$ floor space within the existing building, which with only $320m^2$ of new structure will result in additional space utilization of $725m^2$.
- New facilities for production of SVP, drops and chlorohexidine, managers' offices and personnel services (canteen and clinic) have been created.
- Stores, quality control and laundry areas have been amply enlarged to cater for increased activity.
- Fully equipped workshop has been established at a location very central to the areas of major engineering activities.
- Compressor has been removed from the main plant.
- Water treatment section has been located adjacent to the solution preparation rooms while kept adequately segregated.
- Streamlining of the production operations have been considerably improved.
- Personnel change rooms have been centralised at one end of the building well segregated from the operational area.

Structural changes recommended in the plant building have been illustrated in annex 7 while the annex 8 provides a scheme for relocation of different functions. The general layout of the plant after proposed redesigning and addition of buildings are shown in annex 9. Sectional details with general equipment and furniture layout is illustrated in the blow-up drawings from annex 10 to 16.

c. S.V.P. Production Unit

Floor space allocated for the production of small volume parenterals and drops, measuring about $186m^2$, is divided into three distinct sections of washing, sterilization and preparation, cooling and subdivision and finally labelling and packaging.

These are linearly laid out in a perfectly streamlined pattern and serviced by the water treatment plant on one side and raw and packaging materials stores on the other. The material, personnel and product movements through various stages of production are illustrated in annex 17.

Finishing Specifications

Finishing of the areas where production of SVP is carried out require special attention both with respect to materials and workmanship.

- Wall surfaces in certain areas should be covered with glazed tiles according to the nature of operation:

Washing, sterilization and preparation section	:	upto door heights
Cooling and subdivision	:	upto ceiling
Labelling and packaging	:	only with smooth waterproof plastered surface with non glossy washable paint

- Services and supply lines should either protrude down from the ceiling or concealed within the walls.
- Doors and windows should be flush finished and of waterproof material not requiring paint or varnish.
- Light fixtures should either be flushed in the ceiling or fabricated in "sealed box" design.
- The ceiling should be smooth and coated with non glossy steam/ fumes resistant white paint.
- The floors should be long wearing and capable of withstanding exposure to moisture and chemicals normally used for cleaning/ washing.
- The floor level should have adequate and uniform gradient towards the drains/outlets.

Environmental Control

Maintenance of constant sterility in the cooling/subdivision area and particle/fibre free environments in the washing, sterilization and preparation area are absolutely vital requirements for production of SVP.

The washing, sterilization and preparation area should be constantly fed with clean air with possitive air current towards the outlets. In addition the washing machines should be equipped with overhead laminaire hoods to maintain clean air "cloud" over the washed materials.

The entire cooling/subdivision area is supplied with totally bacteria and particle/fibre free air at a temperature of 24°C and 30 percent R.H. through a specifically designed air handling/conditioning unit. The flow of the air is maintained in a direction always originating from most critical areas (subdivision) to the middle regions and finally to the periferal areas constantly flushing the area with fresh sterile air (annex 13A).

The air flow from the area for blending and subdivision of powders should have an independent outlet to ensure total exhaust of air born particles, eleminating counter air flow and hazard of cross contamination.

The personnel entrance should be adequately buffered to exclude passage of outside air into the sterile zones.

d. Plant Services

The plant and engineering services and the supplies and utilities needed for the SVP unit are already available in the plant to suffice additional consumption.

Necessary modifications, extensions etc of the supply lines have been drawn out and incorporated in the final architectural drawings.

Tentative consumption of major utilities and supplies for the SVP production unit at full operating level are as follows:

i.	Electricity	50 kilowatt hour
ii.	Air conditioning	10 tons
iii.	Water	5,000 litres per day
iv.	Deionised water	500 litres per day
v.	Distilled water	450 litres per day

Further discussion on this matter is included under the section for plant services equipment where additional requirements have been taken into account in assessing the sufficiency of the existing installation.

e. Reconstruction Schedule Guideline

Although it is not possible to avoid loss of production during reconstruction work but certain measures can be taken in advance to minimise such losses.

- Sufficient stocks of the finished products should be built up in advance to cover the sales during the reconstruction period.
- Supply of all relevant building materials and manpower must be ensured in advance.
- Doors, windows and any other prefabricated structures should be kept in readiness in advance.
- Contractors should be made totally committed to time schedules for completion of work and all managerial co-operation and other assistance should be provided to them to ensure smooth progress of work.

In order to keep the level of disruption to a minimum, on the other hand, the construction schedule should be broken down in well identified job and executed in a sequence so as to permit continuation of normal functioning of as many areas as possible.

C. Plant Capacities

The plant design for the manufacture of SVP and drops has been totally governed by the floor space of the plant which could be spared for this purpose. The capacities for various dosage forms which have been possible under the circumstances (Table 2) are just about 15 percent over the computed national requirements. Even the proposed capacities projection was possible after extending the existing six meter width of the present building across the adjacent three meter wide cantilever canopy. Depending upon the two types of technology employed during production, the capacities have been projected in two phases which will also facilitate to phase out the cost of equipment if circumstances require.

- Although the proposed plant capacities are marginally higher than the national requirements, in case of substantial increase in requirements, the dry fill section has a provision of second line while liquid fill section capacity, due to space limitations, can be increased only by replacing the machines with higher speed units. Washing and sterilization section can be operated on extended shifts. It may be possible to increase the capacities by replacing certain machinery by higher speed automatic units.

- Key operation in computing the capacities has been the final packaging lines pontetial. The bulk manufacture and washing/sterilization capacities have been worked back to suffice the finishing lines requirements.

D. Equipment

1. Identification and Layout

Identification : Requirements of the production machinery have been tabulated in annex 18. Based upon the capacities requirements, suitable capacity single units have been selected except in those cases where either the situation necessarily required separate unit or single unit of such high output may not be advisable. The exercise was also guided by the following considerations:

- Balanced capacities of directly interlinked processes.
- Standardised packaging lines through mechanization of key operations on conveyorised systems.
- Maximum automation in the subdivision operation to ensure GMP requirements.

The annex 19 provides approximate costs and procurement schedule of the equipment. The phasing out of the equipment procurement is based on the following considerations:

- Equipment required for"terminally sterilizable"products only are covered in the first phase.
- Equipment for products requiring total asceptic techniques as these cannot be terminally sterilised have been placed in second phase.

It is suggested that the commissioning of the unit should be done with terminally sterilizable products. In subsequent stage the same products should be produced under totally asceptic condition with constant monitoring of product sterility to ensure fail-proof results. Only upon attainment of perfection in asceptic techniques, manufacture of products which cannot be sterilised terminally should commence.

Layout has been developed in agreement with the basic concepts of streamlining and process flow and adequately interspaced to optimise the process segregation and operational efficiency. The annex 13 and annex 17 provide sufficient details of operational main stream and sequential process flows. In addition to equipment, the area is suitably furnished with required work benches and transportation.

2. Sources of supply and costs

In order to make the final selection out of a wider choice of equipment and ascertain the cost more realistically, twenty-seven companies including

This exercise has enabled to make a clear idea regarding the range and type of equipment available to select from and also in preparation of fairly accurate cost estimate for procurement of equipment.

Following this exercise a document providing details of the production unit, capacities, equipment specifications and production techniques flow (Appendix I) has been circulated to the suppliers to facilitate the firms to offer more appropriate equipment at the time of formal invitation of tenders.

Although a fairly clear picture of the type of equipment to be procured has emerged at this stage but the final selection will be possible only after receiving offers with full details and literature of each equipment and identification of most appropriate unit in terms of suitability towards manufacturing technology performance and costs.

3. Plant Services/Utilities Equipment

A detailed review of the existing plant services and utilities was carried out in co-ordination with the engineering department of GPL and the findings have confirmed earlier tentative estimates that the installed services have sufficient spare capacities to comfortably cater for the additional requirements of the SVP unit. The findings are summarised in the following table.

The only services to be installed will be supply of fuel gas and nitrogen to the SVP subdivision area. In view of the quantum of consumption of these gases, however, these can be conveniently supplied through a manifold of 2-3 cylinders bracketted just outside the operational area.

Detailed layout of all supplies have been drawn out in the final architectural drawings.

Service	Capacity	Pressure	UTILISATION		
			Current	S.V.P.	TOTAL
Substation	380 KVA	380 Volts	20%	15%	35%
Deionised Water	1.0^3m/hr	2.5-6 bars	75%	20%	95%*
Distilled Water	400 lit/hr	-	60%	15%	75%
Steam	400kg/hr	8 bars	60%	15%	75%
Compressed air	3.0^3m/min	8.8 bars	50%	10%	60%

*In view of already high utilization levels, the dionization plant capacity increase was planned even before the SVP utilization considerations and provision made in the regular budget of GPL.

E. MATERIALS

The exercise carried out to explore the sources and prices of raw and packaging materials was identical to the exercise conducted for exploring the cost of equipment.

In total nine manufacturers/suppliers of packaging materials and eight suppliers of raw materials were investigated. The response received from most of the packaging materials suppliers (Annex 21) has proven extremely useful in assessing choices of source and type of materials both with respect to quality and cost.

The response from the suppliers of raw materials, however, has remained unsatisfactory till todate (Annex 22) and further efforts will be required to identify competetive sources of supply. Although the available prices of raw materials (single source) appear to be on the higher side, but being the only recently dated quotation available, have been used in the product costing exercise and economics consideration section.

F. COSTS

1. The cost of the project covering redesigning of the buildings, purchase of equipment, operating costs and allocation for contingencies, is estimated at $750,000. This figure includes$250,000 as working capital which is not really a fixed cost and also includes cost of construction of a canteen cum clinic building which should actually be charged to general plant overheads and not SVP project.

These estimates are based upon latest quotation of equipment while cost of civil work has been computed by the architectural section of INDECO using the latest material prices and cost of construction.

- The project is financed through a loan of K6.0 million ($750,000) already secured from ZNPF at an interest rate of 19 percent.
- The project is expected to be completed in two years period and accordingly the interest incurred during this period has been included in the production costs
- The expenditure for import of equipment has been phased out in two stages to permit partial project implementation in a situation of inadequacy of foreign exchange allocation.

2. Project cost breakdown

No.	Item		Costs($)
1.	Builders work	32,589	
	Proportionate preliminaries	8,147	
	Contingencies	9,264	
	Estimated completion cost		50,000
2.	Staff clinic estimated cost		12,500
3.	Workshop estimated cost		68,750
4.	Machinery and equipment		300,000
5.	Working capital		250,000
6.	General contingencies		68,750
	GRAND TOTAL		750,000

G. Implementation

Implementation of the project is scheduled in September 1987 and accordingly the necessary approvals, the preliminaries and other preparatory work have been initiated to ensure that all inputs are available in time and the "ground digging" date could be firmly established.

- Complete architectural drawings covering all aspects of civil work have been finalised and their formal approval obtained.
- Economic evaluation of the project has been carried out and application for release of the approved loan is being submitted.
- Tender papers for civil work as well as for purchase of equipment are being prepared. It is planned that civil work tender should be awarded by the end of July 1987 and the equipment ordered by end of September 1987.
- Technical assistance for the project is actively sought.

It is anticipated that about 18 months would be required to complete the plant in readiness for start-up trials while another 6 months will be spent in area preparations, testing and adjusting of air handling units, trial runs of individual machines, pilot production and finally leading to commercial runs. (Annex 23)

During the operational phase of the project the relevant systems and procedures for operation will be established and on-the-job training will be conducted.

H. Economic Considerations

1. Production Cost

Detailed costing of nine major products representing all product groups (annex 24) was carried out using latest prices of raw and packaging materials and employing the following parameters:

1.	Capacity utilization level	43%
2.	Depreciation	Full
3.	Interest on loan	Full
4.	General overheads	50% percent of the current
5.	Mark-up	12.5%

Since all the finished product is expected to be sold to the public health sector agencies, no sales promotion and marketing expenses have been charged to the product. Cost of transportations are covered under general overheads.

It is evident that sales prices so obtained favourably compare with the landed cost of these products provided by MSL. Comparison with the market prices was not considered necessary at this stage. In any case in view of the prevailing market prices, the comparison would be far more favourable than the MSL import costs.

2. Economic Viability

Basing the calculations on the production costs of the nine products, when produced to fulfil the annual requirements, the following observations have been made:

1. First year production (43% capacity)		3,970,000 units
2. Sales value		$ 842,136
3. Cost of production		$ 769,984
4. Profit before tax		$ 92,152
5. Profit and depreciation		$ 127,882

Benefits at national level can be measured by the following figures:

6. Cost of import		$1,110,604
7. Cost of import of equivalent raw materials		$ 559,578
8. Saving of foreign exchange	(6-7)	$ 551,026
9. Saving at national level	(6-2)	$ 248,468
10. Pumped back into national economy	(2-7)	$ 302,558

3. Economic Evaluation

Employing the same products cost data, a detailed financial appraisal of the project (Appendix II) has been carried out by the Project and Technical Services Department (Economic Evaluation Unit) of INDECO using UNIDO's COMFAR computer model for economic evaluation. The results are summarised below:

Financial Evaluation

Net profit as percent of sales	(in year 5)	17.51%
	(in year 17)	21.00%
Return on investment	(in year 5)	44.00%
Internal rate of Return		44.50%
Pay-back period		28 months

I. Manpower Requirements

Due to their nature, critical quality requirements and risk of total loss of material once a defect has been introduced, the production of SVP requires great care, attention and skill on the part of personnel working in the area. It is, therefore, necessary that the selection of personnel should not be based on qualifications and job orientation only but should also evaluate such human qualities as attitude, discipline, habits and sense of responsibility during job performance.

It is practically impossible to monitor the performance of individuals constantly and therefore they must be trustworthy to maintain discipline and adherence to the stipulated practices and procedures on their own and faithfully. Additionally, each section should be controlled by a supervisor independently.

Working at full capacity, the requirements of the personnel will be as follows:

NO.	GRADE	WASH./STERIL.	SUBDIVISION	PACKAGING	TOTAL
1. Supervisors	G7	1	1	1	3
2. Senior technicians	G6	4	6	-	10
3. Skilled technicians	G5	1	-	16	17
4. Skilled workers	G4	2	1	1	4
		8	8	18	34

During first year of operation, when production is expected to remain at 43 percent capacity utilization, the staffing would be around twenty including the three supervisors.

J. Training

In order to achieve good performance it is important that a high degree of sense of participation/contribution should be inculcated at all levels of plant personnel. It is, therefore, necessary to adopt measures towards motivation of people and propagation of sense of responsibility and team spirit.

Professional training programmes, either in-house or outside are of great value to improve performance standards but at the same time the human elements, such as the following should be equally cared for:-

- General working conditions
- Personnel services and amenities
- Guidance and supervisory attention
- Job performing conveniences and tools
- Grievances realization and eradication

Extensive external training programme has been proposed to cover the entire managerial and supervisory technical staff totalling 72 man months. In addition to specific job training, it is proposed that the managerial staff should also be groomed in the following:

- Systems and procedures
- Plant maintenance and personnel discipline
- Performance monitoring and trouble shooting
- Performance improvement and cost control
- Advanced systems, technology and equipment

VI. FOLLOW UP

Expert technical assistance will be necessary during the project implementation in the following areas:-

1. On the spot supervision and advisory services during redesigning of the building and relocation of the functions.
2. Evaluation of equipment quotation and selection of machinery and equipment before placement of order.
3. Assistance in selection of suppliers of raw and packaging materials and development of their specifications.
4. Equipment installation and start-up.
5. Area commissioning and trials.
6. Pilot scale production and scaling upto commercial runs.
7. Establishment of product development section.
8. Development of systems and procedures.
9. In-house training programme.

