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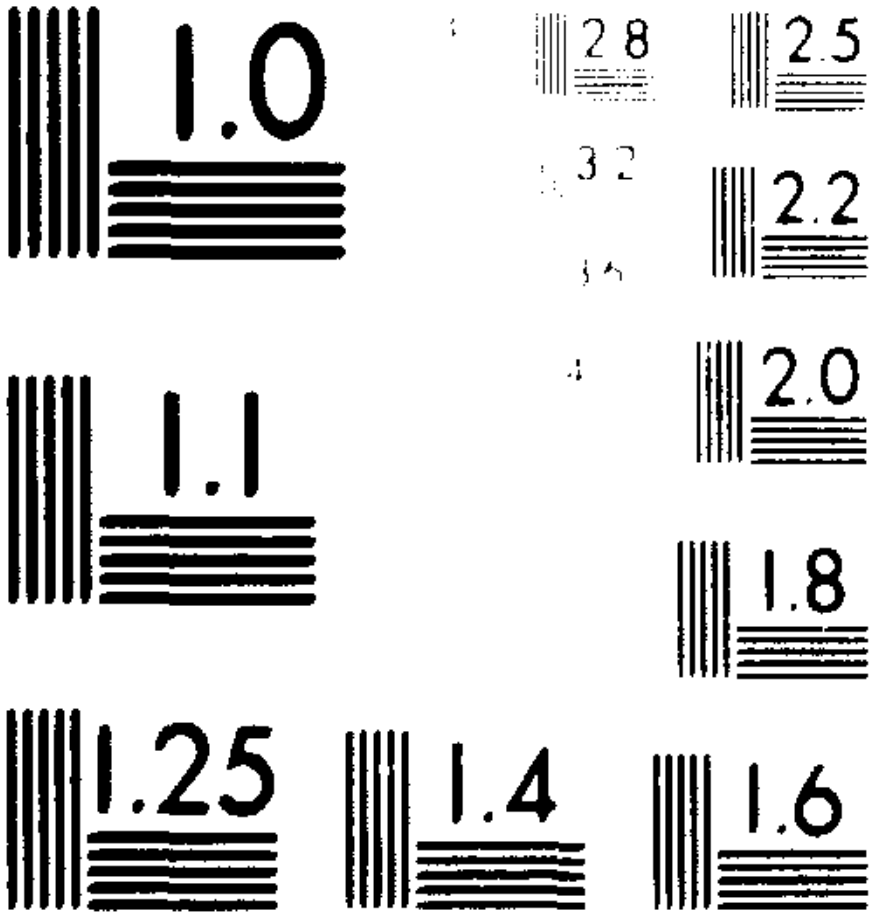

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UNITED NATIONS
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Cameroon.

PRODUCTION OF INTRAVENOUS INFUSIONS (LOCAL PRODUCTION OF PHARMACEUTICAL PRODUCTS)

UC/CMR/80/206

UNITED REPUBLIC OF CAMEROON

Technical Report *

Prepared for the Government of Cameroon

by the United Nations Industrial Development Organization

Based on the work of Riaz Ahmed Khan, Pharmaceutical Expert

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CONTENTS

I INTRODUCTION

1. The United Republic of Cameroon in West Africa, with an area of 475,000 square kilometres, has a population of about 8,500,000. The country produces coffee, cocoa, rubber, bauxite, timber and oil, and exports several of these commodities. It has 159 hospitals, large and small and 380 dispensaries. The number of qualified pharmacists is 102. The financial allocation for public health rose from CFA 3,827,000,000F equivalent to about US dollars 42 millions (CFA 330 = 1 US $) to CFA 17,445,000,000 eq. to US dollars 53 millions in 1982-83 budget, an increase of 35.4%. The allocation for Public Health in the current budget accounts for 7.6% of the National Budget. Major diseases encountered in Cameroon are malaria, helminthiasis, abdominal disorders, respiratory ailments and other diseases of bacterial and parasitical origins. Medical treatment to the general population is given in Government hospitals. This is supplemented through private clinics and church organisations. The Government of Cameroon, since independence has been aiming at providing free medical service (including drugs) to the whole population and is acutely aware of the problem of supplying pharmaceuticals in the promotion of health of its people.

2. The expenditure on pharmaceuticals and other medical supplies rose from about 750,000,000 F in 1975-76 to about CFA 1,000,000,000 F in 1980-81. The budget allocation, on this accout was CFA 1,500,000,000 F in 1981-82 and included other medical supplies like X ray films etc. In the current budget (1982-83) the allocation has been raised to CFA 2,500,000,000 F equivalent to about US $7,500,000 for drugs and pharmaceuticals alone. This shows the importance attached by the Government in its policy of providing an ample supply of drugs. Drugs for the state sector are purchased by the Central Pharmacy and distributed through hospitals and dispensaries. In the private sector, the wholesale druggists supply to retail pharmacies in the main cities. The state sector accounts for 80% of the total drug distribution. At present all drugs are imported through Douala, the main sea-

port and the only international airport. This sometimes results in delays in supplies and consequent shortages of drugs.

3. The need for a local pharmaceutical industry has been keenly felt in the country. The Government in the current Fifth Five Year Plan lays special stress on this subject and states:-

"Considering the diversity and great potential of our medicinal plants, it has become imperative and urgent to create:

1. A pharmaceutical industry in Cameroon, to manufacture basic essential products such as:- heavy aqueous solutions, disinfectants, dressing materials and vaccines. The creation of such an institution will be followed by the training of a qualified team of pharmacists and technicians.
2. A national laboratory for controlling both imported and locally produced drugs.

4. With the above objectives, the Government has sought the assistance of UNIDO for the development of indigenous medicinal plants for which a project is already in existence. Another UNIDO project for the manufacture of sera and vaccines is also making a steady progress. In line with the same strategy, the Government asked UNIDO assistance for a study to be undertaken for the manufacture of Intravenous infusions and also for the local production of drugs. A short term mission was therefore undertaken for this purpose.

