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Zambia.

PRODUCTION OF ORAL REHYDRATION SALTS. GENERAL PHARMACEUTICAL LIMITED

US/ZAM/82/137
ZAMBIA

Terminal report *

Prepared for the Government of Zambia
by the United Nations Industrial Development Organization

Based on the work of M. Alauddin,
Expert in Pharmaceutical Industry

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1. EXPLANATORY NOTES AND ABBREVIATIONS

Explanatory Notes

1. Unless and otherwise stated, the monetary figures used throughout this report are in United States Dollars.

2. Product and materials costing is done in Zambia Kwacha with the following exchange rate :-

   1 US Dollar : 2.43 Zambia Kwacha

3. Drawings of the buildings and civil structure are fairly true to scale but require further architectural details.

4. Dimensions of equipment, fixtures and furniture are close approximations.

5. The text of the report has been kept as brief as possible and adequately illustrated with the help of self explanatory tables, charts and drawings.

Abbreviations

G.P.L.	:	General Pharmaceuticals Limited
INDECO	:	Industrial Development Corporation
M.S.L.	:	Medical Stores Limited
N.C.D.P.	:	National Commission for Development Planning
M.O.H.	:	Ministry of Health
U.N.D.P.	:	United Nations Development Programme
U.N.I.D.O.	:	United Nations Industrial Development Organization
U.N.I.C.E.F.		United Nations Children Fund
W.H.O.	:	World Health Organization
D.D.C.	:	Diarrhoeal Disease Control Programme

II ABSTRACT

Project title

Production of Oral Rehydration Salts.

Project number and purpose

US/ZAM/82/137

To make ORS available to the population at a reasonable price in order to improve the primary health care programme.

Objective

To provide technical assistance for the establishment of an ORS production unit, transfer of technology, trial runs and on-the-spot training of local personnel.

Duration of the mission

Starting date	1 March, 1985
Completion date	31 August, 1985

Activities enumerated under the preparatory phase of the work plan have been accomplished to a satisfactory degree. Main features of the in-puts are summarised below:-

- Design of the ORS unit has been finalised and the construction work has been contracted out which is expected to be ready for installation of the equipment by middle of November 1985.
  Building design for permanent location has also been finalised and will be undertaken alongwith further diversification programme.
- Production equipment has been received in the plant and is ready for installation.

  Quality Control and other plant services have been scrutinised and found adequate to undertake the work connected with ORS production.
- Formula composition and standard packet of ORS has been ascertained and received approval from the Ministry of Health and relevant specifications developed.

- Packaging specifications have been developed and appropriate packaging materials selected and the local supply sources identified.

  Supplies of most of these materials for 1.0million packets have been procured while remaining supplies are expected to be delivered to the plant by the end of September 1985.

- Raw materials sufficient for 1.328 million ORS packets has been procured most of which has been delivered to the plant and remaining supplies are scheduled to arrive by the end of November 1985.

- Studies towards cost improvement of the ORS packets have also been conducted and some proposals are included in this report offering substantial saving.

- Costing of the ORS packets has been worked out in detail and tentative wholesale price has been fixed at K0.45 (US Dollar 0.184) which compares favourably with other commercial supplies in the country.

- Exploration of local sources and or substitutes of the raw materials is in progress and one promising formula has been proposed for clinical trials, later in this report.

- Guidance and advice has constantly been offered to all functions of the plant towards systems, monitoring and control at managerial as well as supervisory levels.

- Preparatory work for compilation of procedures manual and production documentation has been finalised.
  Formal compilation of the manual has been deferred and will be undertaken during the early stages of execution phase as the involvement in additional activities relevant to the diversification programme did not permit allocation of time for this purpose.
  Considerable contribution have been made towards development of well formulated outline as foundation for systematic diversification programme for G.P.L. Although not included in the work plan but this contribution, being closely linked with the present operation and especially with the ORS project, was considered an essential component of the present undertakings.

III RECOMMENDATIONS

At the onset of project activities, efforts were made to prepare a work plan for accomplishment of project outputs within the present project life time. After evaluation of requirement of the inputs and consultation with the management, however, it was deemed necessary to review the project activities and develop a revised work plan in accordance with these activities. The work plan (annex 1), supplemented with implementation schedule (annex 2) divided into "preparatory" and "execution" phases, amply elaborates the extent of field activities spread over a period of one year. In fact, even the original project submitted to UNIDO was designed for technical assistance for a period of nine months.

The activities carried out so far basically cover the preparatory phase completing the planned output and the project now stands at the stage of entering the execution phase. Continuation of UNIDO technical assistance is vital at this crucial stage in order to ensure uninterrupted progress in project activities and to achieve the objectives. In this connection a proposal for extension of the technical assistance, providing detailed justification and a revised job description of the industrial pharmacist has already been submitted (Annex 2).

- Technical assistance for an additional period of six months should be offered in order to complete the immediate objective of the mission.

- G.P.L. should be provided additional technical assistance to prepare detailed production diversification programme which bears promising prospect in view of the preliminary work carried out during the current assistance. Relevant project proposal is under preparation for submission to N.C.D.P. for inclusion in the country development programme.

IV INTRODUCTION

A. PROJECT BACKGROUND

Dehydration, caused by intense diarrhoea and vomiting associated with acute gastro-intestinal diseases is one of the most common causes of death amongst infants and young children in developing countries. Treatment for restoring the loss of fluids and essential salts from the body, however, is simple and economical and equally effective in all age groups. It constitutes oral administration of a glucose - electrolyte solution, prepared simply by dissolving the contents of a packet of ORS in specified volume of potable water, to the ailing person according to a recommended regimen or thirst level until the purging disappears.

Classified under non-prescription medicaments (OTC), the ORS packet can be safely used by mothers in distant rural areas because, unlike I.V. fluids, its administration does not require skilled medical supervision or hospital care.

ORS is a dry powder prepared by blending glucose and other salts essential for body fluids and as such it is stable under normal storage conditions with reasonably long shelf-life.

According to the studies carried out by W.H.O. and U.N.I.C.E.F., the the ORS has been extensively used for successful treatment of dehydration due to acute diarrhoea including cholera, in all age groups. It has been proved a pharmaceutical product of great value in developing countries and accordingly included in the W.H.O. list of essential drugs.

Proposal for establishment of ORS production unit at G.P.L. was made as early as 1981 after assessment of national requirements and close consultations with the Ministry of Health, Republic of Zambia and was backed by preliminary economic evaluation towards cost of ORS production and financial viability of the required investment.

Originally the proposal was based on a production unit with an annual capacity of 625,000 packets which has now been revised upwards to 1,000,000 packets.

In the subsequent years the project could not take-off mainly due to foreign exchange difficulties until in 1983 when U.N.I.C.E.F. offered to provide sufficient foreign exchange cover to G.P.L. against payment in Kwacha for purchase of equipment and initial supplies of raw and certain packaging materials. Technical assistance required for project implementation was made available through technical assistance programme initially for a period of six months.

The U.N.I.D.O. expert was fielded in March 1985, at a time when consignments of equipment, ordered with the assistance of W.H.O./ U.N.I.C.E.F. were expected to be arriving in the country.

B. OFFICIAL ARRANGEMENT

- Request made through the Office of the President, Republic of Zambia (N.C.D.P.)
- Approval by the Programme Development and Evaluation Branch, U.N.I.D.O., Vienna.

- Date of Project becoming operational	1 March, 1985
- Duration of the project	six months
- Start of the mission (fielding of the expert)	1 March, 1985
- Completion of the mission	31 August, 1985

C. CONTRIBUTIONS

1. U.N.I.D.O. Contribution

a.	Expert	6 m/m	43,900
b.	Sundries		1,000
	TOTAL		44,900

2. Government Contribution (Non-convertible by G.P.L.)

a.	Buildings	US Dollars	60,000
b.	Equipment	" "	100,000
c.	Personnel	" "	15,000
d.	Miscellaneous		5,000
	TOTAL	US Dollars	180,000

D. OBJECTIVES OF THE MISSION

1. Development Objectives

To improve the social health sector and promote the primary health care programme by making ORS available to the population at a reasonable price.

To satisfy the country's needs in ORS and to promote its export to neighbouring developing countries.

2. Immediate Objective

To provide technical assistance for the establishment of an ORS production unit, transfer of technology, trial runs, and on-the-spot training of local personnel.

V . ACTIVITIES

A. BUILDING LOCATION AND DESIGN

Preliminary discussions revealed the keenness on part of the Management of General Pharmaceuticals Limited towards further diversification of the operation in order to achieve greater viability of the Company and to substantially supplement the national needs of essential drugs most of which are currently imported in the country. The idea had originated from the fact that the economy of the country could accommodate smaller investments needed for gradual expansion of the sub-sectors more easily than large investments on new plants.

Keeping future expansion of plant activities in perspective, the location for the ORS production unit was investigated in detail resulting in numerous proposals for the consideration of the management. For the sake of expediency, however, it was agreed that the ORS production should be temporarily housed in one part of the existing finished goods warehouse while the permanent location should be developed in harmony with the future diversification plans.

1. Remodelling of existing building

Annex III illustrate the building designed in the existing finished goods store in order to commence the production of ORS immediately.

- The area covering 128m^2, is adequately isolated from the i.v. fluids section in order to avoid cross contamination.
- The building layout is composed of four rooms of equal size.
- First room serving as store can accommodate raw material inventories sufficient for nine months production.
- Second and third rooms will serve for pre-treatment/weighing and blending/quarantine purposes respectively.
- Fourth room will be packaging hall for subdivision and finishing of the ORS packets and is furnished with in-process control facilities as well.
- Remaining 64m^2 of the finished goods store will serve as interim store for finished products awaiting release from quality control.

- Rooms will be equipped with window type air conditioners to control temperature and humidity during warm and rainy seasons. The local climatic conditions are generally dry and cool most of the year round.

Major draw back of this location is inefficient utilization of already scarce floor space as a well designed ORS unit for the projected capacity can be accommodated in 70m^2 (annex 7). Designing such facility within the 192m^2 space of finished goods store would leave 122m^2 spared which cannot be well utilised for any other productive purpose.

2. Permanent Location

Future diversification of production range to include other pharmaceutical dosage form was the prime consideration during identification of a permanent location for the ORS production unit. Activities in this direction, therefore were extended to include detailed scrutiny of present functions and work load of the plant in attempts to optimise the floor space utilization and improvement in operational streamlining.