Draft of a project document (Appendix III) requesting for technical assistance and fellowships for training has been submitted to be included in the UNDP regular assistance programme.

Assistance in Diversification and Expansion of Manufacturing Facilities for Pharmaceuticals in Zambia

FLOOR SPACE EXPANSION/REAPPROPRIATION

BUILT-UP AREA		EXISTING m2		PROPOSED m2	
FACTORY (TOTAL)		1,524		2,007	
DISTRIBUTION					
A. WAREHOUSES	TOTAL		346		591
1. Raw and Packaging Materials		114		323	
2. Finished Goods		200		240	
3. Hazardous Chemicals		24		20	
4. Stationery		8		8	
B. MANUFACTURING	TOTAL		112		96
1. Intravenous Fluids		48		18	
2. Oral Rehydration Salts		64		24	
3. Injections		-		18	
4. Chlorohexidine		-		36	
C. SUBDIVISION/PACKAGING	TOTAL		315		369
1. Intravenous Fluids		251		180	
2. Oral Rehydration Salts		64		24	
3. Injections		-		165	
D. QUALITY CONTROL	TOTAL		108		164
1. Laboratories		60		98	
2. Product Development/Records		-		18	
3. Animal House/Stores		48		48	
E. ENGINEERING SERVICES	TOTAL		180		298
1. Workshop and Stores		42		110	
2. Auto Repair Shop		-		60	
3. Boiler/Compressor		84		80	
4. Water Treatment		54		48	
F. GENERAL SERVICES	TOTAL		463		489
1. Change rooms/Laundry		98		138	
2. Canteen/Clinic		46		96	
3. Offices		21		42	
4. Common Passages		234		159	
5. Unutilised		64		54	
TOTAL ADDITIONAL ALLOCTION					725
NEW CONSTRUCTION					483
RECOVERED FROM EXISTING					242

SI/ZAM/86/905 TABLE II

PLANT CAPACITIES

All Product Groups

Basis : Single shift of 400 productive minute (6.66 hours) per day for 250 working days per year.

NO.	PRODUCT GROUP	TOTAL	CAPACITIES PROJECTION		
			PRESENT	PHASE I	PHASE II
A.	BULK MANUFACTURE				
I	INTRAVENOUS FLUIDS	1,000,0001	1,000,0001	1,000,0001	1,000,0001
II	ORAL REHYDRATION SALTS	21,000kg	21,000kg	21,000kg	21,000kg
III	SMALL VOLUME PARENTERALS				
a.	Sterile Liquids	50,0001	NIL	50,0001	50,0001
b.	Sterile Powders	20,000kg	NIL	NIL	20,000kg
IV	Drops	11,0001	NIL	11,0001	11,0001
B.	SUBDIVISION AND PACKAGING				
		UNITS			
I	INTRAVENOUS FLUIDS	1,000,000	1,000,000	1,000,000	1,000,000
II	ORAL REHYDRATION SALTS	1,000,000	1,000,000	1,000,000	1,000,000
III	SMALL VOLUME PARENTERALS				
a.	Ampoules	2,500,000	-	2,500,000	2,500,000
b.	Vials (Liquid fills)	3,750,000	-	3,750,000	3,750,000
c.	Drops				
d.	Vials (Dry fills)	3,750,000	-	-	3,750,000

SI/ZAM/86/305 ANNEX 1

REQUIREMENTS : PRODUCTS PACK SIZE IDENTIFICATION

A. INJECTIONS

NO.	P R O D U C T	STRENGTH	PACK SIZE	PRESENTATION
1.	Adrenaline acid tartarate	1 in 100ml	1ml	Amp
	" " "	"	30ml	Vial
2.	Aminophyllin	250 in 10ml	10ml	Amp
3.	Atropine Sulphate	0.6mg/ml		Amp
4.	Chloroquin phosphate	40mg/ml	2ml	Amp
	" "	"	5ml	Amp
	" "	"	30ml	Vial
5.	Chlorpromazine HCL (Largactil)	5.0% W/V		
6.	Dextrose	50%	20ml	amp
7.	Diazepam (Valium)	5mg/ml	2ml	Amp
8.	Ergometrine maleate	0.5mg/ml		
9.	Ergometrine/oxytocin	0.5mg/5i.u./ml	20ml	Vial
10.	Frusemide (Lasix)	10mg/ml	2ml	Amp
11.	Iron Dextran	50mg Fe/ml	2ml	Amp
	" "	"	5ml	Amp
	" "	"	20ml	Vial
12.	Promethazine HCL (Phenergan)	30mg/ml		
13.	Vitamin B-Complex		10ml	Vial
14.	Water for injection		2ml	Amp
	" " "		5ml	Amp
	" " "		10ml	Amp
	" " "		50ml	Vial
	" " "		100ml	Vial
15.	Cyanocohalamine	1,000mcg/ml		Vial
16.	Ampicillin (Penibritin)	250mg		Vial
	Ampicillin	500mg		Vial
17.	Benzathine Penicillin	2.4mega		Vial
18.	Benzyl penicillin	0.5,1.0mega		Vial
	" "	5 mega		Vial
19.	Cloxacillin (orbenin)	25[illegible]ug		Vial
20.	Chloramphenical succinate	1.0gm		Vial
21.	Procain penicillin			Vial
22.	Procain penicillin (oily)	300mg/ml	10ml	Vial
23.	Streptomycin sulphate	0.5,1.0gm		Vial
	" "	5gm		Vial

ANNEX 2

SI/ZAM/86/905

REQUIREMENTS : PRODUCTS AND PACK SIZE IDENTIFICATION

B. DROPS

NO.	P R O D U C T	STRENGTH	PACK SIZE	PRESENTATION
a.	EAR (Otic)			
1.	Betamethasone	0.1%	10ml	Dropper bottle
2.	Chloramphenicol		10ml	"
3.	Dexamethasone/framycin	0.05/0.5%	10ml	"
b.	NASAL			
4.	Dexamethasone/neomycin SO_4	0.10/0.50%	10ml	"
5.	Xylomethzoline HQ	0.10%	10ml	"
6.	Tetrahydrozoline Hcl	0.10%	10ml	"
c.	OPHTHALMIC			
7.	Sulphacetamide		10ml	"
8.	Chloramphenicol	0.50%	10ml	"
9.	Tetrahydrozoline Hcl	0.05%	10ml	"
10.	Sod. Chromoglycate	2.00%	10ml	"
11.	Tetracycline	1.00%	10ml	"
12.	Hydrocortisone/Neomycin	1.00/0.50%	10ml	"
13.	Pilocarpine	2.00%	10ml	"

SI/ZAM/86/905 ANNEX 3

NATIONAL REQUIREMENTS : DOSAGE FORM CLASSIFICATIONS AND ANNUAL CONSUMPTIONS

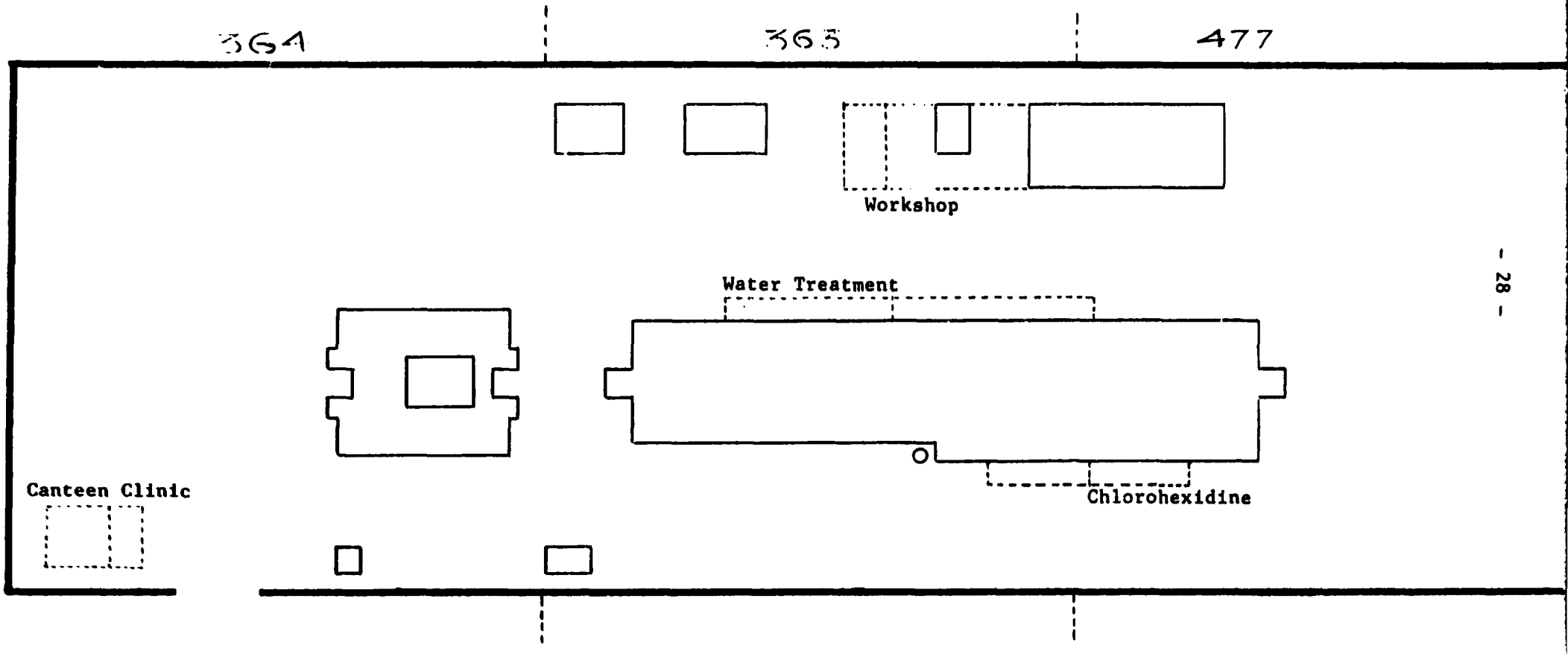
NO.	P R O D U C T	STRENGTH	PACK SIZE	1987
	I. AMPOULES			
1.	Adrenaline Tartarate		30ml	-
2.	Aminophyllin	25mg/ml	10ml	125,000
3.	Atropine sulphate	0.6mg/ml	1ml	80,000
4.	Chloroquin phosphate	40mg/ml	5ml	260,000
5.	Chlorpromazine 50mg/ml	5.0%	2ml	26,000
6.	Dextrose	50.0%	20ml	1,560
7.	Diazepam	5mg/ml	2ml	156,000
8.	Frusemide	10mg/ml	2ml	156,000
9.	Iron-dextran	50mg/ml	2ml	156,000
10.	Iron-dextran	50mg/ml	5ml	156,000
11.	Promethazine	30mg/ml	2ml	405,000
12.	Water for injection	-	2ml	15,600
13.	" " "	-	5ml	470,000
14.	" " "	-	10ml	470,000
				2,477,160
	II. VIALS : LIQUIDS			
1.	Adrenaline tartarate		30ml	15,600
2.	Ergometrine/oxytocin	0.5mg/5i.u	10ml	260,000
3.	Iron-dextran	50mg/ml	20ml	78,000
4.	Vitamin B Complex		10ml	470,000
5.	Water for injection	-	50ml	188,000
6.	" " "	-	100ml	140,000
7.	Cyanocohalamine	1000mcg/ml	10ml	125,000
8.	Procain penicillin (oily)	300mg/ml	10ml	470,000
				1,746,600
	III. VIALS : DRY FILLS			
1.	Ampicillin	250mg	-	468,000
2.	Ampicillin	500mg	-	390,000
3.	Benzathine penicillin	2.4mega	-	234,000
4.	Benzyl penicillin	0.5mega	-	94,000
5.	" "	5.0mega		130,000
6.	Cloxacillin	250mg	-	65,000
7.	Chloramphenicol succinate	1.0gm	-	260,000
8.	Procain penicillin	3.0mega	-	780,000
9.	Streptomycin sulphate	1.0gm	-	780,000
10.	Streptomycin sulphate	5.0gm	-	260,000
				3,461,000

SI/ZAM/86/905 ANNEX 3 (Cont'd)

NO.	P R O D U C T	STRENGTH	PACK SIZE	1987
	IV. DROPS			
	EAR (OTIC)			
1.	Betamethasane	0.1%	10ml	60,000
2.	Chloramphenicol		10ml	96,000
3.	Dexamethasone/framycin	0.05/0.5%	10ml	19,000
	NASAL			
4.	Dexamethasone/neomycin	0.1/0.5%	10ml	84,000
5.	Xylomethzoline HCL	0.1%	10ml	12,000
6.	Tetrahydrozoline HCL	0.1%	10ml	12,000
	OPHTALMIC			
7.	Sulphacetamide			160,000
8.	Chloramphenicol	0.5%	10ml	200,000
9.	Tetrahydrozoline HCL	0.05%	10ml	200,000
10.	Sod. Chromoglycate	2.0%	10ml	36,000
11.	Tetracycline	1.0%	10ml	200,000
12.	Hydrocortisone/neomycin	1.0/0.5%	10ml	200,000
13.	Pilocarpine	2.0%	10ml	12,000
				1,291,000