5. The assignment was therefore divided in two parts for the preparation of:-

Part I A study for the production of intravenous infusions

PART II A plan for local production of drugs

II CHAPTER I - PRODUCTION OF INTRAVENOUS INFUSIONS

1. TECHNOLOGY EMPLOYED

1.1 The technology employed in the manufacture of intravenous infusions may appear to be a simple one, but in its details,

particularly those of its operations, extreme care is to be exercised and numerous precautions observed. Briefly, the process is in the following stages:

a) Preparation of Water for Injection:

The raw water is pre-filtered through a sand - or charcoal-filter, followed by demineralisation through resins in De-ionisers, the capacity of which is determined on the basis of the analysis report on raw water. The demineralised water is then led into a Water Distillation Still of Thermo-compression type, which is capable of producing distilled water to stringent standards of being pyrogen-free

b) Preparation of Solution

The raw materials are weighed accurately and added to a pre-run of distilled water in stainless steel tank or tanks where vigorous stirring is done to dissolve the ingredients completely to form clear solutions. Heat is also applied through heating coils or through steam - jacketting, where higher than normal temperatures are required for dissolving the raw materials. The solutions are then pumped through a suitable filter unit to the Filling Room.

c) Filling

The solution is filled through gravity and/or pressure in the required fixed volumes through Filling Machines mounted on tables and enclosed in Laminar-Flow hoods in order to keep out bacterial contamination. This is followed by putting seals or plugs on containers or bags. The filled volumes are checked through weighing of containers from time to time and adjustments made in the fitting machines accordingly. The bags or containers are suitably overprinted with batch numbers.

d) Sterilisation:

i) The filled containers are placed in stainless steel trays and loaded on the trolleys to be transported to the Steri-lisation Room. The trays are transferred to an Autoclave or Autoclaves to be sterilised at 115-116°C for PVC bags or at 121°C for polypropylene flacons for the requisite time of sterilisation.

Both single-door and double-door autoclaves can be utilised, the former being more economical than the latter. It is not absolutely essential to use double-door autoclaves in this process which are needed mostly where the exit of the sterilised material is in an aseptic or sterile area. The sterilisation of intravenous infusions is of a terminal nature and as such the bags, after sterilisation are passed directly for further packaging, for which only a clean area is required. However, in order to prevent mix-up, double-door autoclaves are preferred.

ii) The autoclaves are made of high quality materials and are fitted with precision monitoring devices for inside temperature and pressure measurements and they have built-in air or other cooling system, to be used when sterilisation is completed. The containers, when loaded inside the autoclaves carry chemical and bacteriological indicators to verify the efficiency of sterilisation inside the entire area of the autoclave.

e) Inspection and Packaging

The containers, after sterilisation, are re-loaded on to the trolleys and transferred for inspection and packaging. The inspection is done to detect particulate matter in the containers or bags against the background of polarised light. After inspection, each bag is wrapped with an outer polythene or other type of bag and sealed. If the containers or bags are blank, they are overprinted with requisite product details. The finished products can then be packed in cartons ready for delivery.

f) Quality Control and Good Manufacturing Practices:

The importance of Quality Control and the need to employ and maintain Good Manufacturing Practices in the manufacture of intravenous infusion cannot be over emphasized. A Quality Control Laboratory, responsible for testing samples at all stages, contains three sections, one each for Chemical Analysis, Bacteriological Control, and Pyrogen Testing including an Animal House.

The equipment required is of international standards and specifications. Good Manufacturing Practice (GMP) not only include basic good housekeeping in the Plant operations, but encompasses the entire activities of the Plant from the start of the receipt of the raw and packing materials to the completion of the finished products. The production operations and methods of quality control are monitored by the procedures laid down in GMP as also the regulations for clean and sanitary conditions in Stores and warehouses. A system of documentation relating to receipt of incoming goods and sale of finished products, production methods and procedures and quality control systems including in-production controls is also prescribed under the GMP Guide.

1.2 Intravenous infusions are used in the hospital in two pack sizes, 500 ml and 250 ml in glass bottles, polyethylene or polypropylene flacons or PVC bags. PLANTECAM in Cameroon produces in polythylene flacons. The entire technology of production is planned on the basis of whether glass, polyethylene, polypropylene or PVC will be used for filling the solutions. Glass bottles are losing favour as they are heavy to handle with the attendant high risk of breakages and the doubt on the compatibility of glass with all types of infusions. Polyethylene may also be ruled out as the sterilisation temperature is 105°C, which is too low for effective sterilisation of the product. This leaves the choice between polypropylene and PVC, where the sterilisation temperatures are within the pharmacopeial requirements for this purpose. Both materials are light-weight and unbreakable, and have been found to be compatible with the infusions in normal use.

1.3 PVC bags are in use in most developing countries and also in the United States and countries of Europe. The technology is usually a semi-automatic one which makes the production more amenable to conditions in the developing countries. However, the production of empty PVC bags is uneconomic in quantities required in small output projects like the present one. PVC bags can only be obtained

from sources which supply the complete technology for the project including equipment for filling and sterilisation etc. The project based on PVC is relatively more economic for the small outputs, but suffers from the disadvantage that PVC bags have to be imported.

1.4 The alternative packing materials are polyethylene and polypropylene, where the technology is different from that used in PVC. The main advantages of polypropylene is that the bags or flacons are more rigid, and the automatic production of bags is from granules, which form the raw material for the flacons. The blow moulding equipment can be run alongside the other operations. One disadvantage encountered is the difficulty of obtaining a proper seal on the containers and frequent complaints of leakage of solution have been reported. The blow moulding equipment can be run alongside the other operations. One disadvantage encountered is the difficulty of obtaining a proper seal on the containers is the difficulty of obttaining a proper seal on the containers and frequent complaints of leakage of solution have been reported. The overall cost of equipment, building, etc are slightly higher than in the PVC - based project. Details of building and equipment for use of polypropylene and PVC are described in this report.