Bracketing the ORS production, belonging to non-sterile dry dosage form group, with the capsules and tablets manufacture was a logical approach offering following advantages:

- Common requirements of environmental control services.
- Similarity in early production steps requiring same equipment.
- Requirement of segregation and avoidance of cross contamination in other product groups.

Annex 4 illustrates the present building arrangements which is further elaborated in annex 5 with the respect to floor space allocated to various functions. Through one of the exercises, centralising the plant services in a new 240m^2 first floor block over the main building and rationate reappropriations of the layout of i.v. fluid section, it was possible to substantially expand the warehouse with centralised pharmacy and still leaving about 240m^2 floor space adequate for establishment of medium size sections for manufacture of diversified dosage form groups within the main block (annex 6).

Considering the G.M.P. and better product group segregation, however, this space, being more suitable for production of small volume injection and possibly ointment and oral liquids, it was agreed to locate the ORS unit alongwith the capsules and tablets in an independent dry dosage form section in a building well segregated from the liquid dosage form sections. The choice thus remained between conversion of the new finished goods store into the production unit and an entirely new block adjacent to it (annex 6).

PROPOSAL I

Annex 7 illustrate the proposed design of the nonsterile dry products section on the ground floor of the new finished goods store. It covers an area of 240m^2 with the ORS production unit located along one length of the building, well segregated tablets/capsules production units along the other length and having the following annual production capacities:-

1.	ORS packets	1,000,000
2.	Capsules	50,000,000
3.	Tablets	250,000,000

Ceiling of this building having a minimum clearance of 6 meters (annex 8), it is recommended to create 240m^2 additional floor space by constructing a mezzanine at three meters height from the floor for storage of light weight and voluminous packaging materials after housing the air filters, dehumidifier and air conditioner over an area of 70m^2.

This proposal, however, will require reorganization of various warehousing facilities comprising 910m^2.

- Supplies of bulky excipients and glass bottles etc could be stored in 400m^2 rented warehouse in town.
- Lightweight packaging materials like tins, plastic, tubes, closures, labels and cartons etc can be accommodated over the 170m^2 mezzanine of non-sterile dry production unit.

- The 340m^2 warehouse in the main block (annex 6) will be sufficient to store the active raw materials, finished products and immediate requirement of other materials when necessary.

PROPOSAL II

This proposal (annex 9) is basically an expansion of the first proposal, located in a new 350m^2 building to be built adjacent to the existing finished goods store (annex 6) and has been designed to accommodate higher production capacities per year:

1.	ORS	2,000,000
2.	Capsules	100,000,000
3.	Tablets	300,000,000

Other advantages of this proposal over the first one are more improved flow of operation, separate provision for small and large unit packaging for capsules and tablets and direct passage of products into the finished goods store.

Structuring of the finished goods store (annex 3) for housing of ORS production unit was contracted out but inspite of constant follow up, the contractors failed to undertake the work and as a consequence the job has been contracted out to another party and is expected to be completed by middle of November 1985.

B. EQUIPMENT LAYOUT AND PROCESS FLOW

Equipment layout as envisaged for the production of ORS at the temporary facility is illustrated clearly in annex 10.

The facility has its own warehousing of raw materials, is served with independent entrance and connected directly to the operational area. It can conveniently accommodate raw materials for 300,000 ORS packets.

Production operation is divided into three rooms:

- Milling and sieving machines are located at one end of the first room while the weighing scale and balance on the other. The milling and/or sieving operations are expected to be rather limited and only for supplies of materials which may have turned lumpy or contain undesirable foreign matter.

- The drum/hoop blender is located in the second room opposite to the entrance from the first room while remaining half of the room is allocated for quarantine for unreleased and released ORS bulk blends.
- The bag opening, dosing and closing machine is installed on one end of the packaging table followed by the bag sealing machine in the middle of the table length in the fourth room. The table has been designed to suit the needs of various stages of packaging operations while in-process control checks facilities are furnished longitudenally along one side wall.
- Finished goods quarantine is provided immediately outside the packaging room.
- The process flow sequence has been demonstrated with the help of arrows in the drawing of equipment layout.

The equipment layout and the process flow of the proposed permanent facility is more or less on the same principles and well illustrated in annex II.

C. EQUIPMENT

1. Selection

Selection of suitable equipment was based on the experience of WHO/UNICEF during establishment of ORS production facility in Sri Lanka. One of the expensive equipment supplied to Sri Lanka, required for drying the raw materials, was deleted because the citrate based formulation, adopted in Zambia, has proved to be more stable and does not require pre-drying of the raw materials.

2. Procurement and Shipment

Taking advantage of the previous experience, for procurement of equipment and arrangements for their shipment, this responsibility was given to UNICEF assisted by WHO for technical evaluation and testing of more sophisticated equipment before despatch to Zambia and also to explore economical, expedient and safe means of transportation.

Equipment delivery statement (Table I) provides detailed information regarding the dates of shipment, arrivals in Lusaka and deliveries in the plant at Kabwe.

TABLE I

US/ZAM/82/137

ORAL REHYDRATION SALTS PROJECT

EQUIPMENT DELIVERY STATEMENT

MASTER REFERENCE	E Q U I P M E N T	QUANTITY	UNICEF P.O. NO.	DATE OF SHIPMENT	DATE OF ARRIVAL (LUSAKA)	DATE OF DELIVERY (IN PLANT)	CONDITION OF CONSIGNMENT
1.	Drums (St.St.) 100kg	8	CS/0096	27. 3. 85	28. 3. 85	21. 6. 85	
2.	Trolley (for drums) 200kg	1	CS/0096	27. 3. 85	28. 3. 85	21. 6. 85	
3.	Drying Oven	1	Deleted (UNICEF REF.NO. SEAAO-84/51/Z/MH of January 1, 1984)				
4.	Sifting and straining Machine	1	CS/0097	18. 2. 85	(15. 3. 85) (DURBAN)	19. 7. 85	
5.	Sieving Machine	1	CS/0098	31. 1. 85	(28. 2. 85) (DURBAN)	21. 6. 85	
6.	Weighing Scale (0 - 100kg)	1	CS/0099			21. 6. 85	
7.	Weighing Scale (0 - 20kg)	1	CS/0101	27. 3. 85	28. 3. 85	21. 6. 85	
8.	Control Balance (50gm)	1	CS/0101	27. 3. 85	28. 3. 85	21. 6. 85	
9.	Check Weigher (Thailand type)	1	CS/0099			19. 7. 85	
10.	Drum-Hoop Mixer	1	CS/0100	18. 2. 85	(15. 3. 85) (DURBAN)	19. 7. 85	
11.	Standard Bag Opening, Dosing & Sealing Machine	1	CS/0109	(1. 4. 85)	2. 4. 85	11. 8. 85	
12.	Hand inprinter	5	CS/0102	27. 3. 85	28. 3. 85	2. 7. 85	
13.	Polyethylene Bag Sealing Machine	1	CS/0103	27. 3. 85	28. 3. 85	2. 7. 85	
14.	Vacuum Cleaner (Industrial)	2	CS/0104	27. 3. 85	28. 3. 85	2. 7. 85	
15.	Set of Shovels (st. Steel)	2sets	CS/0106			22. 3. 85	
16.	Thermohygrographs	2	CS/0105	27. 3. 85	28. 3. 85	2. 7. 85	
17.	Thermohygrometer	2	CS/0105	27. 3. 85	28. 3. 85	2. 7. 85	

1. ALL CONSIGNMENT RECEIVED IN UNDAMAGED CONDITION
2. PERFORMANCES WOULD BE ASCERTAINED AT THE TIME OF TRIAL RUNS

- Shipment of all consignments had been completed by the end of March 1985 except item No.11 which was airshipped to Lusaka on 2 April, 1985.
- Excluding items 4,5 and 10 which were individually shipped by surface carrier via Durban, all other items were packed in specially designed crates under WHO supervision and shipped in one single consignment of air cargo on 27 March, 1985.
- All consignments had arrived at Lusaka air terminal by the end of March except items 4,5,10 and 11.
- The surface consignments via Durban reached Lusaka rather late as some of them were mislaid during transit between Durban and Johannesburg and the UNICEF Lusaka had to make considerable efforts in locating the consignments in South Africa and in expediting their trans shipment to Lusaka.

3. Clearance and In-Plant Deliveries

The equipment delivery statement shows that considerable time was taken for clearance of the consignments from Customs at Lusaka and ultimate arrival in the plant in Kabwe. Aside from the time consumed in locating the individual packages and consignments scattered with other goods in the bonded warehouses, most of the delay was experienced in efforts to obtain exemption from customs duty and sales tax normally levied on all machinery and equipment for industrial use. With the assistance of the Ministry of Health, however, it was possible to avail this previledge.

Almost all consignments were received in the plant between 21 June and 22 July, 1985, while item No.11 was received on 11 August, 1985.

Packages of the entire shipment have been found intact and in undamaged contion. Contents of selected packages have been individually inspected and have been found satisfactory.

In order to ensure safety and protection of unpacked equipment the inspection of larger machines has been deferred till the time of installation and trial runs but in view of extremely good conditions of the crates no shipment or transit damage is anticipated.

D. FORMULA AND STANDARD PACKET

Government of Zambia has formed a special committee under the auspicies of the Ministry of Health to provide expert guidance towards systematic implementation of ORS Programme through primary health care system. The Committee which is presided over by the Director of Pharmaceuticals Services and represented by the concerned officials of the M.O.H., G.P.L., UNICEF, WHO and UNIDO meets every month in order to monitor progress towards field studies, surveys, pilot trials and manufacturing aspects and matters relevant to DDC/ORS projects.

Important decisions relating to the national standards for the ORS and control of its manufacture in the country are summarised below:-

- Name : The ORS will be offered under the name "MADZI-a-MOYO" which literally means "Water of Life".
- Formula : Benefitting from the WHO studies, adoption of the citrate based formulation has been fully endorsed by the committee.
- Standard Packet : A nation wide survey to identify most commonly available and familiar measure to prepare ORS solution by the mother, specially in the remote rural areas has resulted in selection of "MAZOE" soft drink bottle, which was found to be available in almost every household. This bottle is suitable to measure 750ml water to a reasonable accuracy.