SI/ZAM/86/905

BUILDINGS : SITE PLAN : BUILDING EXTENSIONS/ADDITIONS IN DOTTED ENCLOSURES

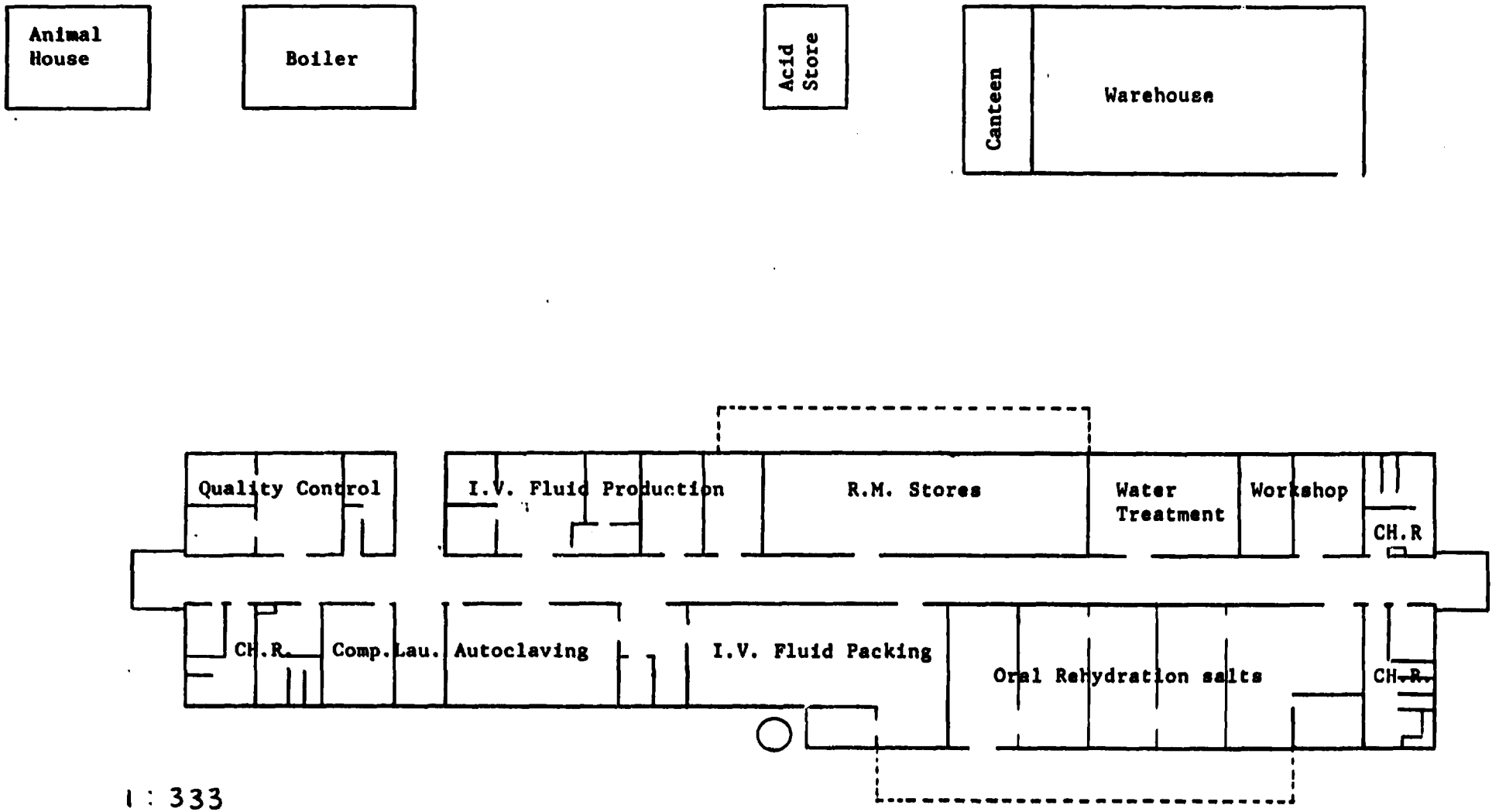


1:666

ANNEX 4

BUILDINGS : EXISTING LAYOUT

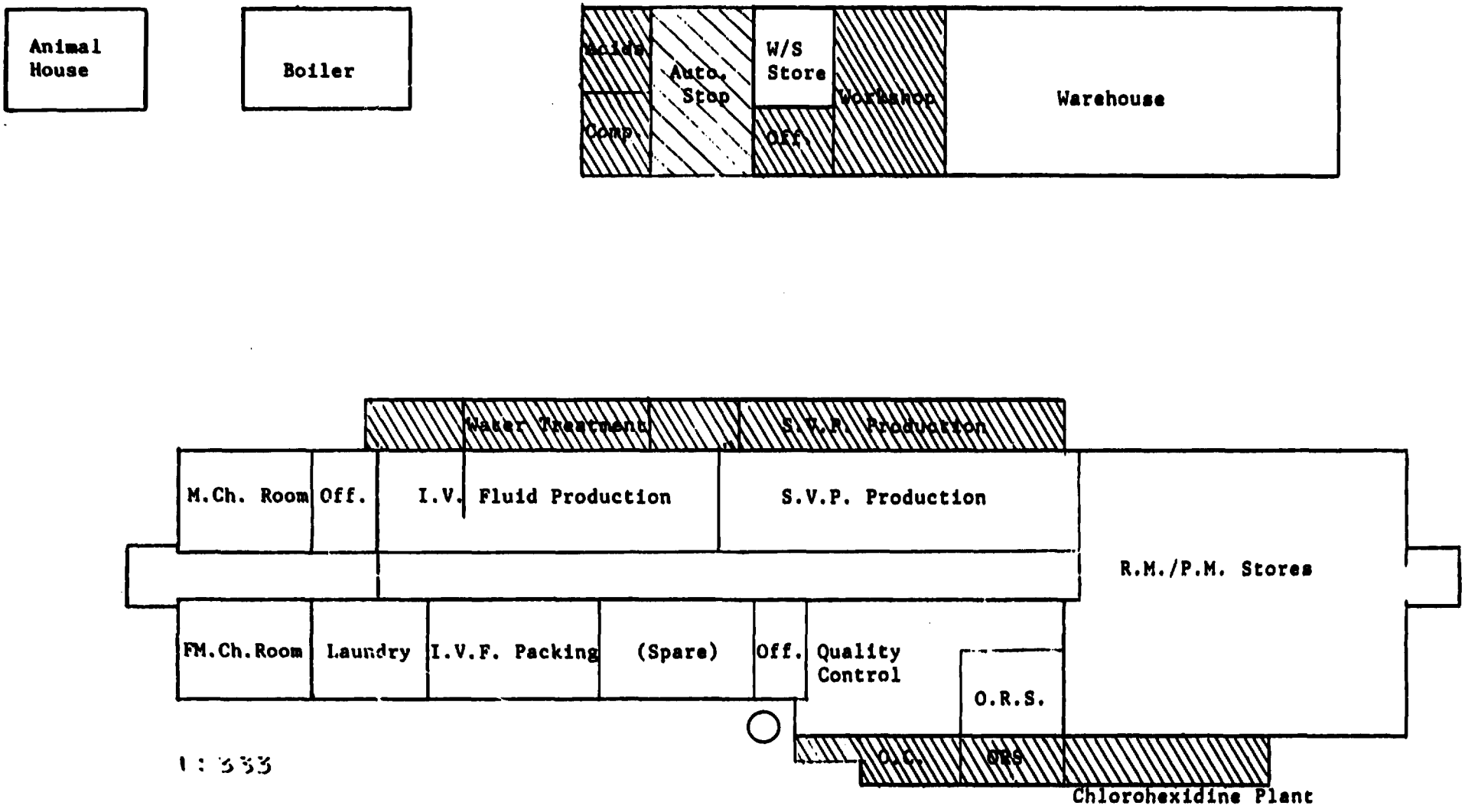
363 477



1 : 333

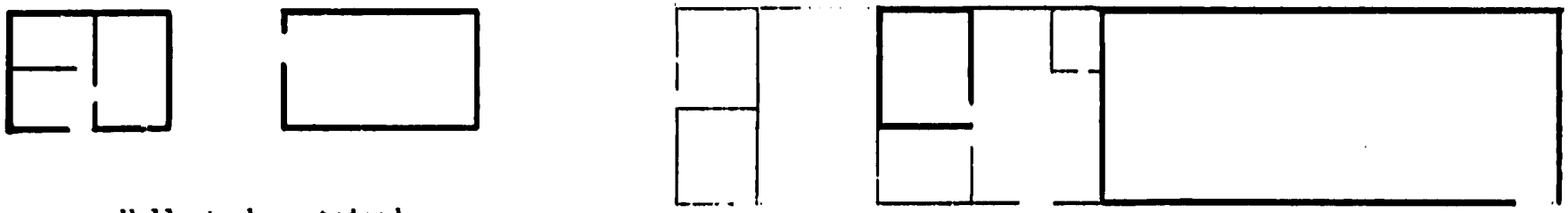
BUILDINGS : REDESIGNED GENERAL LAYOUT

363 477

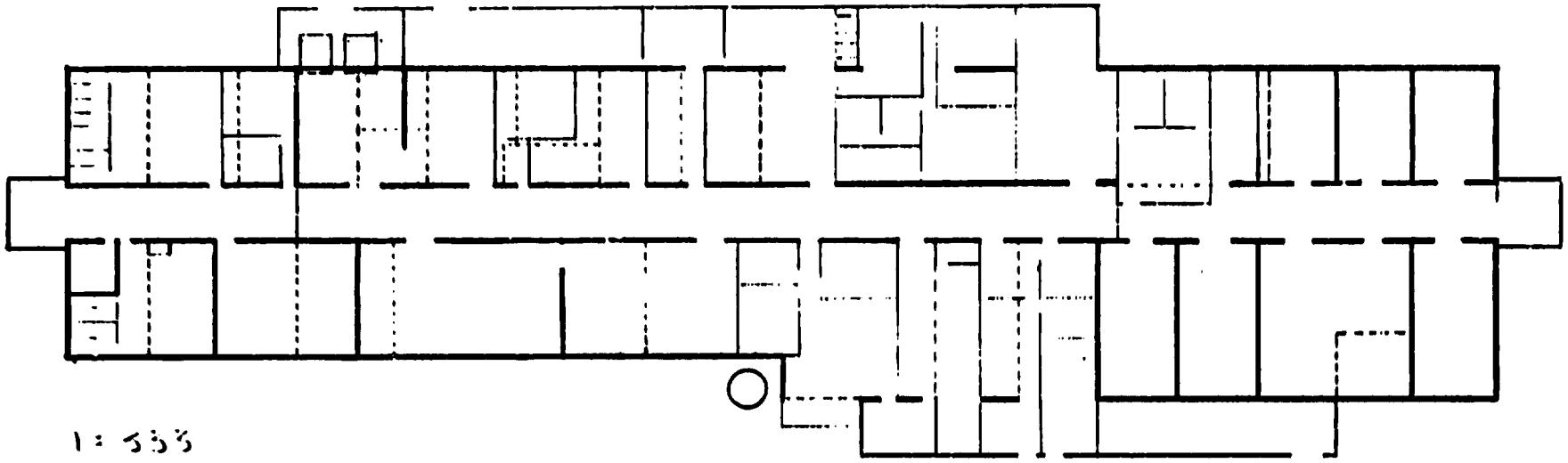


BUILDING : REDESIGNED LAYOUT DETAILS

365 477



Walls to be retained
Walls to be demolished
Walls to be erected



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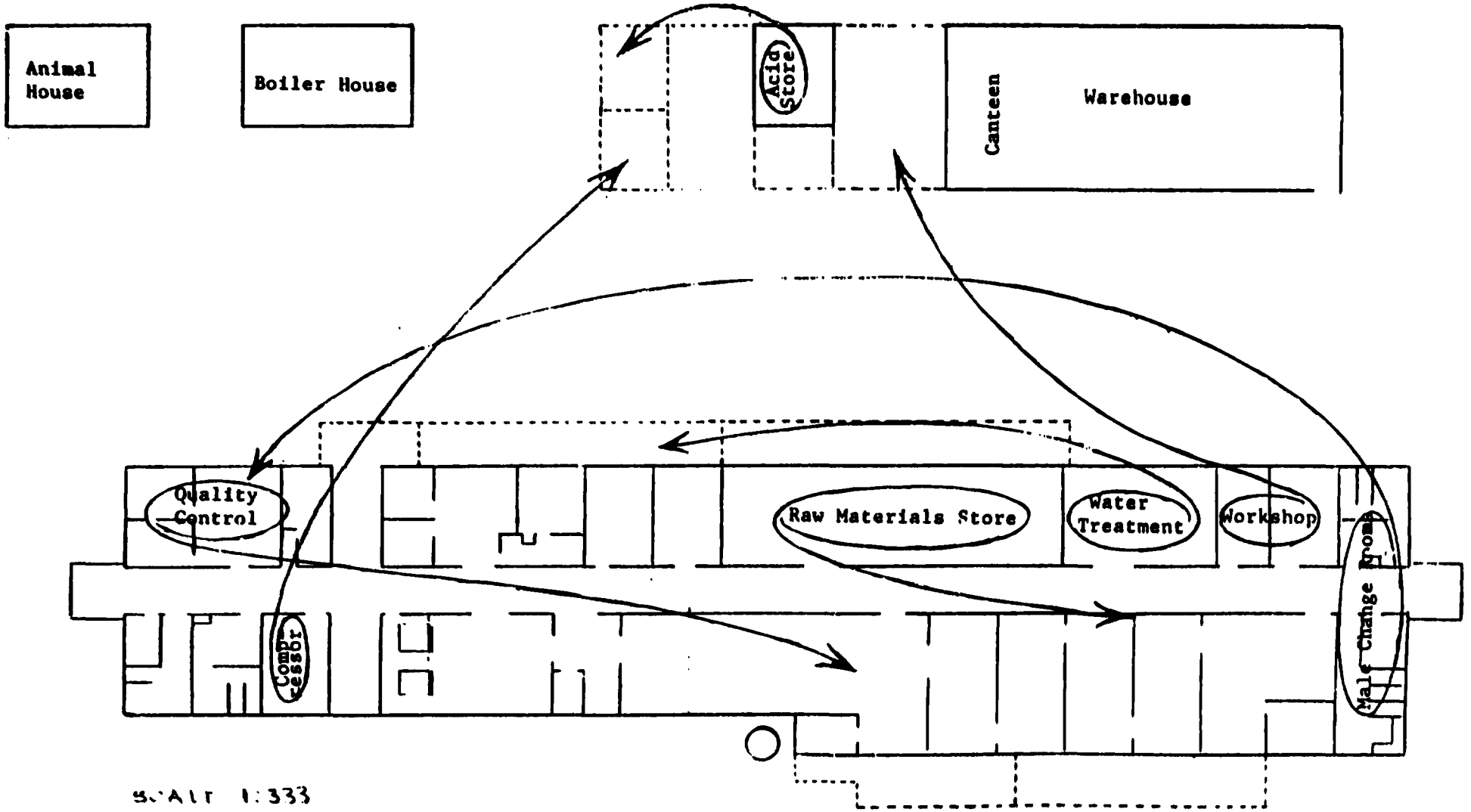
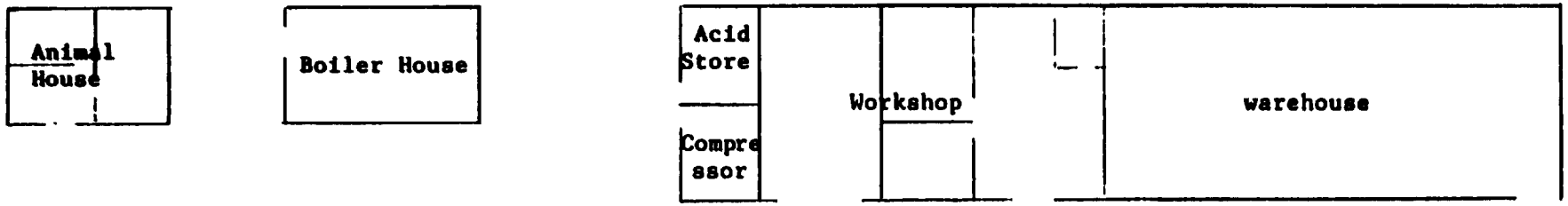

Animal House
Boiler House
Acid Store
Canteen
Warehouse
Quality Control
Raw Materials Store
Water Treatment
Workshop
Compressor
Male Change Room
SCALE 1:333