2. REQUIREMENTS

The country's requirements have been worked out on the basis of purchase of intravenous infusions by the Government for supply to the state hospitals, and by importers/wholesalers to private pharmacies. The former has accounted for 500,000 or bags and latter about 200, 000 making a total of 700,000 units. A meeting with the Surgeon at the Central Hospital and the Pharmacist-in-Charge of the University Hospital Teaching Centre revealed that the true requirements were in excess of what is supplied at present. An initial production programme of 850,000 units has therefore been proposed, out of a planned capacity of 1,000,000 units in one working shift, and is presented in appendix I/3 together with estimates of raw and packing materials required, including prices where available. Future production programme is also indicated.

3. LOCATION AND SPACE

3.1 The project has been initiated by Institute des Recherches Medicales et d'Etudes des Plantes Medicinales (IMPM) which is a part of Delegation General a la Recherche Scientifique et Technique (DGRST). In the plans formulated by DGRST and IMPM, the production of intravenous infusions will be placed in the same area where their other projects will be located. The selected site for a Medical Research Institute, Production of Sera and Vaccine and Production of Intravenous Infusions, will be at Nkomo, 10 kilometres from the centre of Yaounde. The site at present consists of undeveloped hilly land. After completion of land development, utilities common to the three projects will be situated at this site. These include the provision of piped supply of water, setting up of a sub-station for electricity supply, installation of an Air Handling Unit and other amenities common to the three projects.

3.2 It is assumed that the ground at the site will be suitably levelled to accommodate a total of 1150 m^2 or 1250 m^2 of built-up area. The architect will have to decide if the building areas should be on one floor or more depending on the contours of land and the plan he wishes to make. In Appendix I/1a, a line-diagram is presented, which shows the location of a Main Block as envisaged earlier during the assignment to accommodate administration, production, quality control and warehouses and the activities connected with them. The four small blocks are for boiler house and workshop, inflammables' store, pyrogen laboratory and a compressor room. The purpose of each block is indicated by alphabets and the rooms by numbers and presented with dimensions in Appendix I/1b. The Administration room can be sub-divided suitably to accommodate management and accounts. In case, the polypropylene based project is selected, requisite extra space can be provided by the architect through suitable alternation of the design.

3.3 The construction cost has been calculated on the basis of CFA 200,000 per m^2, as advised by the Government. To the required area of 1150/1250 m^2 which includes 3 m wide corridors in Main Block, extra allowance has been made for wall space, whose details will be determined. The height of the walls may be 3 m, but the warehouses may require ceilings of 4 m height. Similarly, the exact sizes and placement of doors and windows will also be designed by the architect. The location of various blocks and rooms in the plan and their dimensions will also be given by the architect, as the present line-diagram shows what is required from the technical view point. The architect, should have full liberty to make minor changes for convenience of construction. The detailed building estimates are shown in Appendix I/10 which amounts to CFA 253,000,000, F equivalent to US dollars 767,000. This estimate includes a 10% overage for cost of incidental miscellaneous items.

4. EQUIPMENT

4.1 The requirements of equipment are based on the technology used for production in PVC OZ polypropylene bags. The list of equipment with prices, divided in each operation and a cumulative total are presented in Appendix I/2a. The names and addresses of prospective suppliers are given in Appendix I/2b. The justification for choice of equipment, where such justification is called for, is given in the following sub-paras. The total cost of equipment is projected as US $ 510,000 = CFA 168,300,000 F for PVC and US $ 627,000 = CFA 207,000,000 F for Polypropylene project.

4.2 A sand-filter for pre-filteration of raw water is chosen, because its price was readily available. An alternative charcoal-filter can be used. One de-ioniser plant is selected, as the analytical report on water supply in Yaounde (Appendix I/2c) shows that the raw water does not show excessive hardness and one de-ioniser will be sufficient for demineralisation. The mixing tanks are to be provided with heating coils, as steam-jacketted tanks are very expensive. The built-in cooling system is more practical than a separate

unit for the purpose. Another similar autoclave can be added in the event of increase in production and requisite space is provided in the Sterilisation Room. The equipment for the Control Laboratory does not include a Flame Photometer, as the production of solutions containing a mixture of sodium chloride and potassium chloride is not visualised at present. If the production of Ringers Solution or Lactated Ringers Solution is programmed in future, the Flame Photometer will be required. In addition, a Visible-UV range Spectrophotometer may also be needed.

5. PERSONNEL AND TRAINING

The requirements of personnel (Appendix 1/4) have been worked out in consultation with the Government counter-parts, taking in consideration the personnel policies of the Government. The necessity of training of the senior personnel was emphasised, particularly for the Head of the Unit, Production-in-Charge, Control Laboratory-in-charge and Plant Engineer. The details of a training programme for each activity are as follows:-

a) Head of Unit:- General Management, including aspects of business policy and administration, finance, personnel and pharmaceutical technology as applicable to operations in the production of intravenous infusions.

b) Production-in-Charge:- Pharmaceutical technology as applied to production of intravenous infusions including detailed study of microbiology in relation to operations in clean aseptic conditions, theory and practice of water purification and sterilisation including monitoring and in-process control, management of stores and warehouse, record-keeping, personnel policies and the enforcement of GMP Guide.

c) Control Laboratory-in-Charge:- Basic knowledge of theory and practice of analytical methods, procedures and techniques in use in pharmaceutical industry, with special emphasis on analysis, control and monitoring of water treatment, microbiological aspects, sterilisation, decision-making for acceptance, collaboration with production and plant maintenance in trouble-shooting in process

and production difficulties, general laboratory management and overseeing the enforcement of GMP Guide.

d) Plant Engineer:- Basic knowledge of mechanical and electrical engineering (with special reference to electronics for precision control instrumentation) in installation, maintenance and reparis of the equipment and machinery with defined schedules and procedures for these purposes, management of workshop and spare stores, and specialised knowledge of sterilisation, clean air procedures and water treatment.