In view of the fact that no other container, even in simple multiples, was so commonly available to measure one litre, and that the authorities in the neighbouring country Zimbabwe also agreed "MAZOE" bottle as standard measure, the committee decided to adopt a standard packet of 21.0g ORS to reconstitute 750ml of ORS solution at the time of use. The composition for the ORS packet, thus works out as below:-

1.	Sodium Chloride	2.625g
2.	Glucose Anhydrous	15.000g
3.	Trisodium Citrate, dihydrate	2.175g
4.	Potassium Chloride	1.125g
		20.925g

- Manufacture : The committee has adopted measures to ensure maintenance of nationally adopted standards for the formula and the packet by other manufacturers of ORS in the country and have already taken steps to maintain uniformity of the ORS packets in the market as well.

E. PACKAGING SPECIFICATIONS AND DESIGN

1. Specifications

Presentation of the ORS packet was basically governed by the principles adopted in Sri Lanka because of economic reasons and availability of the packaging materials from local sources.

- ORS powder will be sealed in a transparent polyethylene bag of 65 x 95mm dimension.
- This bag together with a label cum "direction for use" folder, printed on 90 x 200mm wood free paper and folded into three overlaping sections, will be enclosed and sealed in second transparent polyethylene bag measuring 70 x 105mm.
- 100 ORS packets will be finally packed in two rows of 50 packets, separated by a strip of cardboard, in a corrugated board box with 105 x 140 x 350 mm inner dimensions and overprinted with necessary labelling requirements.

2. Design

Label of the packet has been designed in yellow and black colour with name of the product on top, depicting a mother with child in a circular figure on the right lower middle position, treatment slogan below the name and manufacturers name in the bottom. Other visible face of the folder contains formula, instructions for reconstitution and batch number and date of manufacture.

The label will be printed on one face of the direction folder with pictorial instructions for reconstitution of ORS and other information on the remaining sides of the folder. The ORS packet along with the folder will be inserted into the outer bag ensuring full "window display" of the label faces through the transparent wall of the outer packet. Dummy of the finished ORS packet is attached with the report for illustration purpose.

3. Packaging Material Procurement

One year supply of most of the packaging materials has been secured while remaining items will be delivered in the plant by end of October 1985 (Table II).

4. Improvement Studies

Studies for further improvement in the presentation of ORS are now in fairly advanced stages of progress and will be accomplished well before the present supply of packaging materials is exhausted. The most promising approach, which will improve the presentation of the packet and also reduce the cost of packaging considerably is aimed at single bag presentation having the following components:

i. Bag : preprinted, opaque white polypropylene or polyethylene measuring 65 x 95mm.
ii. Direction folder: 90 x 120mm insert centrally folded to 90 x 60mm
iii. Dispenser Carton: preprinted, white hardboard with inner dimensions of 95 x 130 x 350mm.

The direction folder will be inserted first into the bag, which will then be filled with ORS and sealed. 100 such packets will be arranged in the dispenser carton in two rows of 50 packets and separated by a strip of hardboard.

F. RAW MATERIALS

In plant delivery and transit status of the raw materials, sufficient for 1·328 million ORS packets is detailed in table II. The raw materials have been procured with the assistance of UNICEF.

Consignment of glucose has been received in the plant by 11 August, 1985, while the remaining materials in one consignment after arrival at Dar-es-Salaam port in Tanzania on 2 July, 1985, has been transshipped and arrived in Lusaka on 10 September, 1985. It is due in Kabwe on 30 September, 1985, upon completion of customs formalities and clearance.

US/ZAM/82/137

ORAL REHYDRATION SALT PROJECT

MATERIALS DELIVERY STATUS

TABLE II

NO.	DESCRIPTION	QUANTITY	P.O. NO.	DELIVERIES STATUS			CONDITION
				DATE OF SHIPMENT	DATE OF ARRIVAL (LUSAKA)	DATE OF DELIVERY IN PLANT	
I	RAW MATERIALS						
1.	Glucose, anhydrous	20,000kg	CCSO145	27. 4. 85	26. 7. 85	11. 8. 85	Satisfactory.Meets the specification
2.	Sodium chloride	3,500kg	CCSO143	20. 6. 85	10. 9. 85	30. 9. 85	Satisfactory. Meets the specification
3.	Trisodium citrate, dihydrate	2,900kg	CCSO143	20. 6. 85	10. 9. 85	30. 9. 85	Satisfactory
4.	Potassium chloride	1,500kg	CCSO143	20. 6. 85	10. 9. 85	30. 9. 85	Satisfactory
II	PACKAGING MATERIAL						
1.	Polyethylene bags (65 x 100mm)	1,000,000	CCSO149	6. 5. 85	8. 5. 85	19. 7. 85	Satisfactory.Meets the specification
2.	Polyethylene bags (70 x 120mm)	1,000,000	CCSO149	6. 5. 85	8. 5. 85	19. 7. 85	Satisfactory. Meets the specification
3.	Label/Direction folder (90 x 200mm)	500,000	3715	16. 8. 85[a]	-	30. 9. 85[b]	Correction on label declaration
4.	Outer carton for 100 packets (105 x 140 x 350)	10,000			-	31.10.85[b]	

a: Date of placement of firm order
b: Scheduled date of delivery in plant

G. COSTS

Cost of production of the 21.0g ORS packet works out to be 39.8ngwee, which with a mark-up of 12.5 per cent would sell at 45.0ngwee (18.4 US cents) to M.S.L. and wholesalers. Details of the costing have been provided in table III.

The wholesale price of the ORS packets manufactured by G.P.L., matches very favourably with the ORS packets commercially available in the country. A price comparison, on contents equivalence basis, with the imported (Searle) and locally manufactured (Interchem) ORS packets offered for 1.0litre solution, is also included in section IV of the table.

An amount of K75,000 being the general overhead (II 8) component absorbed in the annual production of 1.0 million ORS would greatly alleviate the high cost pressure currently being sustained by the intravenous fluid production.

Subsequent years production of ORS is expected to be still more economical by switching over to the improved packaging discussed under section E.3. According to the cost estimated based upon prevailing quotations it will result in a reduction of 7.6ngwee per packet in the cost of only packaging materials and direct labour not accounting for an ultimate reduction of general overheads by 1.9ngwee.

H. LOCAL SOURCES OF RAW MATERIALS

Glucose, trisodium citrate and potassium chloride, the components comprising major portion of the raw material cost, are unlikely to be available from the national sources within the foreseable future. Sodium chloride of food grade, however, is available from parastatal distributors locally.

In order to economise costs, regulate supply and reduce dependence on imports under the difficult economic conditions prevailing in the country, however, studies should be carried out with ORS composed of ingredients commonly available and/or manufactured within the country. One such formula is being suggested employing sugar and sodium hydrogen carbonate, the recommended [1] alternates for glucose and trisodium citrate:

1. Sodium chloride 3.50g (locally available)
2. Sucrose (sugar) 40.00g (locally manufactured)

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[1] Treatment and prevention of Acute Diarrhoea: Guidelines for the trainers of Health Workers: Page 13 ; ISBN9241542004

Table III

UC/ZAM/82/137

ORAL REHYDRATION SALT PROJECT : GPL

COST OF PRODUCTION AND SALES PRICE COMPARISON

KWACHA = 0.4115 US DOLLARS (JULY 1985)

		21.0g Packet
I.	DIRECT COST	
1.	Raw Materials	0.079
2.	Pack.Materials	0.141
3.	Labour + Q.C. + Eng.	0.060
4.	Utilities and Supplies	0.015
	T O T A L (i)	0.295
II.	INDIRECT COST	
5.	Depreciation (B: 2.5% ; M. 10%)	0.018
6.	Repair & Maintainance (50%; of depreciation)	0.010
7.	Interest	-
8.	General Overheads (25% of I)	(0.075)
	T O T A L (ii)	0.103
III.	PRICING	
9.	Product cost (i + ii)	0.398
10.	Mark up (12.5%)	0.052
	EX FACTORY PRICE	0.450
IV.	MARKET EQUIVALENTS (WHOLESALE PRICES)	
1.	SEARLE (27.9g packet : 62.5n/packet (imported)	0.4687
2.	INTERCHEM (27.9g packet : 82.0n/packet) (local)	0.615

3.	Sodium hydrogen carbonate	2.50g (locally available)
4.	Potassium chloride	1.50g (imported)

Although glucose and trisodium citrate are preferred ingredients, but atleast eighteen studies have been reported [2] employing "sugar-salt" or sugar-electrolyte solutions for the clinical trials in several countries. The results obtained were generally successful and equally effective against most type of diarrhoea in all age groups except in some of those studies where merely "sugar-salt" solution were employed without sodium hydrogen carbonate and potassium chloride.

Trisodium citrate is preferred basically to improve the stability of the ORS because of the interaction of sodium hydrogen carbonate with glucose, so in fact the suggested formulation only differs from the standard formulation in respect of carbohydrate component but it has been confirmed that injested sugar is readily converted to glucose in diarrhoea patients as the sugar hydrolysis efficacy of the system is not impaired.

It is therefore suggested that the D.D.C. programme in the country may be provided with sufficient supply of packets of proposed "sugar formulation" alongwith standard "citrate formulation" in order to carryout parallel clinical studies. Compilation of sufficient data confirming the efficacy of the proposed formulation amongst Zambian population would thus permit adoption of the proposed formulation as standard ORS in the country.

Detailed costing of the new formulation has yet to be worked out but the preliminary evaluations promise a reduction of over 40 per cent in the cost of raw materials in addition to the advantages of regular supplies of most of the materials from local sources.

I. TRAINING

The project activities, in general, were conducted in close cooperation with the higher level of management of all functions of the plant and during the course of the work necessary guidance and advice has been offered towards development of the vital concepts:

- Objective management
- Advance planning and follow-up
- Personnel motivation
- Production monitoring and controls
- Cost concieousness and standard costing

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[2] Oral Rehydration Therapy: An Annotated Bibliography W.H.O scientific publication 0.445, second edition, 1983.

The ORS unit not in operation yet, on the-job training has been planned to be carried out when the unit becomes operational and the personnel have been assigned their duties.

Grooming of tne supervisory personnel of the relevent plant services has, however, been initiated during the present mission.

J. MANUAL AND DOCUMENTATION

1. Manual

Frame work, upon which the operation manual will be based, has been prepared relating the following functions of the operation:

- General plant procedures: all functions of the plant discipline
- General manufacturing procedures: separate for each section
- Preduction procedures : separate for each product group
- Materials and warehousing procedures
- Repair and maintenance procedures
- Cost control measures

Draughting and compilation of this volume of work, anticipated to comprise about 250 pages of text will be taken up during the execution phase of the project as the current duration of the project life time could not allow allocation of required time for this purpose. Contents of the manual are enumerated in Annex 12.