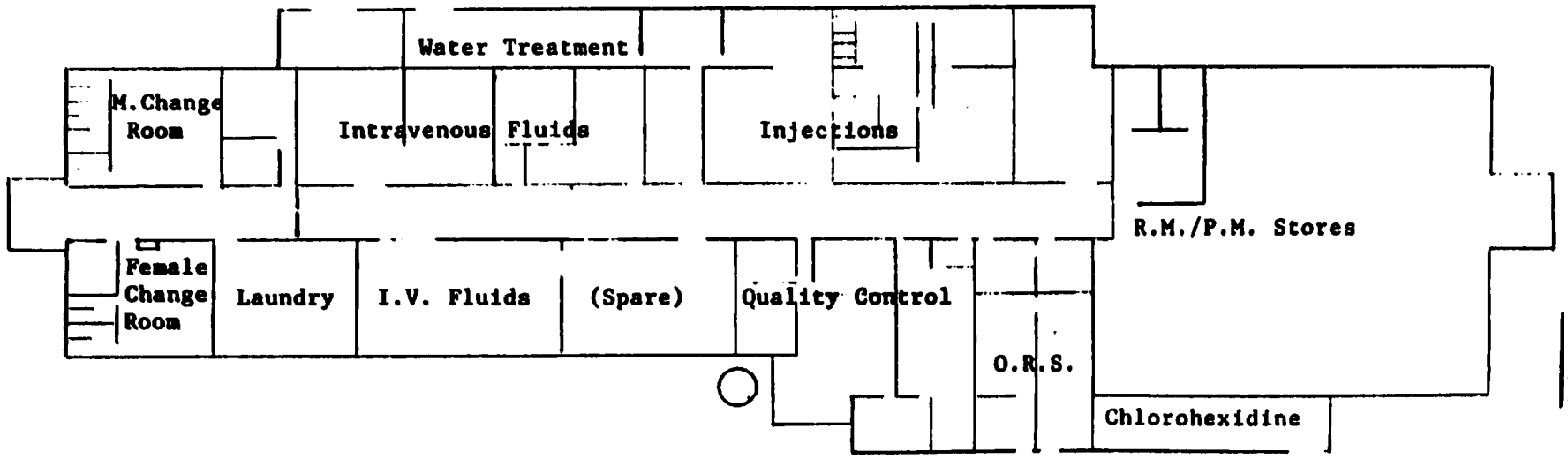
ANNEX 8

SI/ZAM/86/905

PROPOSED PLANT DESIGN - GENERAL LAYOUT

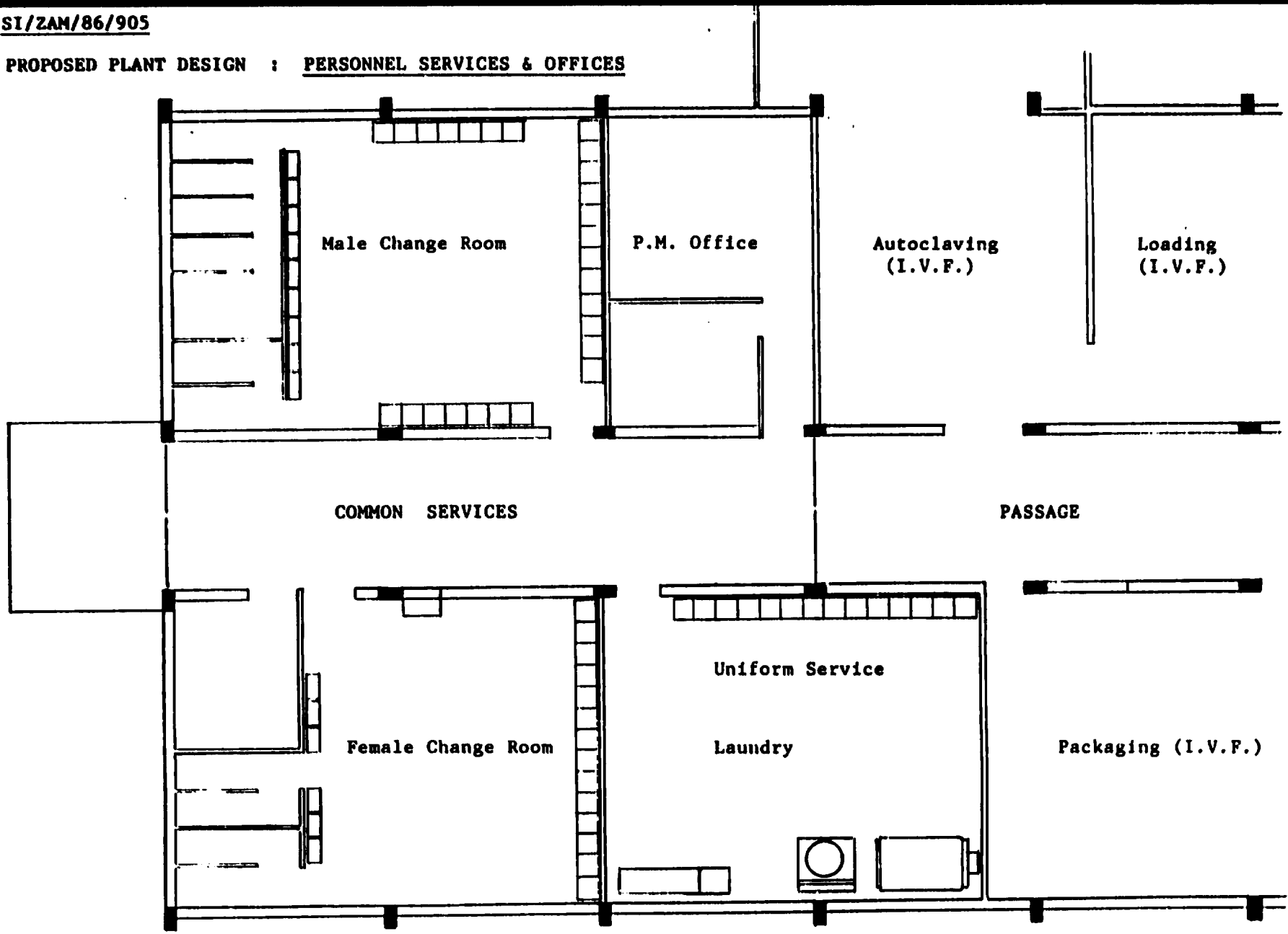
363 477



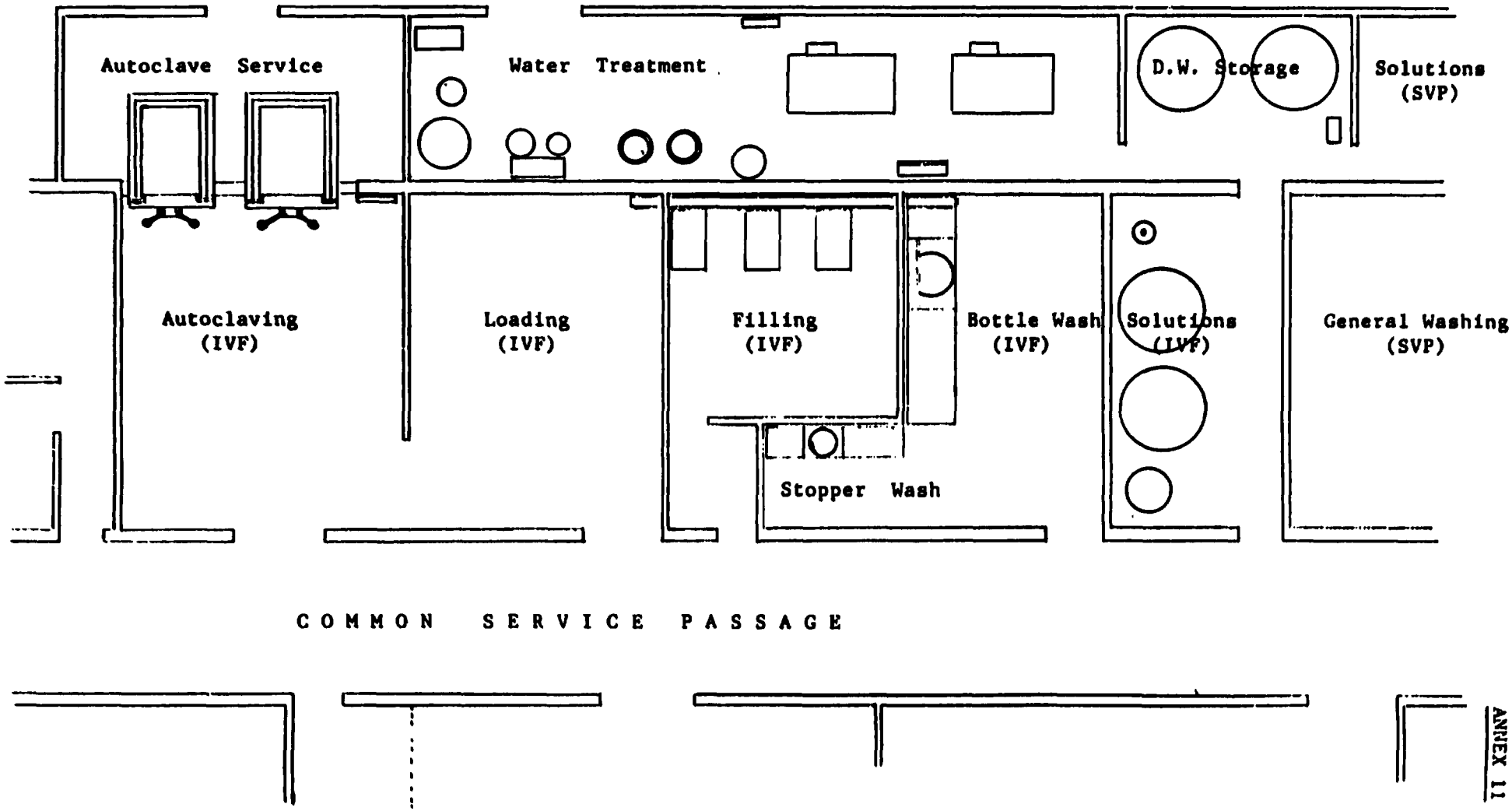


ANNEX 9

PROPOSED PLANT DESIGN : PERSONNEL SERVICES & OFFICES

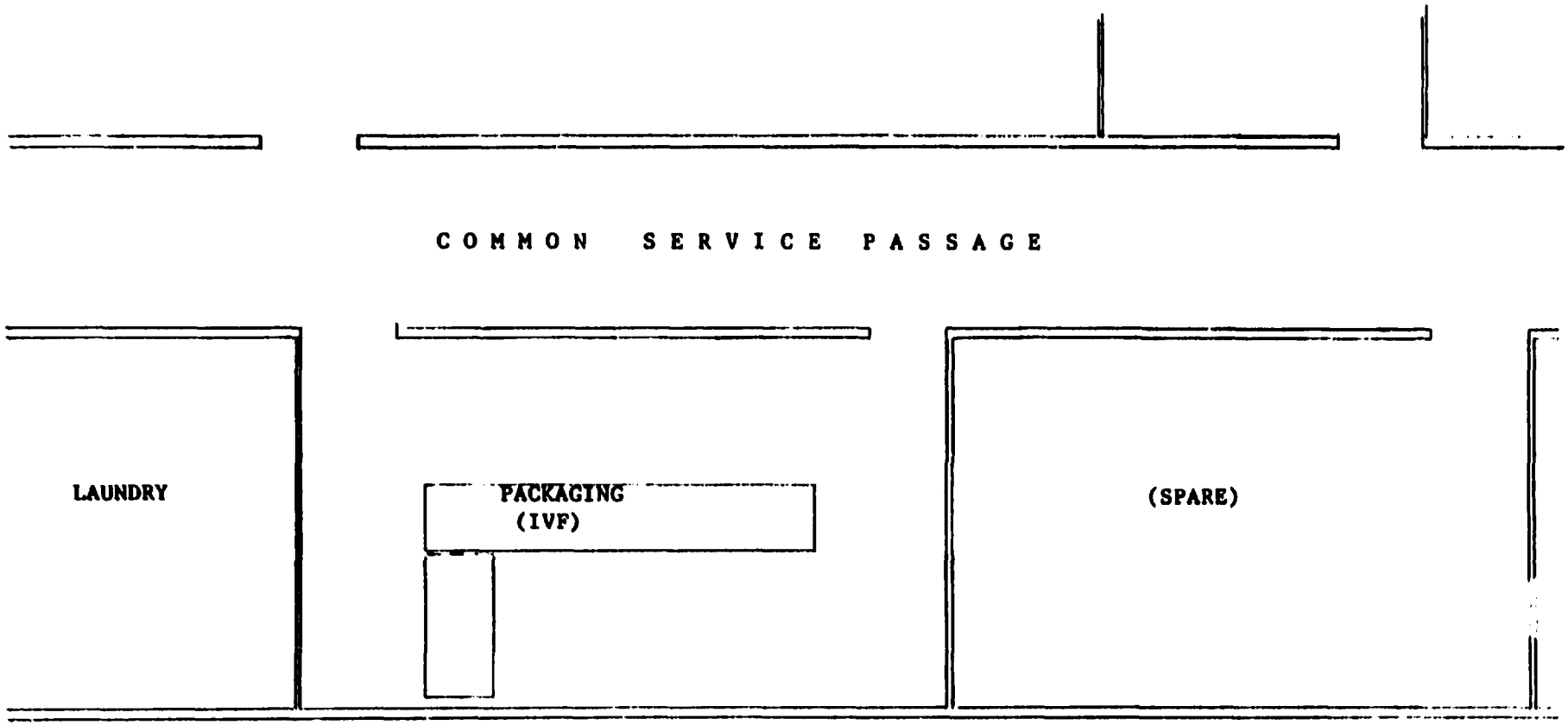


PROPOSED PLANT DESIGN : WATER TREATMENT AND I.V. FLUID PRODUCTION

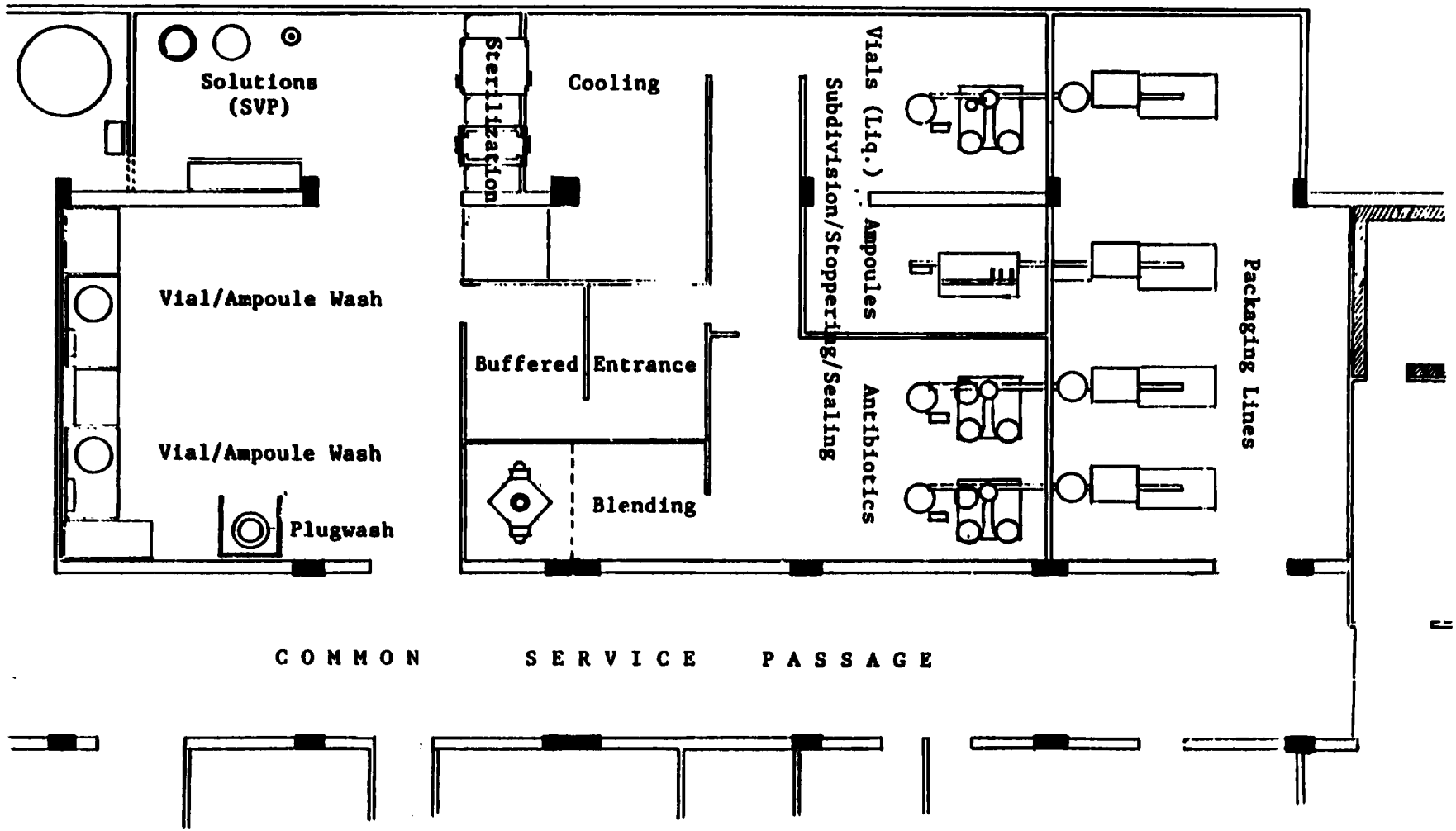


SI/ZAM/86/905

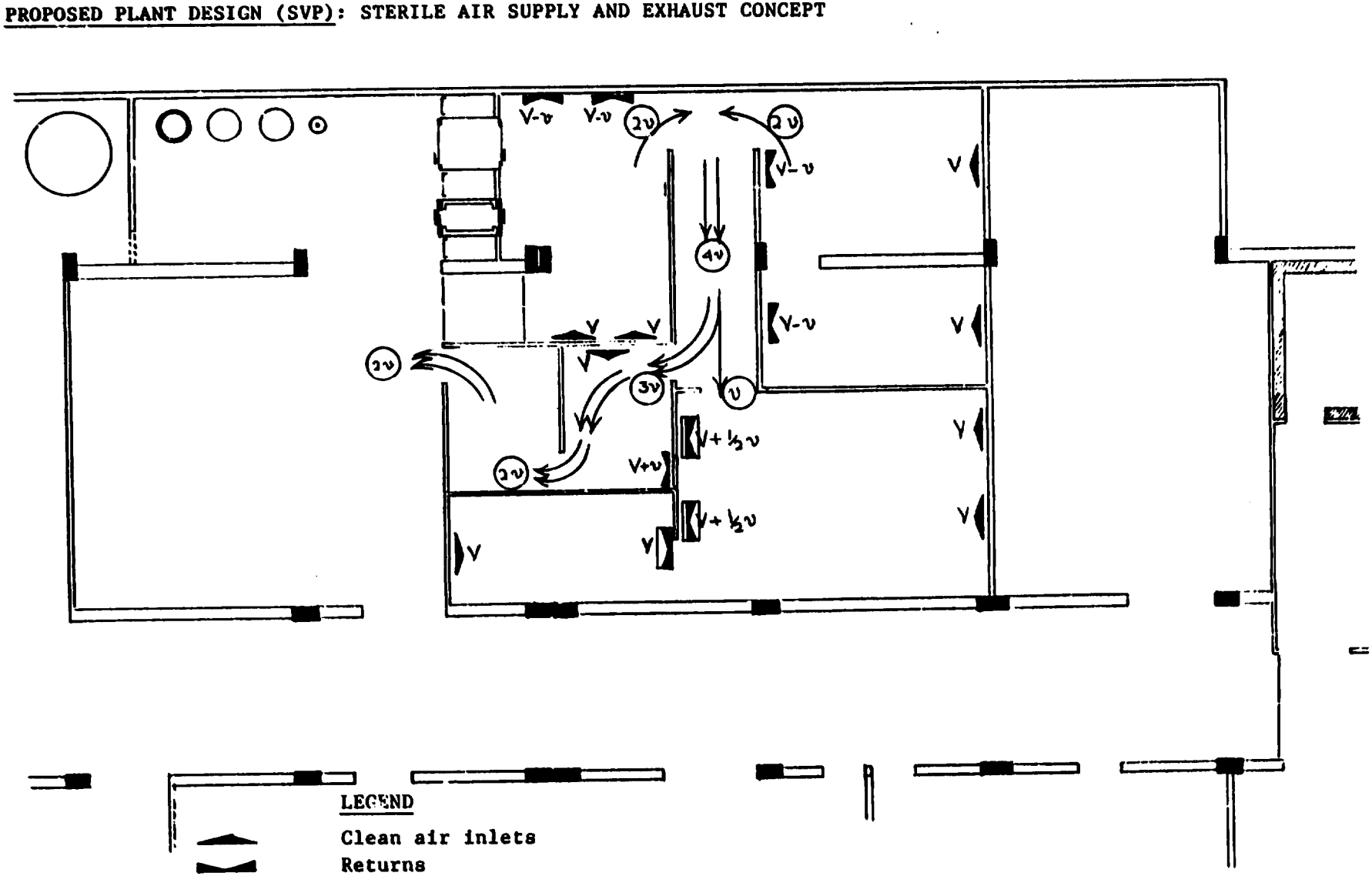
PROPOSED PLANT DESIGN : I.V. FLUIDS PACKAGING



PROPOSED PLANT DESIGN : SMALL VOLUME PARENTERALS (SVP) PRODUCTION

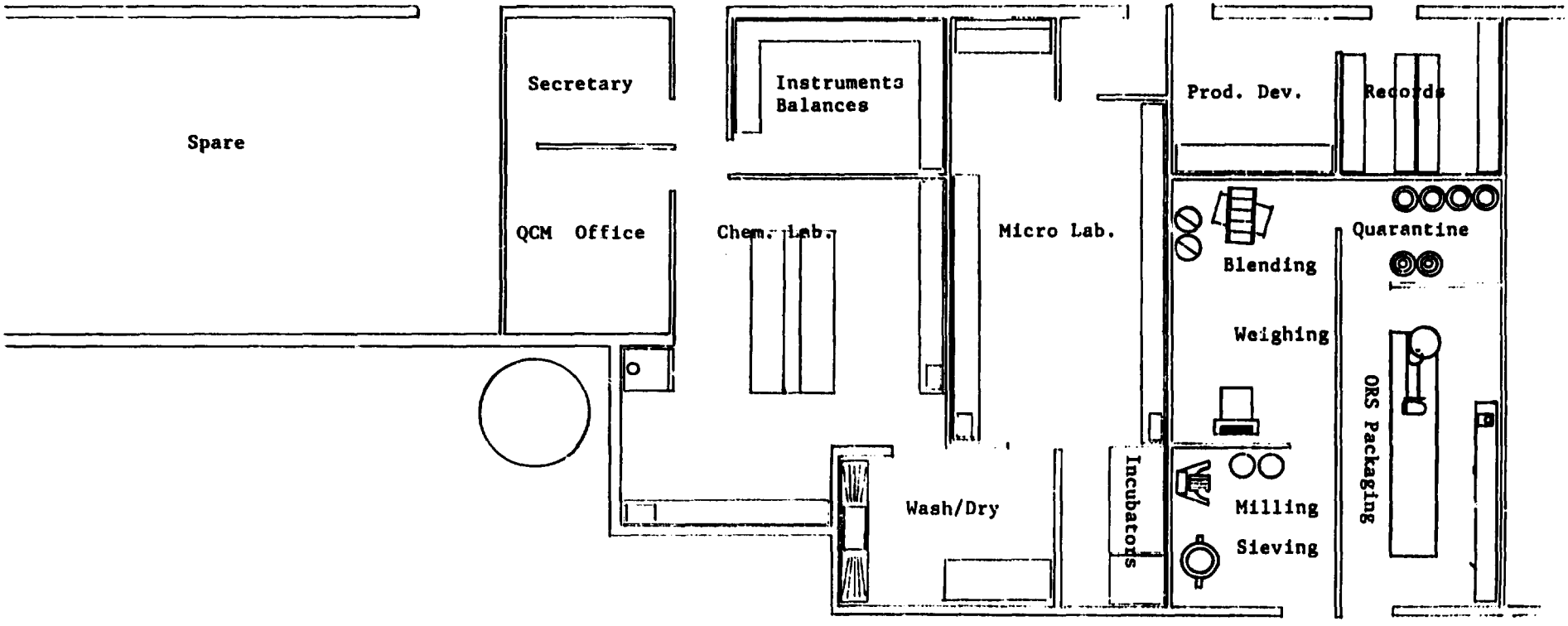


PROPOSED PLANT DESIGN (SVP): STERILE AIR SUPPLY AND EXHAUST CONCEPT



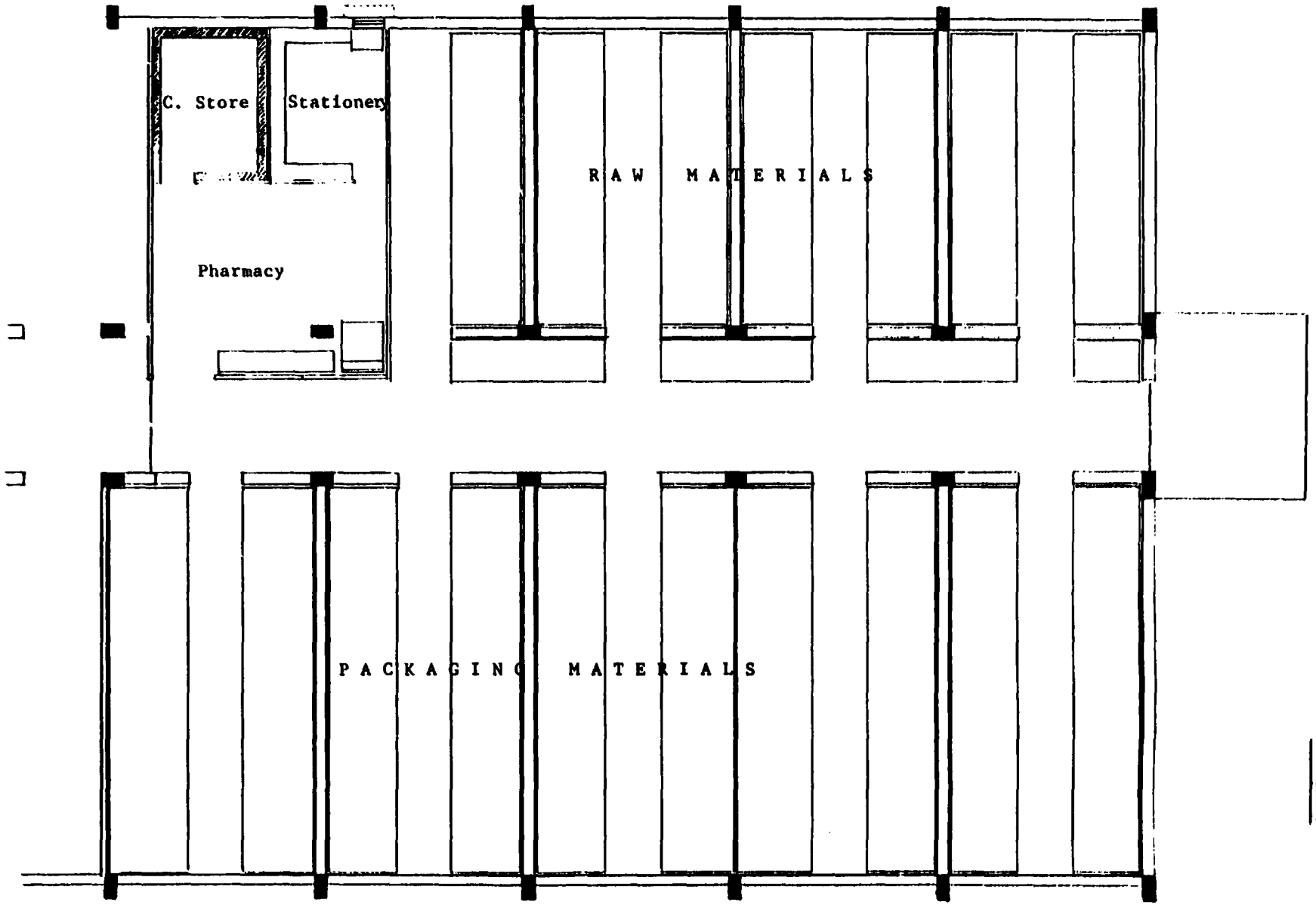
SI/ZAM/86/905

PROPOSED PLANT DESIGN : QUALITY CONTROL AND ORS PRODUCTION



SI/ZAM/86/905

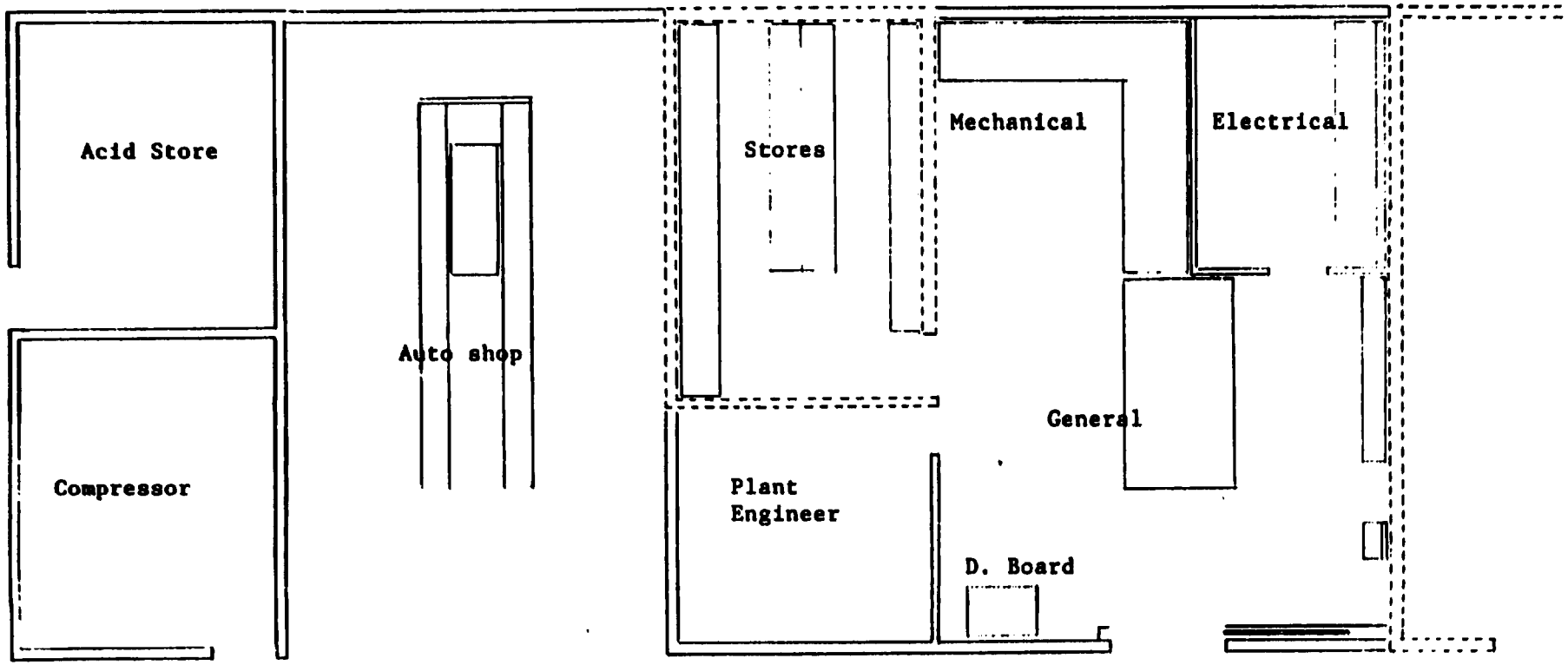
PROPOSED PLANT DESIGN : RAW AND PACKAGING MATERIAL STORES



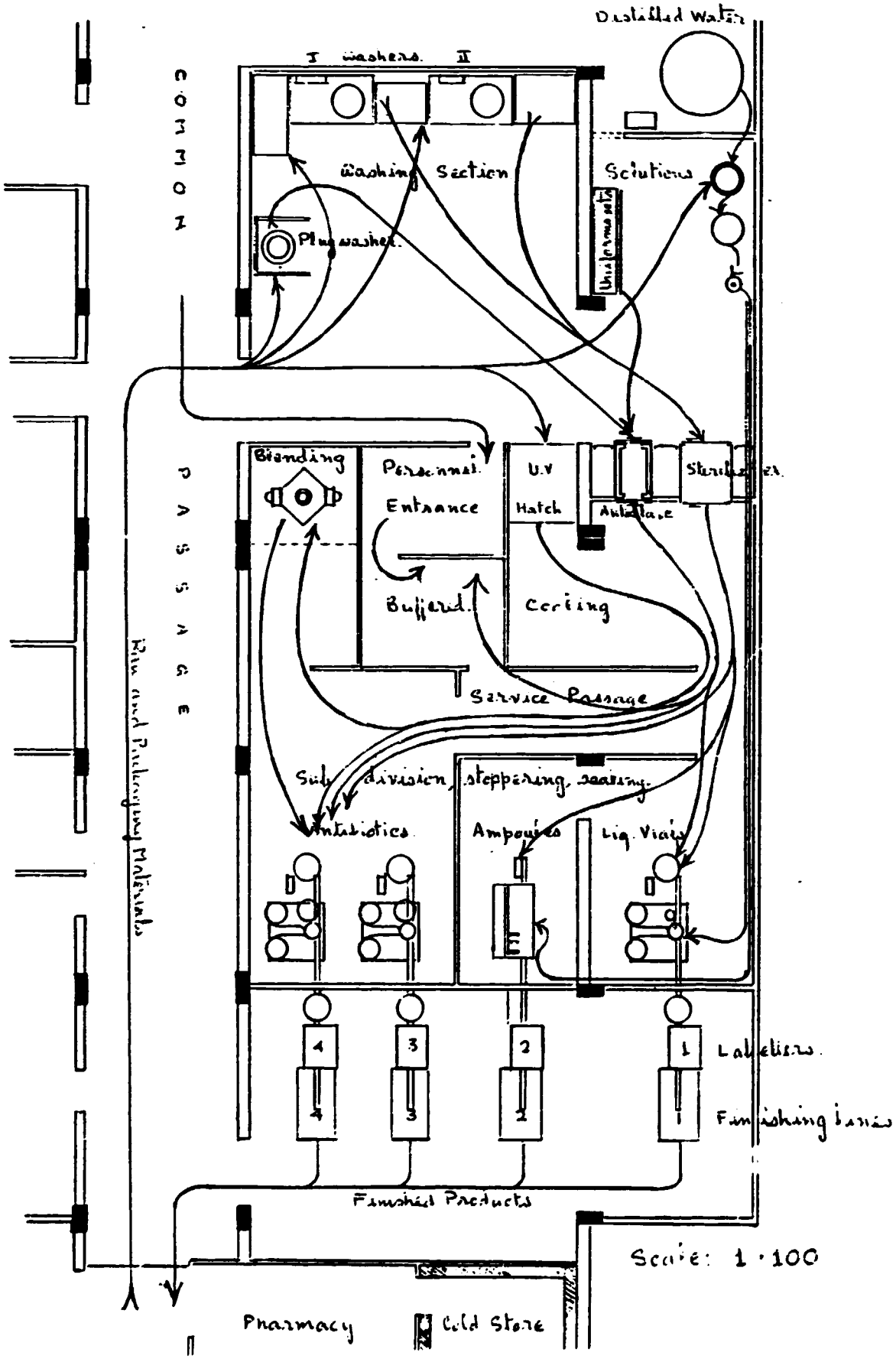
ANNEX 40

SI/ZAM/86/905

PROPOSED PLANT DESIGN : WORKSHOP, COMPRESSOR ROOM AND ACID STORE



SMALL VOLUME PARENTERALS PRODUCTION : PROCESS FLOW



SI/ZAM/86/905

EQUIPMENTS : CAPACITIES EVALUATION AND UNITS IDENTIFICATION

NO.	EQUIPMENT	MAX. OUTPUT/ CAPACITY	WORK CAPACITY			HANDLING / DAY (KGs)		EQUIPMENT STATUS		
			LOAD KG	TIME /LOAD	LOADS /DAY	ONE UNIT	REQUIREMENTS	REQUIRED	AVAILABLE	ADDITIONAL
1.	Plug Washer	10kg/load	10kg	2 hrs	4	40kg	32kg	1	Nil	1
2.	Ampoule Washer	3,000/hr	-	-	-	20,000	35,000	2	Nil	2
3.	Vial Washer		-	-	-					
4.	Sterilizer	1,000 litre	15,000	2.5 hrs	3	45,000	35,000	1	Nil	1
5.	Autoclave	400 litre	-	-	-	-	-	1	Nil	1
6.	Blender	25kg	20kg	2 hrs	4	80kg	20kg	1	Nil	1
7.	Filler/Sealer Amps	30/min.	-	-	-	12,000	10,000	1	Nil	1
8.	F/S/S Vial Liquids	40/min.	-	-	-	16,000	15,000	1	Nil	1
9.	F/S/S Vial Powder	40/min.	-	-	-	16,000	15,000	1	Nil	1
10.	Printer Ampoules	30/min	-	-	-	12,000	10,000	1	Nil	1
11.	Labeller Vials	40/min.	-	-	-	16,000	28,000	2	Nil	2
12.	Tank Processing	250l	200l		2	200l	100l	1	Nil	1
13.	Tank Holding	250l	200l	8	1	200l	100l	1	Nil	1
14.	Membrane Filters	293 & 142mm	-	-	-	-	-	3	Nil	3
15.	Clean Airbench	700 x 1500mm	-	-	-	-	-	4	Nil	4
16.	U.V. Lamp	-	-	-	-	-	-	1	Nil	1
17.	U.V. Tubes	-	-	-	-	-	-	20	Nil	20
18.	Turntables	500mm	-	-	-	-	-	4	Nil	4
19.	Conveyors	2000mm	-	-	-	-	-	2	Nil	2

SI/ZAM/86/905

EQUIPMENT : APPROXIMATE COSTS AND PROCUREMENT SCHEDULE