6. PLANTECAM/MEDICAM

This factory was visited and its organization structure, production techniques, installed and utilised capacities were studied. It appears that PLANTEGAM with an investment of CFA 255,000,000 F started construction in 1977 and went into production in 1979 with an installed capacity of 1,000,000 polyethylene flacons, the present output being 700,000 flacons. The main disadvantage of this plant is that they produce polyethylene flacons, where the sterilisation temperature is 105°C, much lower than that prescribed in internationally accepted pharmacopeias. The factory uses the automatic "Bottle Pack", but does not appear to be free from technical problems. As PLANTECAM is a private company owned wholly by a private foreign group, the Government did not appear willing to reply on this enterprise and would like to undertake the establishment of its own factory.

7. RECOMMENDATIONS FOR IMPLEMENTATION

The following recommendations are made for implementation of the project for the production of intravenous infusions:-

a) The implementation of the Project ma be undertaken in the following manner after requisite financial sanction is available:-

i) the entire work i.e., erection of buildings, ordering the equipment and its installation, training of personnel, etc. is undertaken by Government personnel, or

ii) assistance is obtained from international or bilateral sources through consultants, or

iii) as is advisable in a project of this nature, through a turn-key or sub-contract basis, after making contract specifications and inviting tenders from reputable organisations or companies for both types of the projects i.e. using PVC bags or polypropylene flacons for filling intravenous infusions. The participation of UNDP/UNIDO may be sought on a cost sharing basis in the above task.

b) Assistance may be requested if so desired, from UNDP/UNIDO or other international/bilateral agencies for obtaining training abraod provided it is decided not to include the training programme in the contract specifications, for the following personnel for the period indicated against each

(i)	Head of Unit	3 m/m
(ii)	Production-in-Charge	5 m/m
(iii)	Control Laboratory-in-Charge	4 m/m
(iv)	Plant Engineer	3 m/m

For obvious reasons, the above personnel will need to be trained with the organisation or company, which is awarded the contract.

III. CHAPTER II - LOCAL PRODUCTION OF PHARMACEUTICAL PRODUCTS

1. GENERAL

1.1 As described in the earlier part of the Report, the budget allocation exclusively for drugs in Cameroon has risen to CFA 2500,000,000 F (equivalent to about US dollars 7.5 millions) for the current year, from CFA 1,500,000,000 F in the previous year for drugs and medical supplies. The procurement of drugs is done by Central Pharmacy, which is a part of the Sub-Directorate of Pharmacy in the Ministry of Health. The system involves tendering for imports on an annual basis, and meeting the shortfalls by local purchase from private whole-salers. With the increased budget, the system of drug procurement is in the process of review, with the Government wishing to rely more on its direct procurement. It is intended to do this both by imports and supply from local production. As Cameroon does not have a pharmaceutical industry of its own, planning for urgent and essential supplies, particularly for hospitals is subject to shortages. The Central Pharmacy, therefore, feels a great necessity to have at its disposal means of quick availability. For this purpose, it has been considered essential to set up requisite production facilities whereby essential and large consumption items can be produced on a regular basis, and kept in ready stock for distribution. A list of such items has been prepared in the Central Pharmacy.

1.2 Cameroon does not at present have a pharmaceutical quality control laboratory, which is an essential requirement for the development of a reliable drug supply system. The establishment of a local unit for production of drugs, will include the setting up of a quality control laboratory. This will give a start to the testing not only of drugs produced in the unit, but also of a number of imported products.

1.3 In the light of the above the Government is keen to make a start towards the establishment of a pharmaceutical industry. A project has therefore been proposed divided in two phases as follows:-

Phase I : Production of anti-septic liquids (disinfectants), syrups, ointments and creams, and suppositories and establishment of Quality Control Laboratory for the above products.

Phase II : Expansion in the products of Phase I, production of tablets, capsules and oral rehydration salts, and enlargement of the Quality Control Laboratory for this purpose.

1.4 A plan has therefore been prepared for situating Phase I in the existing old laboratory area adjacent to the office of of the Pharmacist-in-Charge of the Central Pharmacy. A programme for the initial operation of Phase I has been drawn up in Appendix II/2 for the production of the following types of products:-

a)	Syrups	100,000 litres
b)	Antiseptic liquids	100,000 litres
c)	Ointments and creams	1,000 kilograms
d)	Suppositories	500,000

The plan of premises, list of equipment and other details have been worked out to cater for the above Phase I programme. For Phase II, new premises will be required, to which the equipment for Phase I will be transfered and items for Phase II will be made and expansion of the Quality Control Laboratory undertaken. The details of Phase II will be worked out, after Phase I has been in operation for at least one year.

2. LOCATION AND SPACE

2.1 The Unit will be located in the existing laboratories (not in use) in the Central Pharmacy. A line diagram has been proposed for the various functions of the Unit and can be seen as

Appendix II/1. The total area including the main hall, rooms and annexe is approximately 300 m^2, which would contain the production rooms, reserve stores, packaging and a quality control laboratory.

2.2 The structure is an old one and will need extensive renovation and some repairs. The floors need to have new tiles where they are missing or broken, the wall and ceilings to be scrapped and redecorated with oil or emulsion paint. The existing windows will need protective cover to exclude dust, as also the main doors. In fact, the main door opening out on the verandah adjacent to the road, may need to be blocked with sealed glass or perspex. All rooms will require the fitting of exhaut fans. The entire area requires to be air-conditioned.

3. The production areas will need to be partitioned as indicated in the diagram. Air-conditioning will necessarily be required in the ointment and suppositories section. The room at the entrance can be used for labelling of cartons or bulk containers before despatch. The small stores area will be used for holding raw materials and packing materials in accordance with weekly production programme. It also keep on a temporary basis, finished products before despatch to the main stores. Therefore, a Main Stores Area will be required for keeping incoming bulk raw and packing materials and outgoing finished products.