2. Documentation

Documentation work and the relevant formats, currently employed for the manufacture of i.v. fluids have been reviewed and found to be adequate for adoption during the manufacture of ORS.

It has, however, been observed that these could be improved to render them more comprehessive and streamlined. The documentation format work, being closely associated with the procedures manual, has been planned alongwith the preparation of the manual.

VI FOLLOW UP

A draft project proposal (Annex 13) in order to avail the required UNIDO assistance of six months has been submitted through NCDP, attached as appendix to this report, is under active consideration of UNDP/UNIDO.

US/ZAM/82/137

Assistance in the production of Oral Rehydration Salts in Zambia.

REVISED WORK PLAN

PREPARATORY PHASE	DAYS REQD	TOTALS
1. Evaluate suitability of different locations in the existing buildings which can be spared for the ORS production in conjuction with diversification programme in the immediate future.		
a. Drawing up of exact plans of the existing facilities.	3	
b. Development of modified operational plan for the i.v. fluid section in order to rationalise the utilisation of the existing building.	5	
c. Preparation of plans for centralised plant and personnel services and relocation of quality control function.	5	
d. Redesigning of the entire plant incorporating production diversification provisions.	5	18
2. Develop appropriate plant layout for production of ORS recommending specification for construction and finishing and requirements of plant services and utilities.		
a. Preparation of plans for temporary location of the ORS section within the existing finished goods store incorporating W.H.O. recommendation and meeting the national regulatory requirements for industrial buildings.	3	
b. Preparation of several choices of building designs for permanent location of the ORS section incorporated in the diversification plans.	4	
c. Selection of final plans in co-ordination with the Management and INDECO architectural department.	6	
d. Identification of material specifications and finishing of the building within the range of locally available materials.	3	

	DAYS REQD	TOTALS
e. Assessment of existing services and utilities and quantification of additional requirements.	3	19
3. Prepare equipment layout drawings in line with the G.M.P. recommendations and incorporating adequate provision for product integrity.		
a. Preparation of schematic equipment layout incorporating streamlined process flow, and ease in material handling, maintenance and cleaning.	3	
b. Working out environmental control requirements, ventilation system, power load levels and electrical lines.	3	6
4. Prepare equipment delivery programme and maintain liason with UNICEF, WHO and the government agencies to monitor the movement, clearance and delivery of the equipment.		
a. Preparation of periodic shipment status running report following the movement of each consignments of equipment, raw materials and packaging materials.	6	
b. Maintenance of central files for the shipping documents with periodic updating.	3	
c. Preparation of periodic statement of equipment delivery status.	5	
d. Compilation of inspection reports upon arrival of equipment consignments.	3	
e. Maintenance of constant liason with UNICEF and the Ministry of Health regarding delivery status of equipment and keep WHO posted with unusual development.		20
5. Actively participate in periodic meetings of the ORS Committee in order to co -ordinate with the activities of national D.D.C programme.	10	10
6. Finalise package presentation and finished product specifications of the ORS packets in accordance with the WHO recommendations and the national D.D.C programme.		
a. Recommendations towards further improvement in the packaging of the agreed presentation.	5	
b. Exploration of alternate and more economical presentations for further adaptation.	7	

	DAYS REQD	TOTALS
c. Finalization of finished products specifications of the locally manufactured ORS packets.	3	15
7. Workout an action plan for gradual substitution of imported raw materials with materials of local source as far as possible		
a. Identification of materials likely to be available from local source (WHO guidelines).	2	
b. Experimentations with formulation based upon local raw materials.	10	
c. Liason with related chemical industries for possible manufacture of raw materials suitable for ORS production.	5	17
8. Prepare detailed manufacturing procedure and operating instructions for production, in-process controls, equipment usage and quality evaluation of raw and packaging materials and finished products		
a. Compilation of step-by-step manufacturing procedure.	3	
b. Preparation of a guideline for performance control and equipment usage.	3	
c. Instructions for equipment maintenance.	2	
d. Development of standard testing procedures for raw and packaging materials.	5	
e. Finalization of in-process evaluations and finished product specifications.	3	16
9. Develop documentation system for manufacture quality control and product release records		
a. Documents related to material handling and issues.	2	
b. Documents related to manufacturing process.	2	
c. Documents related to quality evaluations.	2	
d. Documents related to product release.	1	7
10. Provide assistance in selection of required personnel and develop in-house training programme		
a. Qualification and aptitude criteria in selection of personnel.	1	
b. Induction of desirable habits and discipline amongst workers.	2	
c. Inculcation of sense of responsibility and desire to perform amongst workers.	2	

	DAYS REQD	TOTALS
d. Development of sense of participation, motivation and accountability amongst workers.	2	7
EXECUTION PHASE		
11. Advise and assist in supervision during the construction work.	Continous	
12. Assist in installation of the equipment, incorporating streamlined process-flow to ensure Good Manufacturing Practices during the manufacture of ORS.	20	20
13. Assist in start-up of equipment, trial runs and scaling-up of production operation to the commercial level.	30	30
14. Provide in-house training for the local development of capabilities in planning, warehousing, production, quality control, maintenance of operating conditions and equipment and establishment of process monitoring, operations control and management systems.	20	20
15. Assist in development of systems and concepts related to reduction in product cost, maintenance of quality and improvement in stability of the product.	10	10
16. Prepare a final report in the light of the findings of the mission and the results obtained and make recommendations to the government on further action which might be beneficial for the project.	20	20
TOTAL WORKING DAYS		225

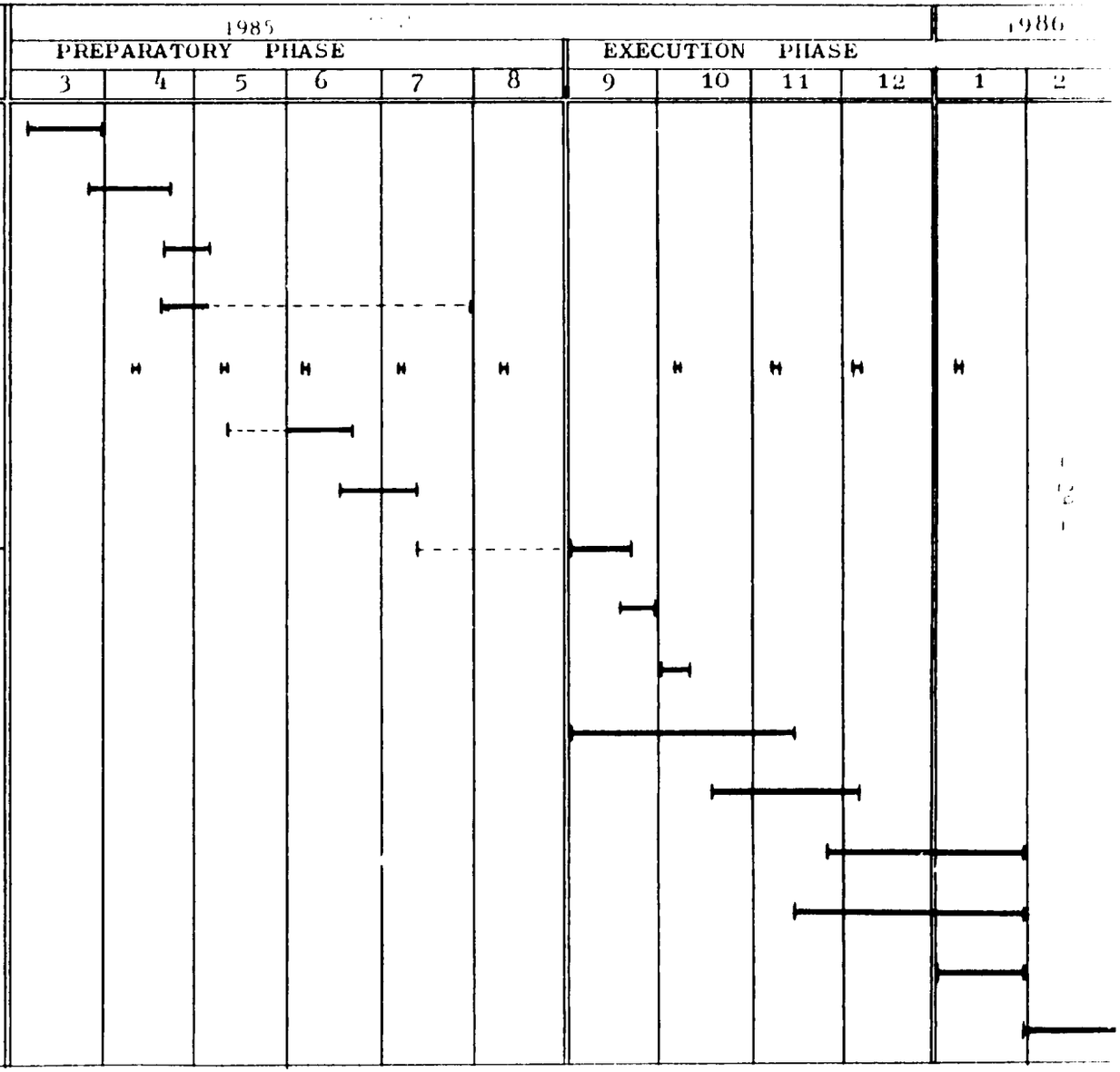
ANNEX 2

US/ZAM/82/137
ORAL REHYDRATION SALTS PROJECT

IMPLEMENTATION SCHEDULE

ACTIVITY

	BRIEF DESCRIPTION
1	Selection of the locatiion for production unit.
2	Design and structural layout of the facility
3	Equipment layout drawing
4	Equipment delivery scheduling and follow up
5	Participation in the ORS meetings
6	Selection of final package components and their specifications
7	Action plan for raw material from local sources
8	Preparation of technical and operating manuals
9	Preparation of documentation for production usage
10	Formalization of in-house training programme
11	Civil work supervision
12	Installation of equipment
13	Start-up, trial runs and scaling up
14	In-house training
15	Introduction of operational controls and monitoring
16	Preparation of final report