NO.	EQUIPMENT	BRIEF SPECIFICATION	APPROXIMATE COST	PROCUREMENT SCHEDULE				
				IMMEDIATE	PHASE I	PHASE II	PHASE III	PHASE IV
1	2	3	4	5	6	7	8	9
1.	Plug Washer	Rotary multiple cycles with filters	14,000	14,000	-	-	-	-
2.	Ampoule Washer)	Automatic, multiple cycles	28,000	28,000	28,000	-	-	-
3.	Vial Washer)							
4.	Sterilizer	Double opposite doors, stainless steel	23,000	-	23,000	-	-	-
5.	Autoclave	Double opposite doors, stainless steel	25,000	25,000	-	-	-	-
6.	Blender	Double cone, mounted on stand	8,000	-	8,000	-	-	-
7.	Filler/Sealer Amps.	Fully automatic	20,000	20,000	-	-	-	-
8.	Fill/Stopper/Seal(Liquid)	Fully automatic line on conveyor	22,000	48,000	-	-	-	-
9.	" " " (Powder)	fully automatic line on conveyor	20,000	-	20,000	-	-	-
10.	Printer Ampoules	Semi-auto mannually loaded magazine	9,000	9,000	-	-	-	-
11.	Labellier Vials	Semi-automatic	11,000	11,000	11,000	-	-	-
12.	Tank processing	Jacketted, pressure valves, port holes etc	5,600	5,600	-	-	-	-
13.	Tank holding	Matching in capacity with above	3,000	3,000	-	-	-	-
14.	Membrane filter	For sterile filtration	3,600	3,600	-	-	-	-
15.	Clean Air Bench	Modular overhanging type	1,600	3,200	3,200	-	-	-
16.	U.V. Lamp	High intensity portable	1,400	-	1,400	-	-	-
17.	U.V. Tubes	500-600mm with deflectors	3,600	-	3,600	-	-	-
18.	Turntable	500-700mm dia	6,000	12,000	12,000	-	-	-
19.	Conveyors	1500-2000mm	10,000	10,000	10,000	-	-	-
		TOTAL		192.4	120.2			

SI/ZAM/86/P01

MACHINERY AND EQUIPMENT : SOURCEWARD COSTS (Converted in U.S. Dollars as on quotation date)

	SOURCE / ITEM	BIOGENAC (ITA)	PHARMESPAND (ITA)	ADELPHI (GB)	J. WEISS (GER)	BOTA (GER)	KING (GB)	NEUMAN (GB)	BRIAFIX (GB)	MILLIPORE (GB)	JOHN BASS (GB)	LANIMAIRE (USA)	MONROVIA (USA)	ALA (BE)	SCUDERI (BE)	STRUNK (GER)	BAUSCH & STRAEBEL (GER)	MILLS OF MULLS (GB)
		24.4.87(FP	3.4.87(FOB)	9.4.87(FOB)	27.4.87(C&F)	6.4.87(E.F)	22.4.87(FOB)	31.3.87(FOB)	1.4.87(FOB)	11.5.87(E.F)	16.4.87(EF)	5.5.87(EF)	28.5.87(FOB)	9.4.87(EF)	23.2.87(FOB)	7.4.87(FOB)	12.5.87(FOB)	12.5.87(EF)
1.	Plug Washer	48,184	-	-	-	-	-	-	-	-	-	-	-	-	13,883	-	-	-
2.	Ampoules Washer		27,840(AV)	2,000(A)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3.	Vials Washer		27,860(AV)	-	-	-	-	-	-	-	-	-	-	-	-	115,000(AV)	64,546(AV)	37,319(V)
4.	Steriliser	59,943		-	-	-	-	-	-	-	-	-	-	22,885	-	-	-	-
5.	Autoclave	72,000	127,284	-	-	-	-	-	-	-	-	-	-	24,372	-	-	-	-