4. The Quality Control Laboratory will be partitioned to house Chemical Laboratory and an Instrument Room. The latter will be used for keeping the sensitive Balances, Spectrophotometer, Polarimeter etc. The existing benches will be repaired and renovated. The laboratory will also require air-conditioning.

4. Equipment

A list of equipment with prices for production and quality control has been prepared and is shown in Appendix II/3a. The prices are purely on an ad-hoc basis and may need to be amended

amended as a result of actual enquiries to be made from the suppliers, whose names and addresses are given in Appendix I/2b. A list of reference books is presented in Appendix II/3b.

5. PLAN OF PRODUCTION

1. A production programme has been drawn up for the first year, this can be modified in terms of actual requirements at the time of start of production. The formulae and methods of production can be obtained from standard reference pharmacopieas and codex, included in the list of books. Further assistance, if needed, can be given by correspondence. A list of raw materials with an approximate price is given in Appendix II/3c.

6. PERSONNEL AND TRAINING

6.1 The following personnel will be required for this unit

(a) Production

i) Head of the Unit, a Pharmacist, who will also be responsible for the Production Sections.

ii) Two Pharmacy Technicians, one for Syrup Section and the other for the rest of the Production Sections.

iii) Three semi-skilled workers, one for each Production Section.

iv) Three unskilled workers, for cleaning and other heavy jobs.

(b) Quality Control Laboratory

i) Head of the Laboratory, a Pharmacist or Analytical Chemist.

ii) Two technicians.

iii) One unskilled worker for cleaning and other jobs.

The Heads of Production and Quality Control will require training abroad for a period of 3 months each.

The total complement of personnel will be 13 persons.

7. RECOMMENDATIONS:

The following recommendations are made for the implementation of the Project:-

a) Approval for Government funds for Phase I be obtained from the Government CFA 52,000,000 F (equivalent to about US $157,600) for equipment, which may be obtained on a cost-sharing basis from UNIDO, or another agency or directly by the Government.

b) Repairs, partitions and redecoration of the existing premises be commenced in accordance with suggestions made earlier in this Chapter.

c) The training programme for the senior personnel be initiated, and assistance may be sought from UNDP/UNIDO or bilateral agencies for placement of the trainees in suitable factories or institutions abroad, preferably in developing countries, where pharmaceutical industry is well established. The details of a suitable training programme are given in Appendix II/4.

d) The services of an international expert in production and quality control may be obtained from the same agencies for a duration of one year, to prepare for and to commission production and quality control for Phase I. A job description for the expert is given in Appendix II/5.

8. WORK PLAN

The following tentative Work Plan for Phase I is suggested:-

	Activity	Target Date
a)	Sanction of funds by the Government	December 1982
b)	Start of training programme	January, 1983
c)	Start of Repairs, Alterations etc	January, 1983
d)	Completion of Repairs, Alterations etc	March, 1983
e)	Inviting quotations, placing of orders for equipment and one year's supply of raw and packing materials	April, 1983
f)	Completion of training programme	May, 1983
g)	Arrival of International Expert	May, 1983

h)	Installation of Equipment	July, 1983
i)	Start-up of trial runs	August, 1983
j)	Commencement of production	October 1983
k)	Departure of International Expert	April, 1984

IV CONCLUSIONS AND RECOMMENDATIONS

1. The Report deals with two projects separately in Chapters I and II respectively for the production of intravenous infusions and local production of pharmaceutical products, for purposes of separate development for early implementation. However, the two projects form part of the overall objective of setting up a pharmaceutical industry in Cameroon. It is, therefore, advisable that there should be a coordination between the two projects, ultimately aiming at one large pharmaceutical industry unit, which may have common utilities, warehouses and quality control laboratories. This will bring about an all round economy, and permit an integrated effective management. The two projects, in their integrated development may find a common location in Nkomo, where other medical and pharmaceutical projects are being planned.

2. As would appear from the Report that intravenous infusions are already being produced in polyethylene flasons by PLANTECAM/MEDICAM at Douala. It can be argued that another plant for the production of intravenous infusions may not be required. However, as discussed in Chapter I of the Report, the Government has ample justification for starting their own production facilities for this purpose. Depending on, and within the framework of the present industrial policy of the Government, it may be possible for the Government to negotiate an agreement with PLANTECAM/MEDICAM, whereby it may be feasible to take effective control and direction, either through equity participation, or any other suitable Government action. In the event of such negotiations taking place, it may be kept in view that changes will be required in plant equipment. For example,

the raw material for the flacons will need to change from polyethylene to polypropylene granules, with consequent modifications, if needed, in the "Bottle Pack" machine. The temperature of sterilisation will also require to be modified from the present 105° C to 120-121° C. If this cannot be achieved in the present autoclave, a new autoclave may have to be acquired.

3. The Government has been presented with three alternatives in terms of technology to choose from, i.e.

a) Use of PVC bags, project cost US $ 1,277,000

b) Use of Polypropylene flacons, cost US $ 1,460,000

c) Conversion of equipment in PLANTECAM from the use of polyethylene to polypropylene flacons. The cost will be minor.