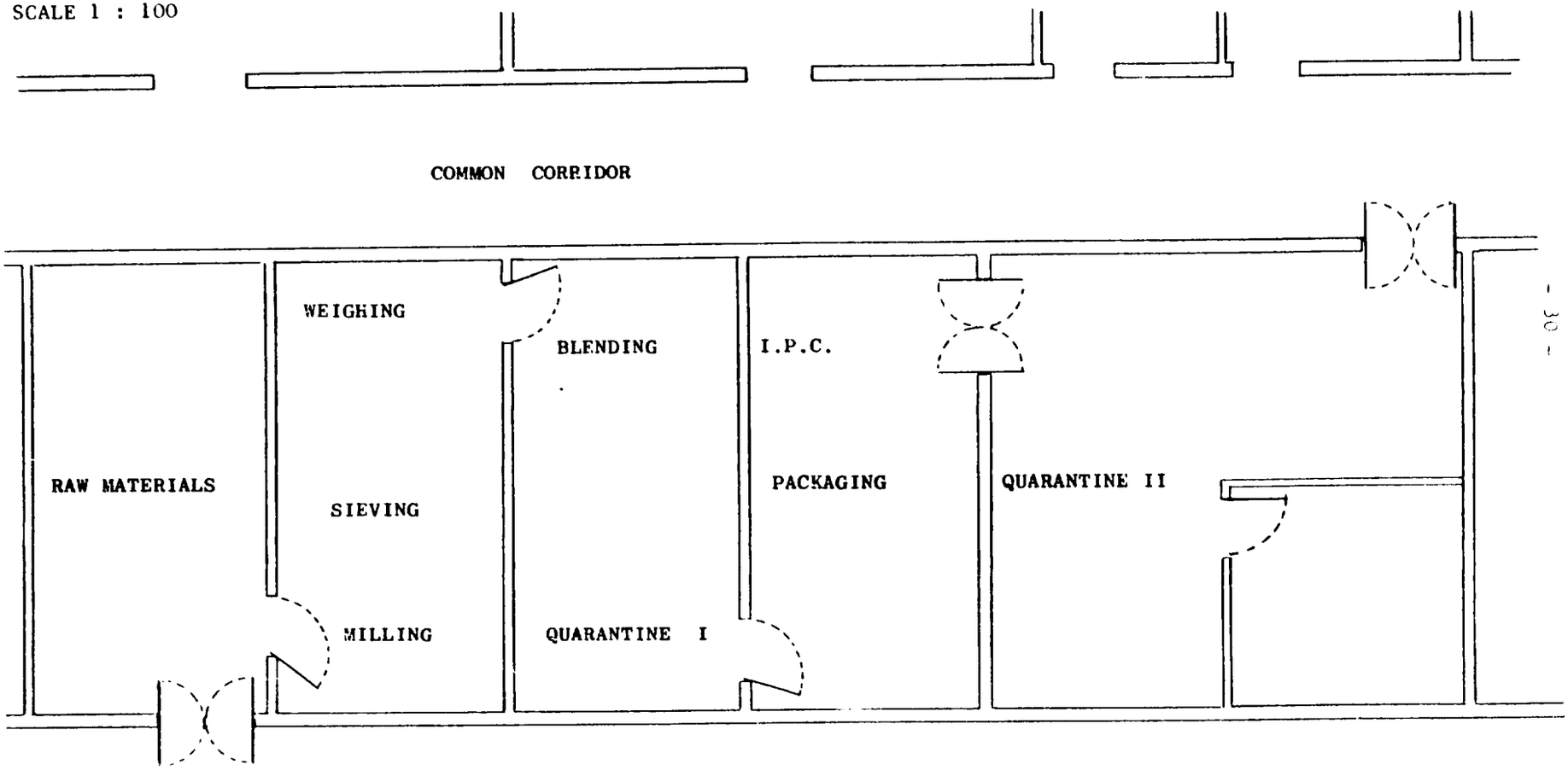
US/ZAM/82/137

ANNEX 3

ORS PROJECT : GPL

ORAL REHYDRATION SALTS : TEMPORARY BUILDING LAYOUT

SCALE 1 : 100



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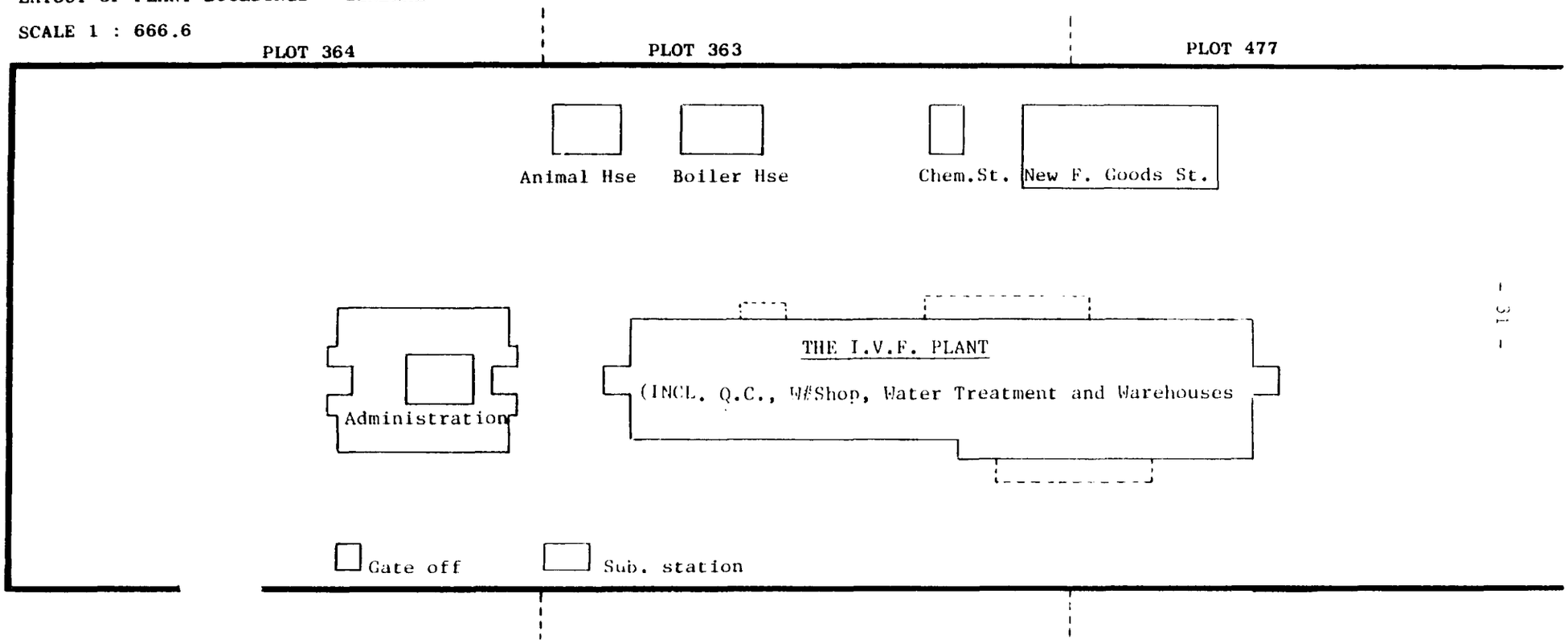
ORS PROJECT, GPL

LAYOUT OF PLANT BUILDINGS - GENERAL

SCALE 1 : 666.6

Annex 4



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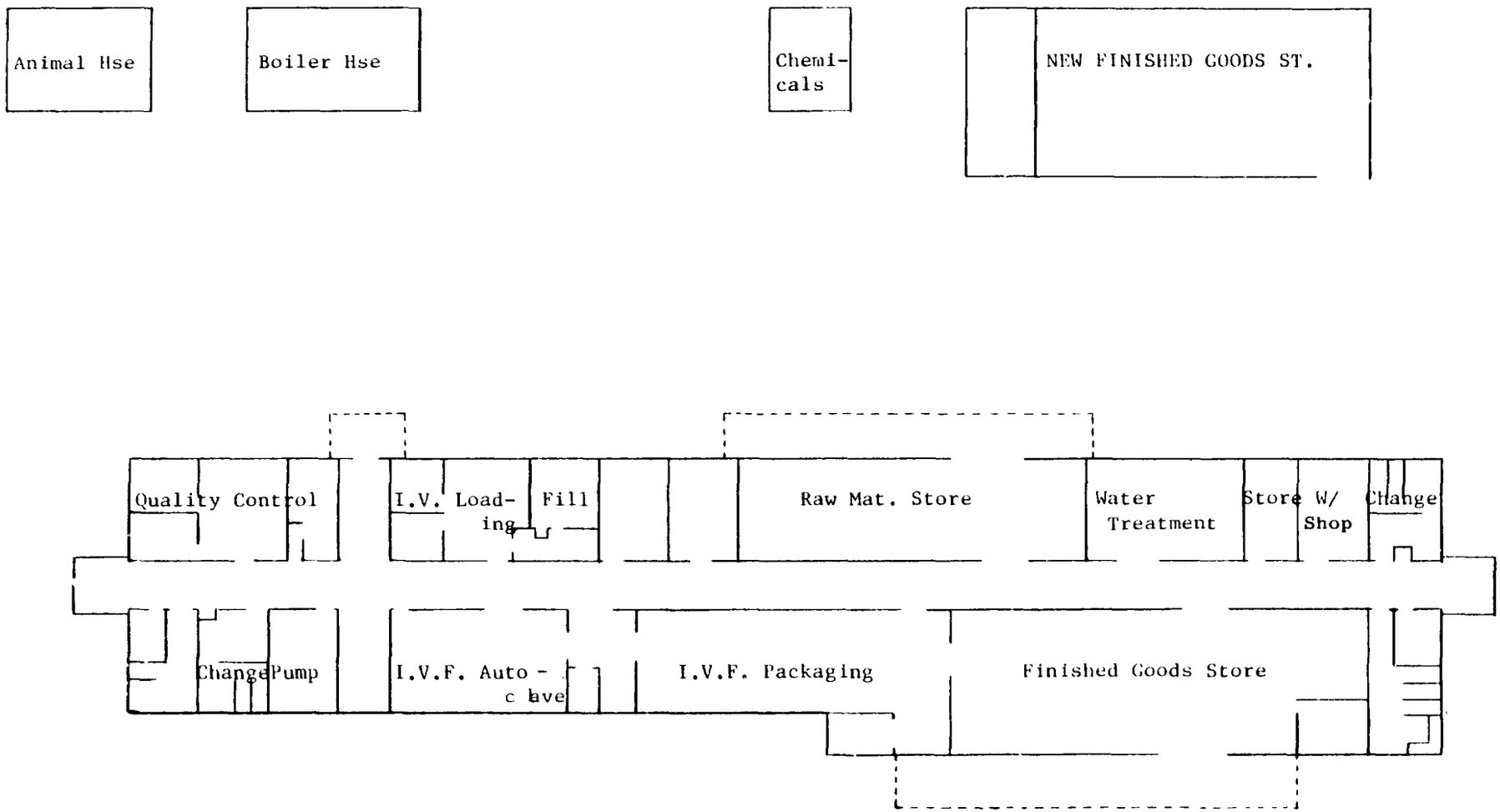
ORS PROJECT, GPL
OPERATIONAL LAYOUT - I.V. FLUIDS
SCALE 1 : 333.3