6.	Filler/Sealer Ampoule		69,920	18,379	-	18,219	-	-	-	-	-	-	-	-	-	98,000	36,463	-
7.	F/S/S. Vials(Liquid)	57,405	48,044	21,576 (filler only)	-	56,815	6,493 (filler only)	-	-	-	-	-	-	-	93,339	189,000	73,283	-
8.	F/S/S. Vials(Powder)	65,870	19,444	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9.	Sealers Vials	38,425	3,824	8,000	-	-	6,438	-	-	-	-	-	-	-	-	-	-	-
10.	Printer Ampoules	-	-	-	34,482	-	-	12,784	8,185	-	-	-	-	-	-	-	-	-
11.	Labeller Vials	-	1,639	-	40,282	-	-	11,187	-	-	-	-	-	-	-	-	-	-
12.	Tank Process	-	-	5,597	-	-	-	-	-	-	-	-	-	13,674	-	-	-	-
13.	Tank Holding	-	-	3,036	-	-	-	-	-	-	-	-	-	6,598	-	-	-	-
14.	Filter Assembly	-	-	-	-	-	-	-	-	3,600	-	-	-	-	-	-	-	-
15.	Clean Air Bench	-	49,713	-	-	-	-	-	-	-	1,625(each)	1,865(each)	-	-	-	-	-	-
16.	U.V. Lamp	-	-	-	-	-	-	-	-	-	-	-	1,400	-	-	-	-	-
17.	U.V. Tubes	-	-	-	-	-	-	-	-	-	-	-	3,600	-	-	-	-	-
18.	Turntables 700mm	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	5,967	-
19.	Conveyor 2000mm	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20.	Conveyor 1,500mm	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

SI/ZAM/86/905

PACKAGING MATERIAL: SOURCES AND PRICES (in US Dollars C&F)
(Prices per 1000 units)

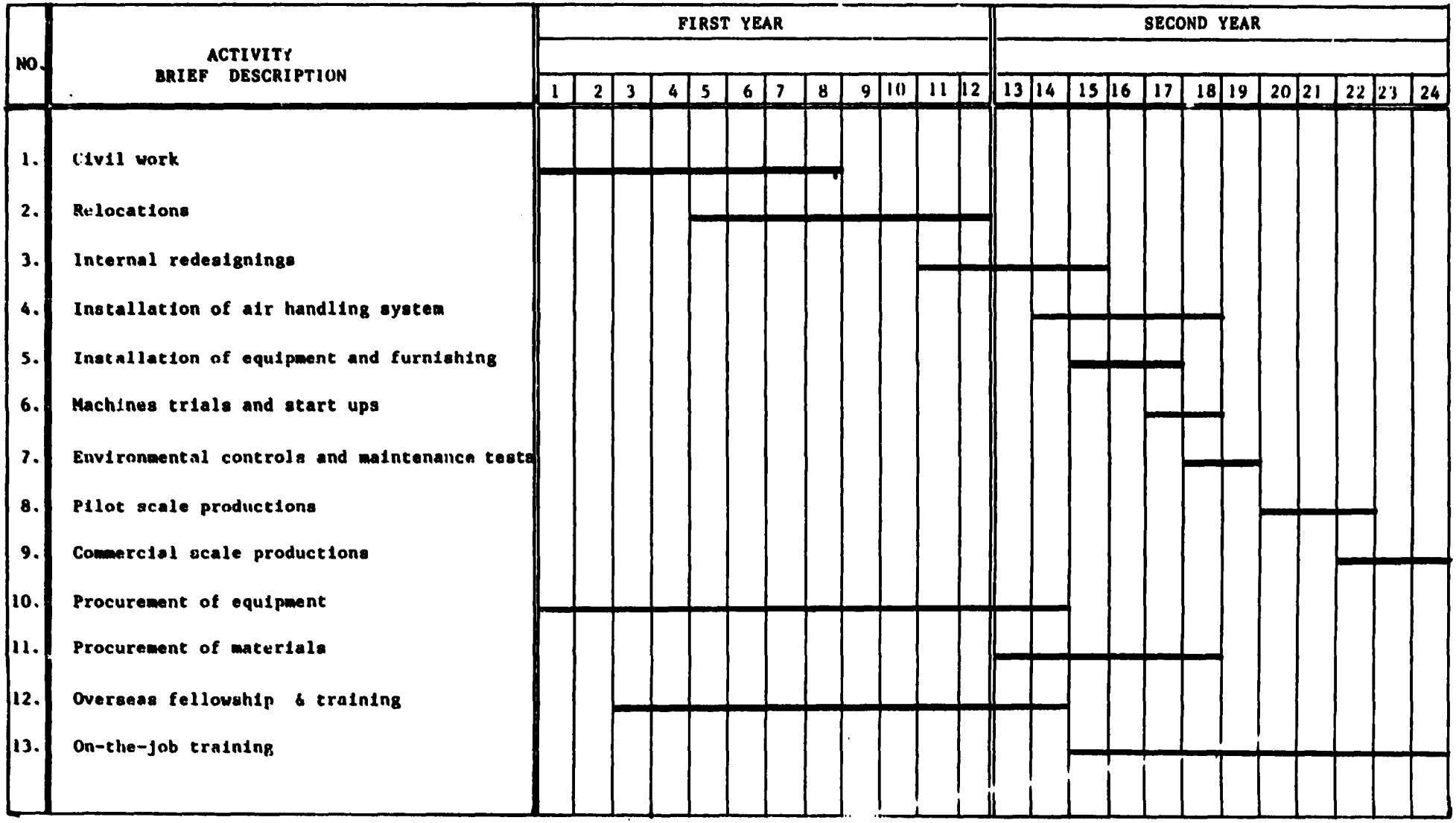
P.M. \ SOURCES	VERLIPACK (BEL)	29/4/87 ST. GOBAIN (FR)	CROWN AGENTS (GB)	27/4/87 ANCHOR (GB)	SARABHAI (IND)	29/4/87 SCHUBERT (DK)	8/5/87 NOUVELLE V. MOMIGNIES (FR)	11/5/87 VERRETUBEX (FR)	20/5/87 BILT (IND)
Bottles IVF(I) 1000ml		I 870.00 II 520.00	-	-	-	1,474.0	910.77	-	-
Bottles IVF(I) 200ml	-	-	-	-	-	-	-	-	-
Bottles IVF(I) 150ml	-	-	-	-	-	-	-	-	-
Ampoules (I) 1ml	-	-	-	-	-	C 29.0	-	C: 21.6250 O: 17.8917	-
" " 2ml	-	-	-	-	-	C 33.9	-	C: 22.6250 O: 18.9833	-
" " 5ml	-	-	-	-	-	C 51.9	-	C: 31.8750 O: 27.7833	-
" " 10ml	-	-	-	-	-	C 73.1	-	C: 45.3333 O: 39.6667	-
Vials (I) 10ml	-	M 60.16	-	TD 60.250	-	M 83.85	-	-	-
" " 20ml	-	M 118.33	-	TD 107.080	-	M 99.08	-	-	-
" " 50ml	-	M 144.17	-	TD 225.920	-	M 144.41	-	-	-
" " 100ml	-	M 201.17	-	TD 348.810	-	M 247.93	-	-	-
Vials (III) 8ml	-	28.33	-	35.464	23.4146	-	-	-	29.858
" " 14ml	-	40.67	-	-	32.1316	-	-	-	39.894
" " 30ml	-	56.67	-	-	44.9435	-	-	-	46.751
Combiseals 1000 ml	-	72.00	-	-	-	87.77	-	-	-
Combiseals 20MM	-	22.166	-	26.067	-	26.55	-	-	-
Bottles 10ml	-	M 46.33	-	TD 56.210	-	TD 71.52	-	-	-
Droppers	-	62.50	-	90.218	-	63.39	-	-	-
Stoppers 20MM	-	12.80	-	-	-	-	-	-	-
Seals 20MM	-	4.50	-	-	-	-	-	-	-