V ACKNOWLEDGEMENT

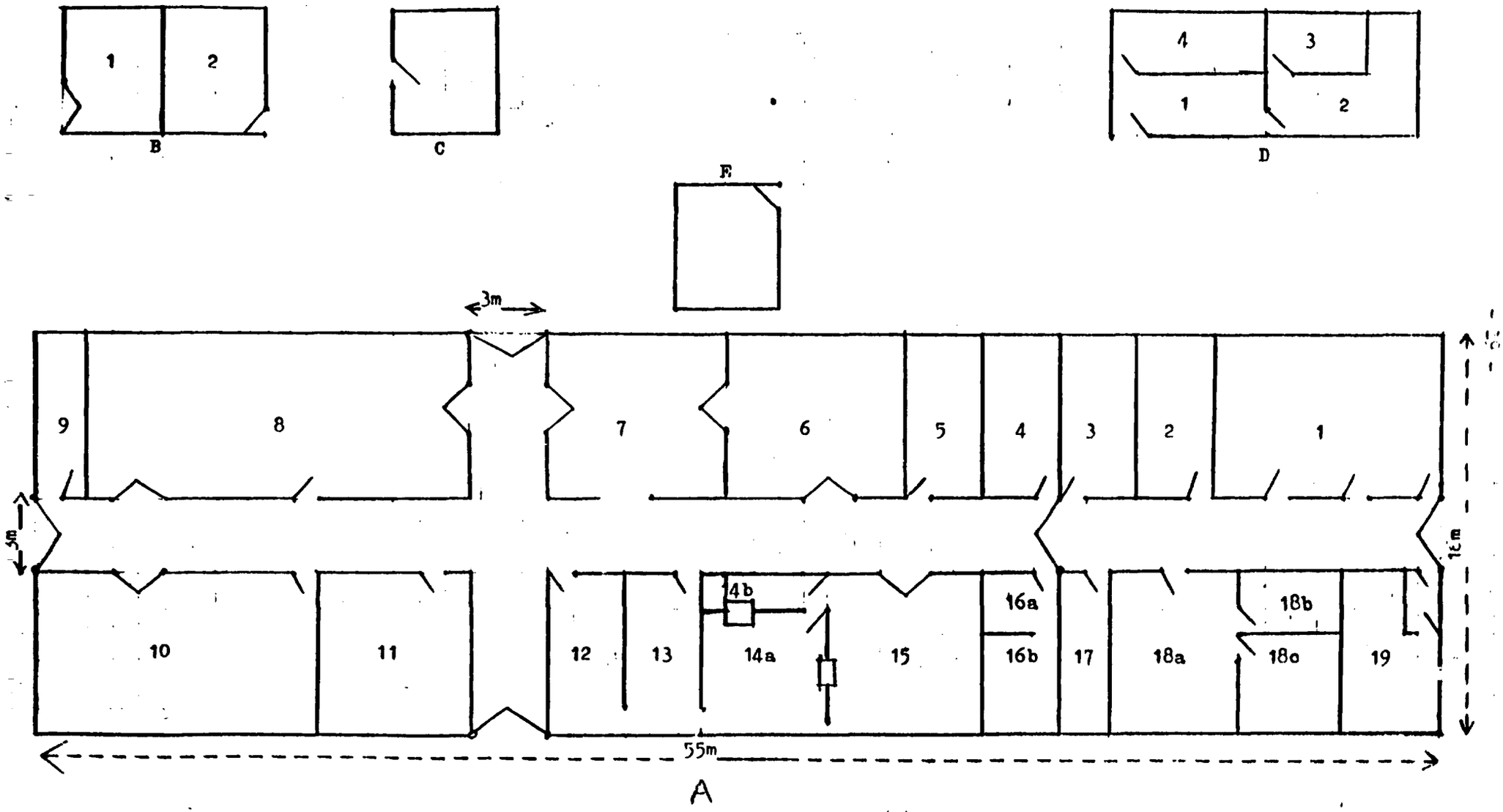
Appreciation is expressed for the kindness and consideration shown by the Honourable Mr. Athanase ETEME-OLOA, Minister of Public Health for granting an audience to the UNIDO SIDFA and the UNIDO Adviser.

The co-operation and assistance received from Professor A. Abondo, Director of IMPM and Dr. Johnson JATO, Deputy Director and their colleagues, Madame G. Abondo, Chief Pharmacist of Central Pharmacy and her colleagues particularly Dr. P. Mbanga is gratefully acknowledged.

The constant help and ready co-operation extended by Mr. A. BENBOUALI, UNIDO SIDFA and his staff deserves special gratitude.

Appendix I/1a

PROJET ONUDI UC/CMR/80/206-- PRODUCTION DES SOLUTES MASSIFS-- PROJET DE PLAN D'USINE



RAK/Juillet 1982

Echelle 0.2 cm = 1m

APPENDIX I/1b

A.	**Bloc Principale**		
	1. Administration	9 X 6.5 m	= 58.5 m^2
	2. Toilet (Hommes)	3 X 6.5 m	= 19.5 m^2
	3. Toilet (Dames)	3 X 6.5 m	= 19.5 m^2
	4. Vestiaire (Hommes)	3 X 6.5 m	= 19.5 m^2
	5. Vestiaire (Dames)	3 X 6.5 m	= 19.5 m^2
	6. Salle de Sterilisation	7 X 6.5 m	= 45.5 m^2
	7. Emballage, Etiquetage et Inspection	11 X 6.5 m	= 71.5 m^2
	8. Magasin de produits Finis	15 X 6.5 m	= 97.5 m^2
	9. Stockage de divers	2 X 6.5 m	= 13.0 m^2
	10. Magasin de Matieres Premieres	11 X 6.5 m	= 71.5 m^2
	11. Salle de Traitement de l'eau	6 X 6.5 m	= 39.0 m^2
	12. Salle de Pesee	3 X 6.5 m	= 19.5 m^2
	13. Salle de Preparation des Solutions	3 X 6.5 m	= 19.5 m^2
	14. Salle de Remplissage	5 X 6.5 m	= 32.5 m^2
	15. Lavage des Bouchons et Chargement des Chariots	6 X 6.5 m	= 39.0 m^2
	16. Responsable de la Production	3 X 6.5 m	= 19.5 m^2
	17. Infirmiere	2 X 6.5 m	= 13.0 m^2
	18. Laboratoire de Chimique	9 X 6.5 m	= 58.5 m^2
	19. Laboratoire de Bacteriologie	4 X 6.5 m	= 26.0 m^2
	20. Salle de "Blow Moulding"(for Polypropylene based project)	13 X 6.5 m	= 84.5 m^2
B.	**Chaudière et Atelier**		
	1. Chaudiere	4 X 5 m	= 20 m^2
	2. Atelier	4 X 4 m	= 20 m^2
C.	**Magasin des Inflammables**	4 X 5 m	= 20 m^2
D.	**Laboratoire des Pyrogenes**		
	1. Salle d'Essai de Pyrogenes	6 X 2.5 m	= 15 m^2
	2. Animalerie	6 X 2.5 m) + 2 X 2.5 m)	= 20 m^2
	3. Reserve d'Aliments	4 X 2.5 m	= 10 m^2
	4. Magasin	6 X 2.5 m	= 15.0 m^2
E.	Salle du Compresseur	4 X 5 m	= 20 m^2