PLOT 363 | PLOT 477



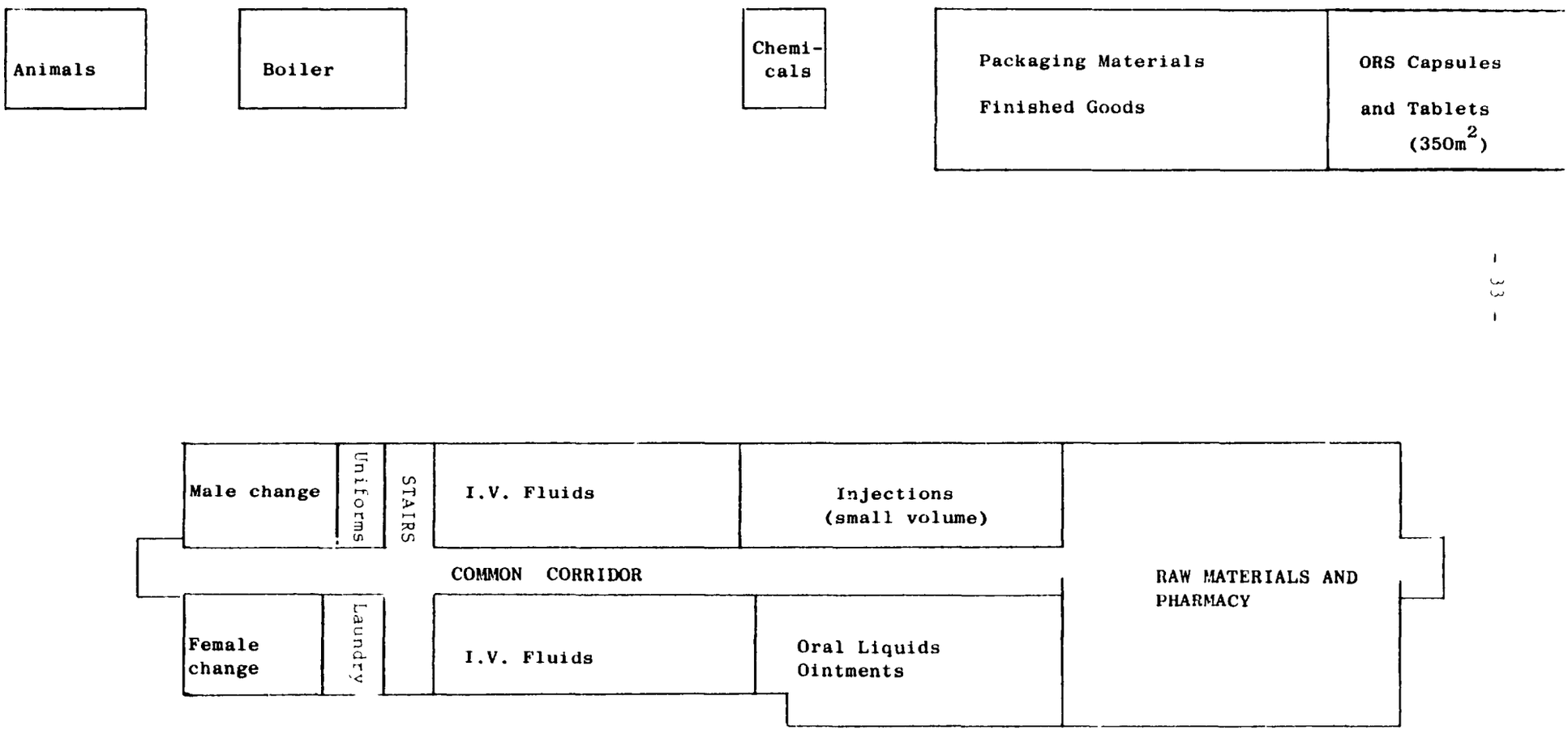
US/ZAM/82/137

ORS PROJECT, GPL

DIVERSIFICATION : PROPOSED BUILDING LAYOUT

SCALE : 1:333.3

Annex 6



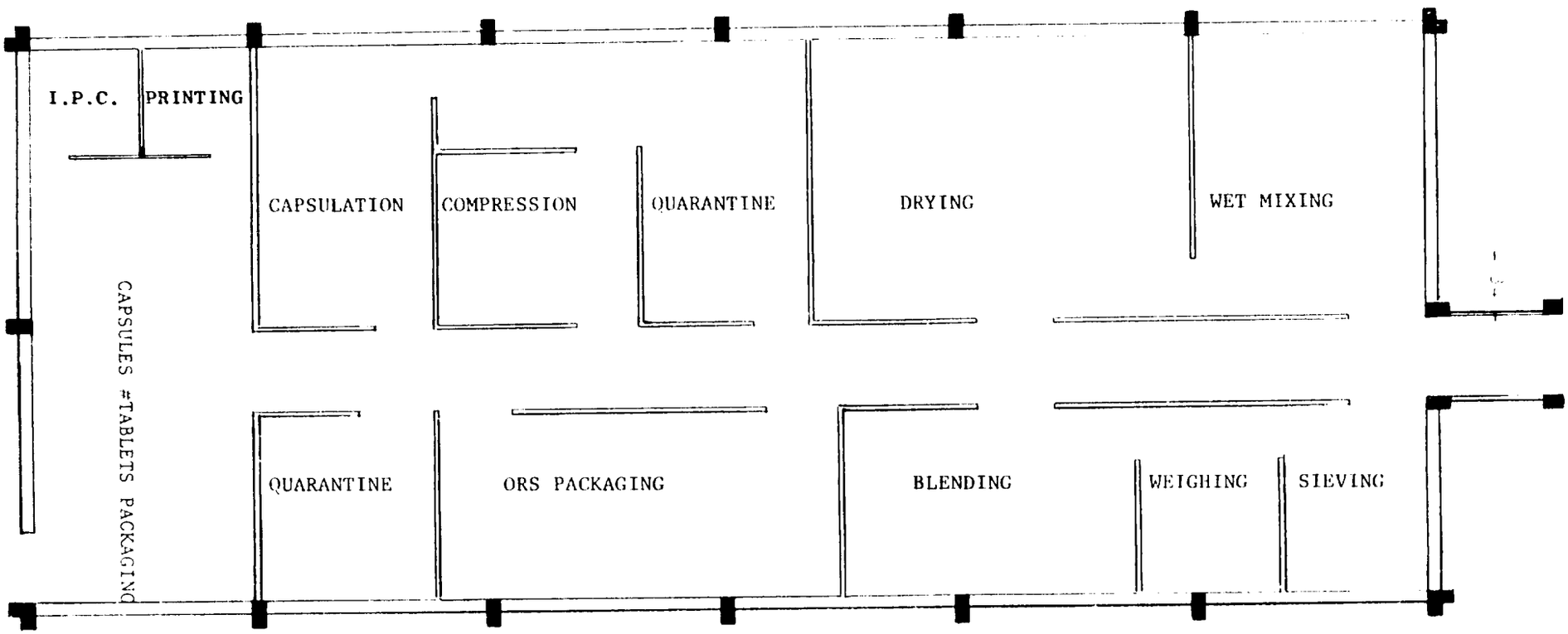
US/ZAM/82/137

ANNEX 7

ORS PROJECT, GPL

NON-STERILE DRY PRODUCTS
Proposal I : Conversion of New Finished Goods Store ground floor

Scale 1 : 100



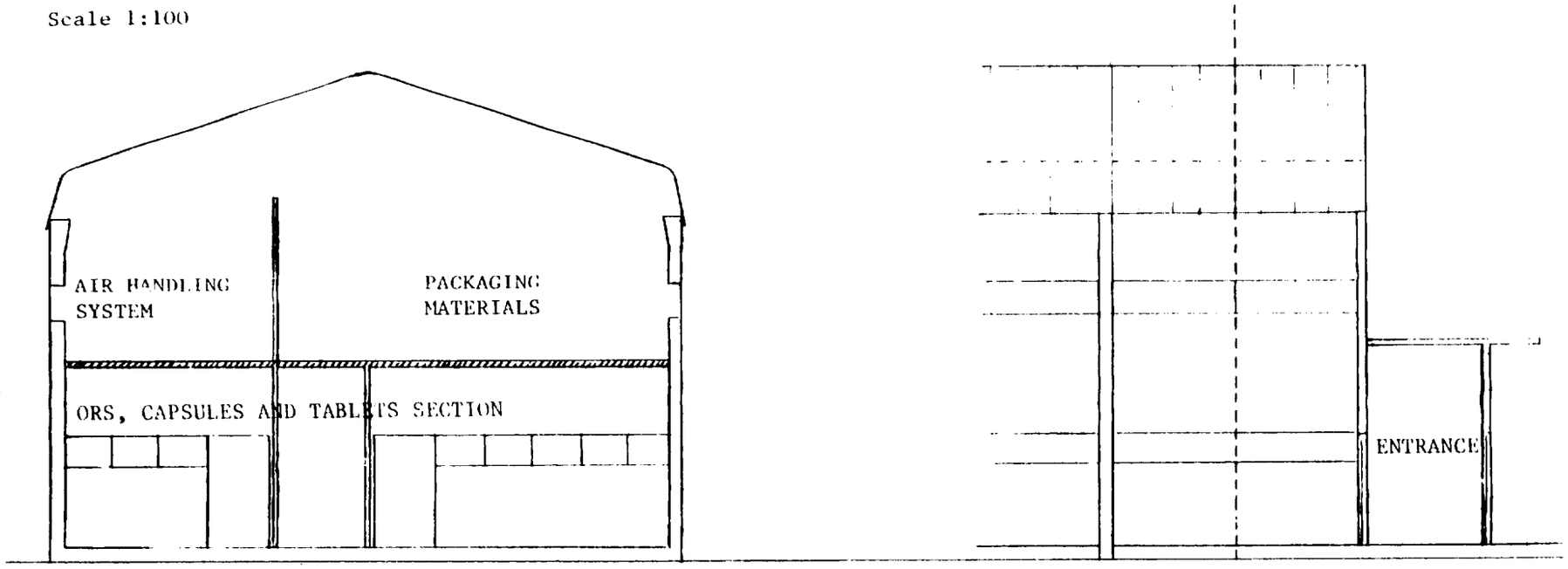
US /ZAM/82/137

ORS PROJECT, GPL

NEW WAREHOUSE

PROPOSAL I Section showing packaging materials storage provision on mezzanine floor