SI/ZAM/86/905

RAW MATERIALS : SOURCES AND PRICES (in U.S. Dollars, F.O.B)
(Prices per Kg unless otherwise expressed)

SOURCE / R.M.	SAD-RSA (RSA)	AFROTEK (ZAM)	LEKKER (GER)	SOURCE / R.M.	SAD-RSA	AFROTEK (ZAM)	LEKKER (GER)
Aminophyllin	26.362	-	-	Ampicillin Sodium	154.937	-	-
Atropine Sulphate	0.985 (GM)	-	-	Benzathine Penicillin	73.537 (BOU)	-	-
Chloroquin Phosphate	21.178	-	-	Benzyl Pencillin	74.000	-	-
Chlorpromazine HCL.	73.815			Cloxacillin	296.000	-	-
Diazepam	122.100	-	-	Chloramphnicol Na.Succ.	102.675	-	-
Frusemide Sodium	90.187	-	-	Proc. Penicillin	59.662	-	-
Iron Dextran 5%	-	-	-	Proc. Penicillin(oily)	-	-	-
Promethazine HCL	127.187	-	-	Streptomycin Sulph.	35.150	-	-
Adrenaline Acid Tart.	-	-	-	Benzylalcohol.	9.250	-	-
Ergometrine Maleate	-	-	-	Chlorocresol	16.303	-	-
Oxytocin (500i.u./MG)	-	-	-	Xylocaine	35.612	-	-
Vitamin B_1	59.662	-	-	Sod. Formaldhyde Sulphoxylate	-	-	-
Vitamin B_2	228.937	-	-	Ethylene Diamine Hydrat	32.875	-	-
Vitamin B_6	56.425	-	-	Sod. Hydroxide	1.85	-	-
Cynocobalamine	10.375 (GM)	-	-	Maleic Acid	32.875	-	-
				Sod. Metabisulphite	1.85	-	-
				Sulphuric Acid	4.509 (L)	-	-

PROJECT IMPLEMENTATION SCHEDULE



SI/ZAM/86/905

UNIT PRODUCTION COSTS

PRODUCT SUB-GROUP	AMPOULES			R.C.V. LIQUIDS			R.C.V. POWDERS		
ANNUAL REQUIREMENTS	2,500,000			3,000,000			3,750,000		
PRODUCT PACK SIZE	PROMETH. 30mg/ml 2.0ml	CQUIN. 40mg/ml 5.0ml	WFI.10 10ml.	VBC. 10ml.	WFI.100 100ml.	CPHCOL. 10ml (drop)	AMPCIL. (500mg)	PROC.PEN. (3.0mega)	STREPTO. (5.0gm)
DIRECT COST									
Raw Materials	0.0087	0.0048	0.0002	0.0050	0.0020	0.0059	0.0790	0.1825	0.2689
Packaging Materials	0.0350	0.0600	0.0800	0.0840	0.2300	0.0840	0.0500	0.0590	0.0760
Labour	0.0060	0.0060	0.0060	0.0060	0.0060	0.0060	0.0060	0.0060	0.0060
Utilities/Supplies	0.0010	0.0010	0.0010	0.0010	0.0010	0.0010	0.0010	0.0010	0.0010
TOTAL I	0.0507	0.0718	0.0872	0.0960	0.2390	0.0969	0.1360	0.2485	0.3519
INDIRECT COST									
Depreciation	0.0090	0.0090	0.0090	0.0090	0.0090	0.0090	0.0090	0.0090	0.0090
Repair and Maintenance	0.0020	0.0020	0.0020	0.0020	0.0020	0.0020	0.0020	0.0020	0.0020
Interest	0.0250	0.0250	0.0250	0.0250	0.0250	0.0250	0.0250	0.0250	0.0250
General Overheads	0.0100	0.0100	0.0100	0.0100	0.0100	0.0100	0.0100	0.0100	0.0100
TOTAL II	0.0460	0.0460	0.0460	0.0460	0.0460	0.0460	0.0460	0.0460	0.0460
UNIT COST	0.0967	0.1178	0.1332	0.1420	0.2850	0.1429	0.1820	0.2945	0.3979
Mark up @ 12.5%	0.0121	0.0147	0.0166	0.0177	0.0356	0.0178	0.0227	0.0368	0.0497
Ex-Factory Sale Price	0.1078	0.1315	0.1488	0.1587	0.3196	0.1597	0.2037	0.3303	0.4466
M.S.L. IMPORT COST	0.1900	0.2775	0.1137	0.2687	0.5375	0.245	0.2650	0.3725	0.550

PROMETH. - PROMETHAZINE
CQUIN. - CHLOROQUINE PO_4
WFI 10 - WATER FOR INJECTION 10ML

VBC. - VITAMIN B COMPLEX
WFI.100 - WATER FOR INJECTION 100ML
CPHCOL. - CHLORAMPHENICOL

AMPCIL. - AMPICILLIN
PROC.PEN. - PROCAINE PENICILLIN
STREPTO. - STREPTOMYCIN

APPENDIX 1

Our Ref: GPL/MA/ak Your ref:

Date 11 May 1987

(For Distribution see attached List)

Dear Sirs,

This communication is the follow-up of our earlier telex enquiries for injections production machinery and provides guidelines for offering appropriate units for the project. This machinery is required for a facility to manufacture parenteral dosage forms under sterile conditions with following annual production capacities.

I. STERILE LIQUIDS

a.	Ampoules	(1,2,5,10 & 20mls)	2.5 million units
b.	Vials	(10,20,50 & 100mls)	2.5 million units

II. STERILE DRY FILLS (antibiotics)

a.	Vials antibiotics	(10ml)	2.5 million units
b.	Vials antibiotics	(15 & 30ml)	1.5 million units

Drawing of the building-designed for this purpose and a brief sketch of operational flow is also enclosed.

1. The choice of machinery should be based on simplicity of mechanism, ease of maintenance and servicing but incorporating mechanization/ automation, specially in the machines for filling, stoppering and sealing.

2. Offers should be made of most economic choices as this project is sponsored by the government on non commercial basis and technically assisted by United Nations.

3. The plant services available include steam, compressed air, deionised water and distilled water in sufficient quantities to meet the requirements of the new section.

4. Liquid petroleum gas (LPG) is locally available and can be provided in conjuction with compressed air or oxygen.

5. The electrical specifications for the machinery are :

   220-240V 50Hz single phase AC
   380-440V 50Hz three phase AC

6. Sterile air handling units for sterile area (320 m^3) can be developed through local agents.

   Offer for relevant interlinkable components, however, can be made. Ducting system, installation and commissioning will be contracted out locally.

   Air quality requirement. Bacterial free air at 24°C and 30% RH
   Ambient maximum day temperature 28°-35° over the year
   Relative Humidity lowest 62% at 32°C August
   highest 94% at 32°C March

7. Appropriate samples will be provided for fabrication of change parts/ accessories whereever required.

In view of wide range of options for these machines the specifications have been developed from user needs only. Identification of most appropriate items is left with the supplier with respect to the mechanics of operation and cost considerations.

The offers will include one set of change parts as standard and recommended spares for two years single shift operation. The additional change part set should be quoted separately.

Offers should be based on C+F Kabwe, Zambia, seafreight either via Durban or Dar-es-Salaam.

The terms of payment will be through irrevocable letter of credit opened with the suppliers banker.

The offers should be accompanied with illustrated brochures.

In case some offers have already been made, please review them in line with the present details and send additional offers for those in your range which you consider more appropriate to our needs.

We would like to express our appreciation for your assistance and co-operation for the collection of initial cost estimates of the machinery and their technical specification. We are certain that our relationship with you will be mutually beneficial and lasting.

With best personal regards.

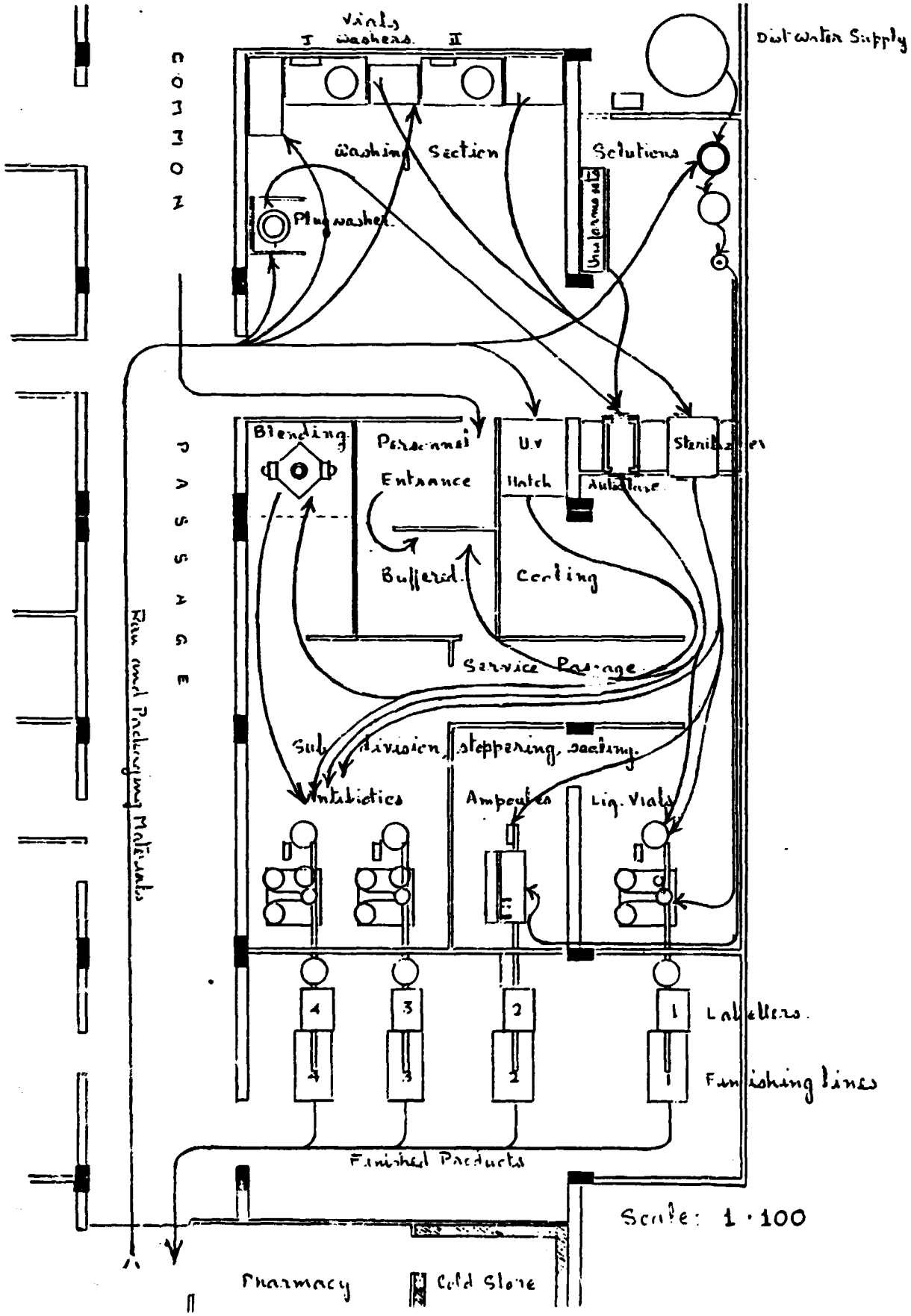
Yours faithfully,
GENERAL PHARMACEUTICALS LTD

DR. M. ALAUDDIN (UNIDO)
PHARMACEUTICAL ADVISOR

ENCS.

SI/ZAM/86/905

INJECTIONS PRODUCTION UNIT: GENERAL PHARMACEUTICALS LIMITED



LIST OF MACHINERY

(PRODUCTION OF INJECTIONS)

1. PLUG WASHER : For rubber stoppers/aluminum seals
specifications : Multiple washing stations, built in water heater/filter controls for washing cycles and timings.

Capacity:- 10kg of rubber stoppers or equivalent volume.

2. AMPOULES WASHER: For ampoules of diameter ranging from 10-22 mm and capacities from 1 to 20ml generally German DIN specifications.

Specifications:- Multiple washing stations, steam/water filters, and option of water heater. Mannual loading bay and collection into replaceable receptacles at the end of washing cycles.

Capacity :- 2000 ampoules/hour of upto 15mm diameter (5ml capacity)

3. VIALS WASHER : For antibiotic and liquid injections vial of diameters ranging from 20-50 mm and capacities from 10 to 100ml generally German DIN specifications.

Specifications :- Multiple washing stations on rotary principle. Steam/water filter with option of water heater. Mannual loading bay and collection into a replaceable receptacle at the end of washing cycle.

Capacities : 2000 vials/hour of 25 mm body diameter.

NOTE: A unit capable of handling ampoules and vials both with a washing output of upto 5000 units per hour may be considered.

4. STERILIZER ; Dry heat for glass container batch loading in trolleys.
Specifications : Hinged doors at both ends, top mounted blower, air circulator, filter and safety interlocks for doors.
Heating elements for 250°C working with thermostat control pannel with recorder, timer lamps.
Sterilization chamber AISI-304, insulated, outer casing rust proof alloy
Capacity :- 1000 litres
Accessories : Two sets of trolleys AISI-304 and trays with covers of annodised aluminium durable alloy (tray size to be provided at the time of firm order).

5. AUTOCLAVE : For rubber stoppers, annodised aluminium seals, workers uniforms and assorted metal, rubber and P.E. and P.V.C. articles.
Specifications:- Working pressure upto 4 bar of steam, wall mounting, door at each end with safety lock.
Material of construction AISI-316 for the chamber and AISI-304 for all other parts.

Control pannel, recorder, timer and lamps.

Capacity . 400 litre cubical or cyllindrical chamber. Accessories :- Two sets of loading and unloading trolley AISI-304. Two sets of annodised aluminium boxes and/or cages (size to be provided at the time of firm order).