APPENDIX I/1c

BUILDING ESTIMATES

A. BUILDING	Polypropylene	PVC
1. Main Block	990.5 m^2	906 m^2
2. Pyrogen	60 m^2	60 m^2
3. Boiler house/workshop	40 m^2	40 m^2
4. Inflammable materials store	20 m^2	20 m^2
5. Compression Room	20 m^2	20 m^2
6. Allowance for walls, etc.	119.5 m^2	104 m^2
TOTAL	1250 m^2	1150 m^2
(a) Cost of construction at CFA 200,000 per m^2	CFA 250,000,000 F	CFA 230,000,000 F
(b) + 10% for misc. items	CFA 25,000,000 F	CFA 23,000,000 F
TOTAL	CFA 275,000,000 F	CFA 253,000,000 F
	= US $ 833,000	= US $ 767,000

B. LABORATORY AND PRODUCTION BENCHES : INCLUDED IN THE CONSTRUCTION COST

APPENDIX I/2a

A. WATER FOR INJECTION

	US $
1. Pre-filter (sand)	2,500
2. De-ioniser plant, app 200 litres per hour capacity, with storage tanks 200 litres each for acid and alkali	20,000
3. Thermocompression water still 200 l/hr for producing pyrogen - free distilled water, all stainless steel	60,000
4. Storage tank, stainless steel, 2000 litres capacity, complete with transfer pump	7,500
TOTAL (A)	90,000

B. SOLUTIONS PREPARATION

1. Weighing scale, 200 kg capacity) 2. Weighing scale, 20 kg capacity)	5,000
3, Two mixing tanks each 1000 litres capacity with heating coil, all stainless steel, complete with stirrers	20,000
4. Filter unit, 50 l/hr with pump	11,000
5. pH meter	1,000
6. Accessories and spares	3,000
TOTAL (B)	40,000

C. FILLING UNIT	US $
1. Washing machine for plugs, complete with filter and tank of 200 litres capacity, 600/hr	12,000*
2. Printer for batch numbers	1,000
3. Four filling machines	7,000
4. Four Laminar flow hoods complete with prefilters and Hapa filters	12,000
5. Conveyor belt	6,000
6. Balance, capacity 5 kg.	2,000
7. Spares	1,000
TOTAL (C)*	41,000

* Item 1 above, not needed for Polypropylene based project as such total for C in this case will be US $ 29,000

D. STERILIZATION	
1. Autoclave, stainless steel, direct loading, steam sterilization, temp 115-116°C/121°C internal volume 1.5 m^3, automatic locking and safety, complete with Air Cooling system	100,000
2. Five trolleys with suitable trays to fit in the autoclave	20,000
3. Accessories and spares	5,000
TOTAL (D)	125,000

E. PACKAGING AND MISCELLANEOUS	US $
1. Conveyer belt (Two)	12,000
2. Heat sealing machine, output 300 seals/ hour	3,000
3. Two Fork lifts manually operated	4,000
4. Two polarised lamps	2,000
T O T A L (E)	21,000

F. CONTROL LABORATORY	
1. Polarimeter for dextrose determination	3,500
2. Titrimetric equipment, complete with automatic burettes	2,000
3. (a) Laboratory pH meter	1,000
(b) Portable pH meter	500
4. Oven, vacuum drying, inner capacity about 50 litres temp. range 30-150°C	3,000
5. Analytical balance 160 grams capacity accuracy ± 0.1 mg	4,000
6. Vacuum pump, motor ¼ h.p., explosion proof	2,000
7. Muffle furnace, up to 1200°C, capacity 30 litres	5,000
8. Laminar flow hood	5,000
9. Sterility test unit	2,000
10. Refrigerators (2)	1,000
11. Incubator for bacteriology, inner volume about 40 litres, up to 80° C thermostatically controlled.	2,000
12. Miscellaneous glass ware and apparatus	2,500
13. Pyrogen test Electric Thermometer	1,500
14 Drying oven 30 -270 C	2,000
15. Cages (50)	5,000
T O T L ( )	45,000

G. UTILITIES AND SERVICES	US $	CFA
1. Electricity (triphasic)	To be shared with the Medical Research Institute	
2. Water supply		
3. Land development		
4. Air handling unit, central complete with air filtration, cooling and dehumidification.		
5. Steam boiler, complete with feedtank and automatic regulation, output 300 kg/hr.	36,000	
6. Exhaust fans (24)	4,000	
7. Air Compressor	10,000	
TOTAL (G)	50,000	
H. INSTALLATION MACHINERY		
(valves, piping, joints, etc.)	50,000	
I. BLOW MOULDING EQUIPMENT		
(for Polypropylene only)	120,000	

TOTAL COST OF EQUIPMENT	PVC	Polypropylene
A. Water for Injection	90,000	90,000
B. Solutions	40,000	40,000
C. Filling	41,000	29,000
D. Sterilization	125,000	125,000
E. Packaging and Inspection	21,000	21,000
F. Control Laboratory	45,000	45,000
G. Utilities	50,000	50,000
H. Installation Machinery	50,000	50,000
I. Blow Moulding Equipment	-	120,000
TOTAL	462,000	570,000
+ 10% accessories and spares	46,300	57,000
GRAND TOTAL US $	508,300	627,000
= CFA	167,739,000 F	CFA 206,910,000 F