Scale 1:100



SECTION

SIDE ELEVATION

US/ZAM/82/137

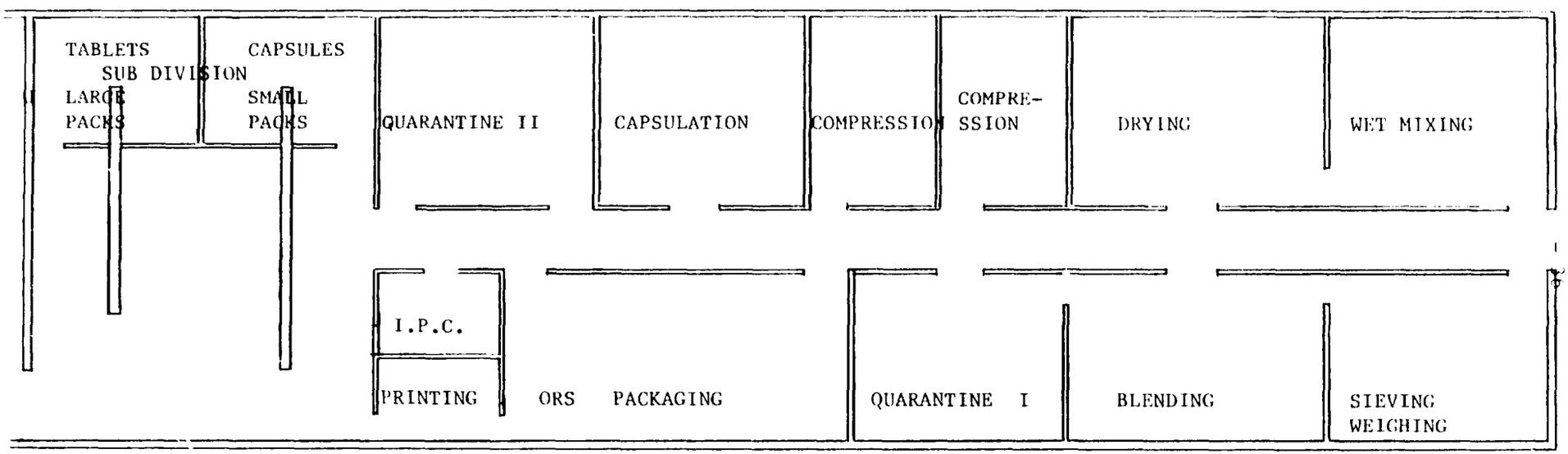
Annex - 9

ORS PROJECT, GPL

NON-STERILE DRY PRODUCTS

Proposal II : New Building

Scale 1:133.3

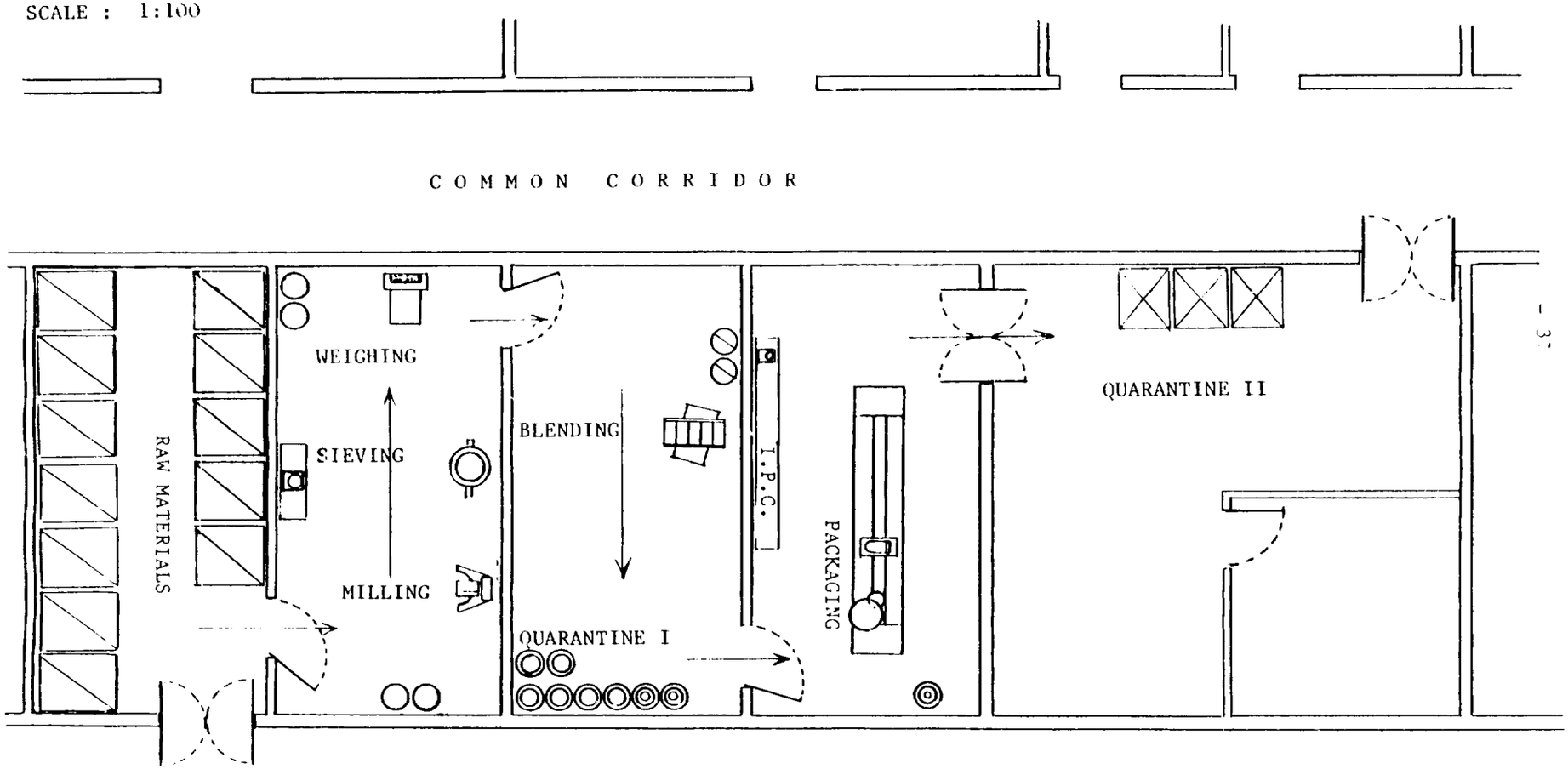


US/ZAM/82/137
ORS PROJECT, GPL

Annex 10

PRODUCTION UNIT : EQUIPMENT LAYOUT (Temporary)

SCALE : 1:100



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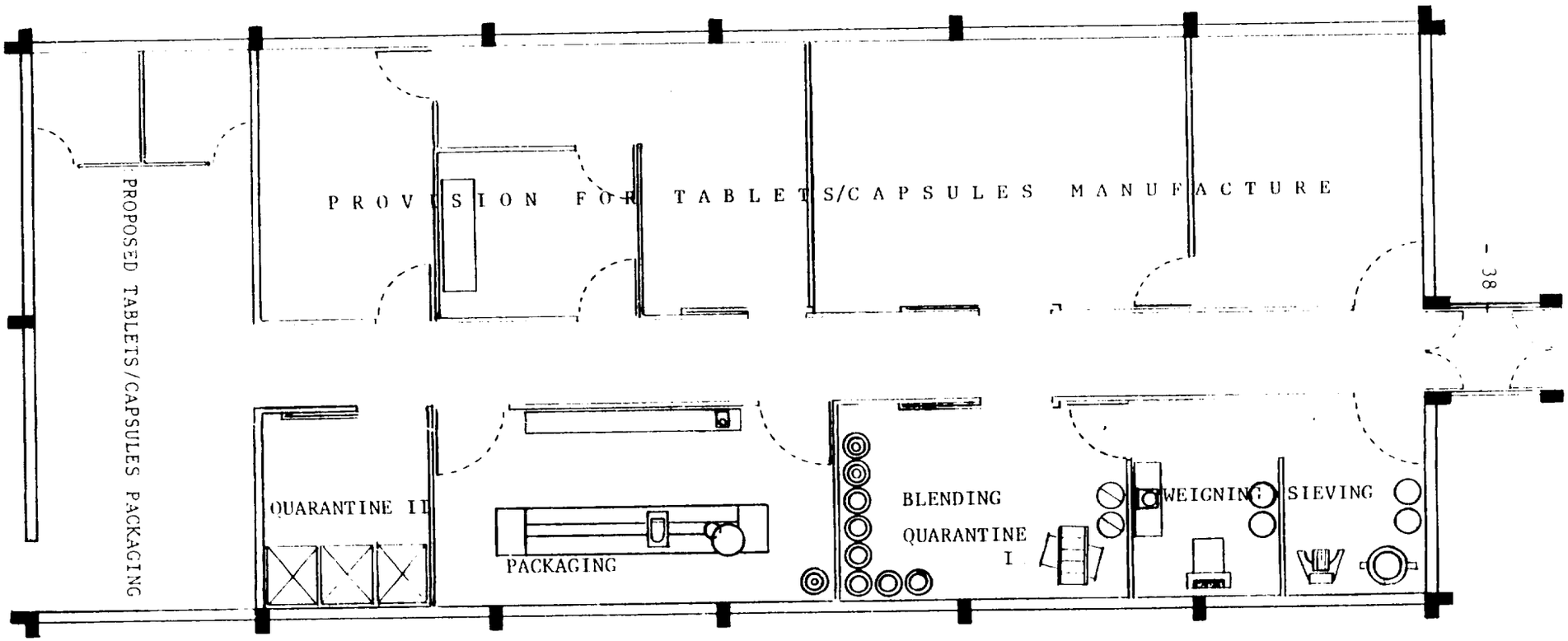
US/ZAM/82/137

Annex 11

ORS PROJECT, GPL

PRODUCTION UNIT: EQUIPMENT LAYOUT (Permanent)