6. FILLER/SEALER - AMPOULE

For cutting, filling and sealing of closed ampoules of diameter ranging from 10-22 mm and capacities from 1 to 20 ml generally German DIN specifications.

Specifications : automatic ampoule opening (cutting) filling and sealing. Gas purging, fused tip sealing and collection at the mannually replaceable receptable.
Capacity : 2,500 ampoules/hour based on 5ml ampoules
Options Preheaters for non-uniform supplies and scoring device to be quoted separately.

FILL/STOPPER/SEAL SYSTEMS

Combination of filling, stoppering and spin-roll sealing machines.

7. FOR LIQUIDS : Fill range : 10 - 100ml (aqueous or low viscosity solutions)
Body diameter : 20 - 50 mm
Neck finish : 20mm OD standard antibiotic vial.
Output : 1500 per hour (for 100 ml fill)

8. FOR ANTIBIOTIC POWDERS

Fill range : 0.33 - 15-0gm of antibiotic powders
Body diameter : 20-40mm
Neck finish : 20mm OD standard antibiotic vial
Output : 2500 per hour (for 1500 mg fill)

Separate units for each function (fill, stopper, seal), suitable for installation on the conveyor, can also be offered for consideration.

9. PRINTER AMPOULES : Semiautomatic screen printing in one colour and without vetrification station. For ampoules ranging 1ml to 20ml sizes (10-21mm OD)
Formation of breaking ring attachment as optional.
Capacity : 2000 ampoules per hour.

10. LABELLER, VIALS : Specifications - Mannual feed, automatic labelling operation with wet glue of pre-cut labels. For vials ranging from 10ml-100ml (20-60mm OD). Attachment for batch printing to be quoted as optional.

Capacity : 2000 vials per hour

11. TANK PROCESSING : Working volume 200l, with steam jacket, sight glass, light glass, inlet, outlet with mannual valve on steam jacket, airvent, dial thermometer gass purging valve and valve on outlet with manhole and agitator mounted on wheeled stand. Contact surface AISI 316 other AISI 304.

12. TANK HOLDING : Same as above but without steam jacket nor agitator nor pressurised.

13. FILTER ASSEMBLY : Pressure filter holders for in-line use. Stainless with tripod stand for membrane filtration of aqueous parenteral solutions, with provision of pre-filter. For membranes of 293 and 142mm dia.

14. CLEAN AIR HOOD : Verticle overhead mounting over the operational surfaces such as washing and filling machines. Modular with built in fans. Materials of construction rustproof, unpainted metallic parts of annodised aluminum alloy. Similar to Bassaire S series standard module 700 x 1000 and 700 x 1500mm sizes.

15. U.V. LAMP : High intensity ultra violet, vertically mounted tubes on a portable pedestal for irradiation of sterile rooms before or end of the sterile operations.

16. U.V. TUBES : 1. High intensity for installation in the U.V. irradiation chamber for surface sterilization of bulk containers and similar items.

2. Normal intensity tubes with protection shield for roof mounting in the sterile operations room and burning permanently.

17. TURNTABLES : Diameter 500mm.
Mounted on height adjustable legs frame.
Quote for both inlet and outlet types.

18. CONVEYOR BELT TABLE WITH DRIVE MOTOR :

Stainless steel slats conveyor of about 100mm width and provided with adjustable vial guides, leg stands, belt supports etc.
Please quote the standard versions ranging from 2000mm to 4000mm length.

BRIEF DESCRIPTION OF OPERATIONAL FLOW

WASHING/PREPARATION SECTION

Vials/ampoules will be mannually loaded on and collected from the washing machines installed under verticle laminaire hood and equipped with rotary multiple washing station.

The plug washer will be mannually charged and discharged with a fixed quantity per load.

The washed materials will be collected in appropriate covered trays/ boxes loaded on trolleys will be transferred to the sterilization equipment.

The dosage form solutions will be prepared in batch tanks in a separate area of this section and will be piped directly to the sub-division machine through in-line membrane filter.

Sterile powder will be transferred in original sealed containers after cleaning and surface sterilization in the U.V. irradiation chamber.

Set of sterile apparel, prepared in the preparation room and other supplies will be transferred to sterile area after autoclaving.

Personnel will enter the subdivision/sealing area through buffered entrance following the asceptic technique drill and changing over to sterilised uniforms.

SUBDIVISION/SEALING SECTION

This area will be maintained under constant sterile environments.

The materials will be collected from various sterilization system and transferred to the point of use in suitably designed push trolleys.

Subdivision and sealing operations will be carried out on automated machines installed under verticle laminaire hoods. In case of ampoules the units will be fully automated with mannual loading and collection station at the outlet.

Subdivision and sealing of vials will be in succession by mannual feeding on semiautomatic rotary machines. The sealed vials will be mannually pushed out to the finishing area through guided roller station (will be transported rhrough power conveyors in future).

FINISHING/PACKING SECTION

After visual inspection of sealed containers, over-printing of ampoules and labelling of vials will be carried out on semiautomatic machines followed by a packing conveyor where the packaging will be carried out mannually.

Provision for full automation of fill/stopper/seal/label line for the future has been incorporated in the plans.

(A sketch of the injections production units showing approximate machine locations and process-flow is attached as guideline)

... NICOMAC (Att: P H Atlas)
20133 MILANO
Via Pascoli 60
Italy

... PHARMEXPAND/BONAPACE (Att: Dino Romanatti)
Via Canova 6-12
20145 MILANO
Italy

... BAUSCH STROBEL (Att: Messrs H K Thomas/L Schaile)
Maschinenfabrik GmbH & Company
Postf 20 D-7174 ILSHOFEN
West Germany

... STRUNK & Company
Lichtstrasse 30-34
5000 Koln
EHRENFELD
West Germany

... G.G. BODE & Company GmbH
Hamburg 90
SCHLOSSMUHLENDAMM 11
West Germany

... ALA/AARUPP
Inginior Firma & Maskinfabrik A/S
Sydvest, Vej 107
DK-2600 GLOSTRUP
Denmark

... ADELPHI Manufacturing Company
Mill Green Road
W. SUSSEX RH161XO
United Kingdom

... ZANASI (Att: Mr Reno Magni)
40064 Ozzano Emilia
BOLOGNA
Italy

... C.E. KING (Att. Catherine King)
41 London Street
Chertsey
SURREY KT16 8AR
United Kingdom

APPENDIX II

Reference

Financial Appraisal of the Project

prepared by the UNIDO's COMFAR computer model

for economic evaluation

UNITED NATIONS DEVELOPMENT PROGRAMME

APPENDIX III

PROJECT PROPOSAL

PART A - BASIC DATA

COUNTRY/REGION	Zambia
PROJECT NO.	DP/ZAM/87/
PROJECT TITLE	DIVERSIFICATION AND EXPANSION OF PHARMACEUTICAL MANUFACTURING FACILITIES IN ZAMBIA
SCHEDULED START	September 1987
SCHEDULED COMPLETION	August 1989
ORIGIN AND DATE OF OFFICIAL REQUEST	Letter from the Ministry of Finance (NCDP), Government of the Republic of Zambia dated
GOVERNMENT COUNTERPART AGENCY	INDECO, General Pharmaceuticals Limited (INDECO)
UNDP CONTRIBUTION	U.S. Dollars : 421,000
GOVERNMENT CONTRIBUTION	U.S. Dollars : 1,130,000
CURRENCY REQUIRED	
i. UNDP (convertible)	U.S. Dollars : 421,000
ii. Government	
a. Convertible	U.S. Dollars : 740,000
b. Non-convertible	U.S. Dollars : 390,000
UNIDO BACKSTOPING SUBSTANTIVE SECTION	Pharmaceutical Unit, C.I.B., D.I.O.
PROGRAMME COMPONENT	32 I.D.

PART B - NARRATIVE

1. OBJECTIVES

a. Development Objectives :

- To expand indigenous capabilities for production of essential drugs for the health sector
- To supplement the imports substitution programme by local production of pharmaceutical dosage forms.
- To contribute towards national economic development by increasing employment opportunities and technological infrastructure.

b. Immediate Objectives

- To provide technical assistance during establishment of a unit for manufacture of injections and drops at General Pharmaceuticals Limited.
- To assist in expansion of quality control activities and creation of new sections namely product development and in-process control.
- To assist in organizing manpower utilization and traing programme.
- To assist in introduction of systems for effective planning, controls and economics of production.
- To explore potential for further diversification of production range.

2. SPECIAL CONSIDERATIONS

NIL

3. BACKGROUND AND JUSTIFICATIONS

The Government of Zambia has directed that continued efforts be made towards self reliance in the provision of essential drugs for the national health sector and towards import substitution.
Inspite of economic constraints and difficult operating environments, the pharmaceutical industries in the public sector have been performing reasonably well. This performance has encouraged the government to expand the activities of the pharmaceutical sector both in terms of capacities and product range, to cover more and more of essential drugs.

In view of financial resource limitations, because of which projects requiring large investments could not be materialised in the past, the current approach towards modernization and expansion of the existing facilities is logical and expected to offer reasonable growth of the industry requiring considerably lower financial outlay.

Under current 1987 technical assistance of UNIDO (SI/ZAM/86/905) detailed plans for establishment of a section for production of injections and drops at General Pharmaceuticals Limited are being prepared for implementation in the late part of 1987.
Funds required for implementation of this project have already been earmarked and expected to be released at the time of project implementation.

In order to ensure speedy and successful implementation of the project, the government is anxious to receive technical assistance from United Nations Industrial Development Organization in the form of the services of a pharmaceutical industries expert to undertake:-

- Training of national staff
- strengthening of quality control and plant maintenance facilities, and,
- arrange provisions for engineering consultancy services at certain stages of project implementation.

4. OUTPUTS

- Establishment of a modern facility for manufacture of injections and drops with the following installed capacities:-

PRODUCT GROUP	INSTALLED CAPACITY	NATIONAL REQUIREMENTS
I. STERILE LIQUIDS		
a. Ampoules	2.5 million units	2.47 million units
b. Vials	2.0 million units	1.75 million units
II. STERILE POWDERS		
a. Single dose	2.5 million units	2.57 million units
b. Multiple dose	1.6 million units	1.40 million units
III. EYE, EAR & NOSE DROPS	1.5 million units	1.30 million units

- Expansion of quality control facilities for
  (i) evaluation of injections including in-process control systems and,
  (ii) for building in capability of undertaking new product development on a reasonable scale.
- Expansion of plant engineering services to include machines and installation testing functions with necessary instruments and identified shops for electrical, mechanical, carpentry and auto-repair
- Prepare and secure training arrangements for supervisory personnel in various technical functions with emphasis in production technology, quality control and engineering (plant maintenance).

5. PROJECT ACTIVITIES

- Activities will be based on the following implementation schedules, finalised as first activity and governed by a master work plant.
  - . Construction and restructuring of the buildings
  - . Installation of sterile air handling and air treatment systems.
  - . Procurement and installation of plant furnishings, fittings and fixtures and machinery.
  - . Designing of uniforms for sterile area workers.
  - . Development of specifications for raw materials, packaging materials and finished products.
  - . Start ups, trial runs and commissioning.
  - . Manpower development and training

The following specific activities will be undertaken in accordance with the above implementation, schedules and timed accordingly.

- General supervision and guidance during construction and restructuring of the buildings to ensure recommended design and finish.
- Assistance during final selection of plant machinery and equipment and follow up on procurement progress.
- Specifications development of plant furnishings and guidance during their fabrication.
- Supervision during laying out of furniture and installation of fixtures, fittings and machinery.
- Guidance in designing and installation of sterile air handling and other air treatment/flow systems.
- Development of raw and packaging materials and finished products specifications and follow up on materials procurements schedule.
- Drawing up and execution of training programmes in production, planning, process technology, quality assurance, warehousing and plant engineering services.
- Preparation of the project terminal report.

6. PROJECT INPUTS

a. Government inputs

1. Financial

1.1.	Buildings	US Dollars 150,000
1.2.	Equipment	US Dollars 610,000
1.3	Working capital	US Dollars 280,000
1.4	Contingencies	US Dollars 90,000
	TOTAL	US Dollars 1,130,000

2 National Staff

2.1 General Manager of General Pharmaceuticals Limited will be the national counterpart of the UNIDO Technical Adviser.

2.2 Entire managerial staff will assist and cooperate with the Technical Adviser to facilitate carrying out of his duties effectively.

2.3 GPL will ensure timely availability of finances and other inputs in accordance with respective implementation schedules.

2.4 Secretarial and other office facilities/supplies/services will be available to the Technical Adviser in accordance with the work requirements.

3. Miscellaneous

3.1 The government will arrange furnished residential accommodation for the Technical Adviser.

b. U.N.D.P. INPUTS

11.	Experts			
	11.01 Technical Adviser	24m/m	US Dollars	192,000
	11.05 Consultancy provision	6m/m	US Dollars	48,000
15.	Project Travel		US Dollars	5,000
39.	Training	72m/m	US Dollars	144,000
49.	Equipment			
	49.1 Quality Control		US Dollars	8,000
	49.2 Workshop testing instruments		US Dollars	10,000
	49.3 Project Vehicle		US Dollars	12,000
59.	Miscellaneous		US Dollars	3,000
99.99	GRAND TOTAL		US Dollars	421,000

7. EVALUATION

7.1 Project progress will be reviewed in annual tripartite meetings of UNDP,UNIDO and the government three months before the annual programme review in order to incorporate revisions whenever deemed necessary.

7.2 The terminal report by the Technical Adviser will be evaluated by UNDP, UNIDO and the government three months before termination of project activities.

8. ENVISAGED FOLLOW-UP

Follow-up activities will be determined in accordance with the findings of the terminal report and recommended course of action.

UNITED NATIONS

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

UNIDO

JOB DESCRIPTION

DP/ZAM/87/001/11.01

Post title Technical Adviser

Duration Two Years

Date required 10 September 1987

Duty station Zambia

Purpose of project To provide technical assistance for introduction of new production technology and institution of standardised procedures for manufacture, quality evaluation and performance controls; strengthening of capabilities towards planning, performance monitoring, cost controls and manpower development, in the establishment of a production unit for injectables and drops at GPL, thereby diversify and expand the pharmaceutical manufacturing facilities in Zambia to meet the requirements of essential drugs.

Duties: The Technical Adviser will be expected to carry out the following duties:

- To provide guidance and general supervision during construction and restructuring of the buildings in accordance with the recommended design and finish.
- To design the specifications of plant furnishing, fittings and fixtures and to offer guidance in procurement and fabrication.
- To provide supervision during laying out furniture, fittings, and fixtures and during installation of machinery.
- To provide guidance in designing and installation of sterile air handling and other air treatment/flow systems.
- To develop technical and operative specifications for the raw and packaging materials and finished products and follow-up materials procurement schedules.
- To compile operating procedures for various functions of the plant and assist in their implementation.
- To evolve standardised manufacturing instructions for production of individual ..jection dosage forms scheduled for first two years of production.
- To draw up detailed training programmes for the national staff and to assist in their execution according to preformulated schedule.

..../..

- To provide assistance and guidance during the trial run of the machinery, start-up of the operations, pilot scale production and commercial production runs of identified products.

- To prepare the terminal report of the project identifying the achievements and enumerating recommendations for future course of action.

QUALIFICATIONS : Industrial pharmacist with high academic achievement and extensive experience in :

. Designing, restructuring and expansion of pharmaceutical plants with diverse production capabilities and their realization in developing countries.

. Planning, budgeting in and management of pharmaceutical plants.

. Product designing and new products development.

. Development of operating systems and procedures pertaining to all functions of the pharmaceutical plants.

. Development and execution of manpower development and training programmes.

- LANGUAGE : English