SCALE : 1:100



PROCEDURE MANUAL

CONTENTS

SECTION I : GENERAL PLANT PROCEDURE

GPP	1	Personnel Health, Hygiene, Habits and Competence
GPP	2	Personnel Entrance, Movements and Exit
GPP	3	Housekeeping, Cleaning and Maintenance
GPP	4	Janitorial Services
GPP	5	Insects, Pests and Rodent Control
GPP	6	Operating Environments Maintenance
GPP	7	Machinery, Equipments, Fixtures and Furniture Maintenance
GPP	8	Maintenance and Control of Utilities and Supplies
GPP	9	General Material Handling and Transportation
GPP	10	Documentation
GPP	11	Assistance from Engineering
GPP	12	Assistance from Quality Control
GPP	13	Co-ordination with planning, Stores, Quality Control, Repair and maintenance, Administration and Finance

SECTION II : GENERAL MANUFACTURING PROCEDURES

GMP	1	Machine Cleaning and Set-up
GMP	2	Machine Trials, Start-up and Closing down
GMP	3	Machine Operation Control
GMP	4	In-Process Materials Identification, Handling and Staging
GMP	5	Packaging Materials Identification, Handling and Staging
GMP	6	Sampling

GMP 7 Washing, Cleaning and Maintenance of Ancillaries and Utensils

GMP 8 Washing, Drying and Sterilisation of Containers, Closures and Seals

GMP 9 Pre-washing of Reuseable Containers

GMP 10 Checking and Overprinting of Packaging Materials

GMP 11 Packaging Operations Practices

GMP 12 Sterile Area Techniques and Practices

GMP 13 Performance Monitoring and Follow-up

GMP 14 Direct Labour Control and Standard Manning

GMP 15 Machine Utilisation Control

SECTION III : PRODUCTION PROCEDURES

PP 1 Production Planning

PP 2 Standards for Batch Sizes, Processing and Packaging

PP 3 Material Request

PP 4 Material Receiving

PP 5 Product Manufacture

PP 6 Manufacturing Completion and Finished Product Transfer

PP 7 Yield and Line-Losses Computation

PP 8 Re-working of Recoverable rejects

PP 9 HandLing and Disposals of Total Rejects

PP 10 Production Documents Flow Monitoring

SECTION : IV MATERIAL PROCEDURES

MP	1	Procurement
MP	2	Re-Ordering
MP	3	Receiving and Storing
MP	4	Quality Control Release
MP	5	Issue for Manufacture
MP	6	Maintenance and Housekeeping
MP	7	Storage and Handling of Enflamable, Corrosive and Other Hazardous Materials
MP	8	Revalidation/Disposal of Old Stocks
MP	9	New Sources Exploration
MP	10	Disposal of Rejected Materials

SECTION V : QUALITY CONTROL PROCEDURES

QC	1	Raw Materials Specifications
QC	2	Packaging Materials Specifications
QC	3	Finished Products Specifications
QC	4	Sampling
QC	5	Work Scheduling and Assignment
QC	6	Analyses, Evaluation, Final Report Compilation and Distribution
QC	7	Warehouses Control
QC	8	Environmental Control
QC	9	In-Process Control
QC	10	General Plant Up-Keep Control
QC	11	Product Release Programme and Central Records
QC	12	Revalidation and Disposals

QC	13	New Products Development
QC	14	Products Behaviour Review, Complaints and Recalls
QC	15	New Sources of Materials Exploration
QC	16	Plant Technical Audit

SECTION VI : REPAIR AND MAINTENANCE PROCEDURE

RM	1	Job Request Receiving, Processing and Allocation
RM	2	Job Execution and Progress Follow-up
RM	3	Technical Performance Control
RM	4	Performance Monitoring and Review
RM	5	Emergency Job Handling
RM	6	Preventive Maintenance and Machine Performance Evaluation
RM	7	Overhauling and Re-conditioning of Machines
RM	8	Shift Work and Overtime Control
RM	9	R and M Stores
RM	10	Utilities and Services Planning and Monitoring
RM	11	General Plant Maintenance and Care-taking
RM	12	Liason with Other Workshops and Utilisation of Outside Services
RM	13	Supplies Receiving and Inspection

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

PROJECT PROPOSAL

PART A - BASIC DATA

COUNTRY/REGION	ZAMBIA
PROJECT NUMBER	SI /ZAM/85
PROJECT TITLE	Technical Assistance for commissioning and operation of the Oral Rehydration Salts production unit.
SCHEDULED START	Immediately after approval
SCHEDULED COMPLETION	6 months after approval
ORIGIN AND DATE OF OFFICIAL REQUEST	National Commission for Development Planning, Zambia
GOVERNMENT COUNTERPART AGENCY	INDECO, General Pharmaceuticals Limited, Kabwe, Zambia
UNIDO CONTRIBUTION	US$ 45,000
GOVERNMENT CONTRIBUTION	
CURRENCY REQUIRED	
FOR UNIDO INPUT	US$ 45,000
CONVERTIBLE	US$ 45,000
OTHERS	
UNIDO SUBSTANTIVE BACKSTOPPING SECTION	Pharmaceutical Industries Unit CHEM/DIO
PROGRAMME COMPONENT CODE	32.1.D.

PART B - NARRATIVE

1. OBJECTIVES

(a) Development Objective :

To improve the social health sector and promote primary health care programme by making ORS available to the population at a reasonable price.

(b) Immediate Objective:

To satisfy the country's needs in ORS through local manufacture and to promote its export to neighbouring countries.

2. SPECIAL CONSIDERATIONS N.A.

3. BACKGROUND AND JUSTIFICATION

Dehydration, caused by intense diarrhoea and vomiting associated with acute gastro-intestinal diseases is one of the most common causes of death amongst infants and young children in developing countries. Treatment for restoring the loss of fluids and essential body salts, however, is simple and economical and can be effectively used in all age groups. It constitutes oral administration of a glucose electrolyte solution, prepared simply by dissolving the contents of packets of oral rehydration salts (ORS) in specified volume of potable water, to the ailing person according to recommended regimen or thirst level.

Classified under non-prescription medicaments, the ORS packets can be safely used in distant rural areas as, unlike i.v. fluids, its administration does not require medical supervision or hospital care.

ORS is a dry powder composed of glucose and other salts essential for body fluids and as such it is fairly stable with reasonably long shelf life.

According to the studies carried out by WHO and UNICEF, the ORS has been successfully used for treatment of dehydration due to acute diarrhoea, including cholera, in all age groups. It is a pharmaceutical product of great value in developing countries and accordingly included in the WHO list of essential drugs.

Proposal for establishment of ORS production unit at GPL was made in 1981 after assessment of national requirement in consultation with the Ministry of Health, Republic of Zambia and preliminary economic evaluation of the unit towards cost of ORS and financial viability of the proposal.

The proposal was based on a production unit with a capacity of 625,000 packets annually - which has now been revised to 1,000,000 packets.

In the subsequent year the project could not take off mainly due to foreign exchange difficulties until in 1983 when UNICEF offered to provide sufficient foreign exchange cover to GPL against payment in Kwacha for purchase of equipment and initial supplies of raw and certain packaging materials, while technical assistance was made available through UNIDO technical assistance programme for a preparatory phase of six months.

Progress so far made towards project implementation is summarised below:

- Building design and equipment lay-out have been finalised for the temporary as well as permanent location for the production . The necessary civil work has been initiated and is expected to be complete by middle of November 1985.

- The production equipment has been received in the plant, has been inspected and is ready for installation.

- Standard packet size for ORS has been determined and approved by the authorities.

- Packaging specifications have been finalised and most of the supplies have been procured. Remaining packaging material is scheduled to be delivered in the plant by the end of September 1985.

- Raw material for one years production has been procured and delivered to the plant.

- Costing of the ORS packets has been worked out in detail and comes out to be favourably competitive with the commercial supplies available in the market.

- Preparation for installation of equipment and commissioning of production have been completed.

- Preparations of relevant technical manuals and standard documentation systems is in progress at this stage.

- Exploration of sources of raw and packaging materials within the country has been initiated and formulation plans propased.

4. PROJECT OUTPUTS

- Installation of equipment and commissioning of oral rehydration salts' production unit with a capacity of 1.00 million packets annually.

- Carrying out trial runs, scaling up and commercial production of oral rehydration salts.

- Development, implementation and standardization of manufacturing and quality assurance procedures.

- Training of local personnel in production technology, quality assurance, plant maintenance, production and cost control and production planning and management.

- Development of plant operations procedure and manufacturing control documentation system.

- Carrying out preliminary studies towards extent of diversification possibilities within the present location of the plant.

5. PROJECT ACTIVITIES

(a) Assistance in installation of the equipment, incorporating streamlined process-flow to ensure implementation of good manufacturing practices.	1st month
(b) Guidance in installation of necessary environmental maintenance services in the O.R.S. unit.	1st month
(c) Assistance in start-up of equipment, trial runs and scaling-up of production to commercial levels.	2nd month
(d) Implementation of training programme towards: capabilities development in planning, warehousing, production, quality control	
Plant and equipment maintenance systems	
Process monitoring and operations controls.	1st and 2nd month
(e) Assistance in development of concepts related to cost controls, quality maintenance and product stability	3rd month
(f) Finalization of an action plan for gradual substitution of imported raw materials with materials of local source as far as possible	4th and 6th months
(g) Compilation of a manual of operating procedures for all functions of the plant.	1st and 4th months
(h) Formalization of a documentation system for maintenance of manufacturing history records	1st and 4th months
(i) Preparation of a final report in light of the findings of the mission and the results obtained and make recommendations to the government on further action which might be beneficial for the project and future diversification programme.	6th months

6. PROJECT INPUTS

(a) Government inputs

National staff

- The General Manager of General Pharmaceuticals Limited will serve as counterpart to UNIDO expert.
- Services of secretary, office facilities and transportation will be provided to UNIDO expert for the duration of the mission.

(b) UNIDO Inputs

11-51	International expert in pharmaceutical industry	6 m/m	44,400
51-00	Sundries and preparation of final report		600
		TOTAL	45,000

7. EVALUATION

A terminal self-evaluation exercise will be required for this project in accordance with the requirements of UNIDO's internal evaluation systems, preferably at completion of project operations.

8. ENVISAGED FOLLOW-UP

Follow-up activities will be taken-up in accordance with the government's plan to develop and diversify the pharmaceutical industry in Zambia.