APPENDIX I/2b

LIST OF SUPPLIERS FOR EQUIPMENT

A. Production Equipment

1. BARNSTEAD, Sybrion Corporation,
   225, Riversmoor Street
   BOSTON, Mass. 02132, USA

2. T. GUISTI
   Belle Isle Works
   202/228, York Way
   LONDON N7 9AW, United Kingdom

3. Dott Bonapace,
   Via Canova 12
   20145 MILAN, Italy

4. Klein Apparatebau
   Niederndorfer Strasse 20
   5905 FRIEDENBURGE (Niederndorf)
   West Germany

5. John Bass Ltd.,
   Bassaire Building
   Duncan Road
   Southampton SO3 7ZS
   United Kingdom

6. H. Strunck GmbH
   Lichtstrasse 30
   5000 COLOGNE
   West Germany

7. ROVEMA Verpack GmbH
   Postfach 2920
   6300 GIESEN 3
   West Germany

8. Clea Japan Inc.
   2, Inari Building, 20-14
   Aobadai - 2, Meguru-Ku
   TOKYO
   Japan

9. LEQUEX SA.
   Rue Gay Lussac 64
   75005 Paris
   FRANCE

10. SANTASALO - SOHLBERG Corp
    Hankasuontic 4
    SF - 00390 HELSINKI, 39
    Finland

11. BAY (Friedrick U. Karl) GmbH
Postfach 266
D - 7120 BIETGHEIM-BISSENGEN
West Germany

12. C. A. KING & CO.
41, London Street
Chertsey, Surrey KT16 8AR
United Kingdom

13. SILVERSONS Machines Ltd
Waterside, Chesham, Bucks HP5 IPQ
United Kingdom

14. OSKAR KRIGER Machinen
Fredenrgestrasse 1
4132 MUTTENZ
SWITZERLAND

15. REJAFIX Ltd
Harlequin Avenue, Great West Road
BRENTFORD, MIDDLESESS TW8 9EH
United Kingdom

16. W & T AVERY Ltd.
Smethwick, Warley B66 2LB
United Kingdom

17. DELITT & HELLYER Ltd
Walworth Road
Andover, SP10 5AA
United Kingdom

18. BATTENFELD MASCHINENFABRIKEN GmbH,
Postfach 1164/65,
D - 5882 MEINERZHAGEN,
West Germany
(for Blow Moulding Equipment)

B. Laboratory Equipment

1. A. Gallenkamp & CO. Ltd.
Christopher Street
LONDON EC2
United Kingdom

2. VWR International
P.C. Box 3200
SAN FRANCISCO CA 94119
U.S.A.

3. ELLAB A/S, (for Electric Thermometer only)
9, Krondalvej
COPENHAGEN 2610 RØDOVRE
Denmark

NB. In addition to the above, other suppliers in Europe and United States may also be approached for quotations

Appendix I/2c

1 er Juin 1981

LE PHARMACIEN CHIMISTE PAGES Jacques
CHEF DU SERVICE DE BIOCHIMIE
CENTRE PASTEUR DU CAMEROON

RAPPORT D'ANALYSE HYDROLOGIQUE

Eau de robinet prelevee dans une bouteille plastique de contenance 1 500 cc.

Resultats des analyses pratiquees :

- pH = le pH mesure par technique electrometrique est de 7,7.

- Titre alcalimetrique complet : (T.A.C.) :
  TAC = 0,5 Meg/1 soit 25 mg de C CO3/1

- Durete totale = (Methode complexometrique).
  DT = 3,2 degres hydrotimetriques francais
  soit 0.64 mEg/1

- Durete calcique : (Methode complexometrique).
  D.C. = 0,44 mEg/1 soit 8,8 mg/1 de calcium.

Conclusion : L'eau analysee a une teneur moderee en elements alcalino-terreux (calcium/magnessium). La valeur de son pH est dans la limite des normes admissibles.

APPENDIX I/3

1. PRODUCTION PROGRAMME FOR FIRST YEAR

1.	Sodium chloride solution,	0.9%	500 ml	200,000	Units
2.	Sodium chlorise solution,	0.9%	250 ml	100,000	"
3.	Glucose solution,	5%	500 ml	350,000	"
4.	Glucose solution,	5%	250 ml	150,000	"
5.	Glucose solution,	10%	500 ml	5.000	"
6.	Glucose solution,	30%	500 ml	5,000	"
7.	Sodium bicarbonate solution	1.4%	500 ml	10,000	"
8.	Mannitol solution	10%	500 ml	10,000	"
9.	Rheo-macrodex 10% (dextran 4000) with sorbitol /5%/dextrose		500 ml	20,000	"
	T O T A L			850,000	"

II. PRODUCTS TO BE ADDED IN FUTURE

1. Darrows solution
2. Ringers solution
3. Ringers lactate solution
4. Glucose 5% withsodium chloride 0.9%

(ii)

RAW MATERIALS CONSUMPTION (annual basis)			ESTIMATED PRICE CFA
1. Sodium chloride	(Pro-injection)	1,500 kg	500 F per kg
2. Glucose, anhydrous	(Pro-injection)	15,000 kg	700 F per kg
3. Sodium bicarbonate	(Pro-injection)	100 kg	600 F per kg
4. Mannitol	(Pro-injection)	700 kg	1000 F per kg
5. Dextran 4000	(Pro-injection)	1,200 kg	10,000 F per kg
6. Sorbitol	(Pro-injection)	600 kg	Not known

PACKING MATERIALS CONSUMPTION (annual basis)

1.	PVC bags	500 ml	700.000 CFA	10,000 F per 100
2.	PVC bags	200 ml	300,000 CFA	7,000 F per 100
3.	Rubber plugs with aluminium caps		1,000.000 CFA	350 F per 500

NOTE: The quality of the bags to be determined in accordance with the filling and sealing equipment

POLYPROPYLENE GRANULES CONSUMPTION (annual basis)

(Information to be supplied later)

APPENDIX I/4

PERSONNEL DE L'UNITE PRODUCTION DE SOLUTES MASSIFS
(45 personnes)

A. ADMINISTRATION

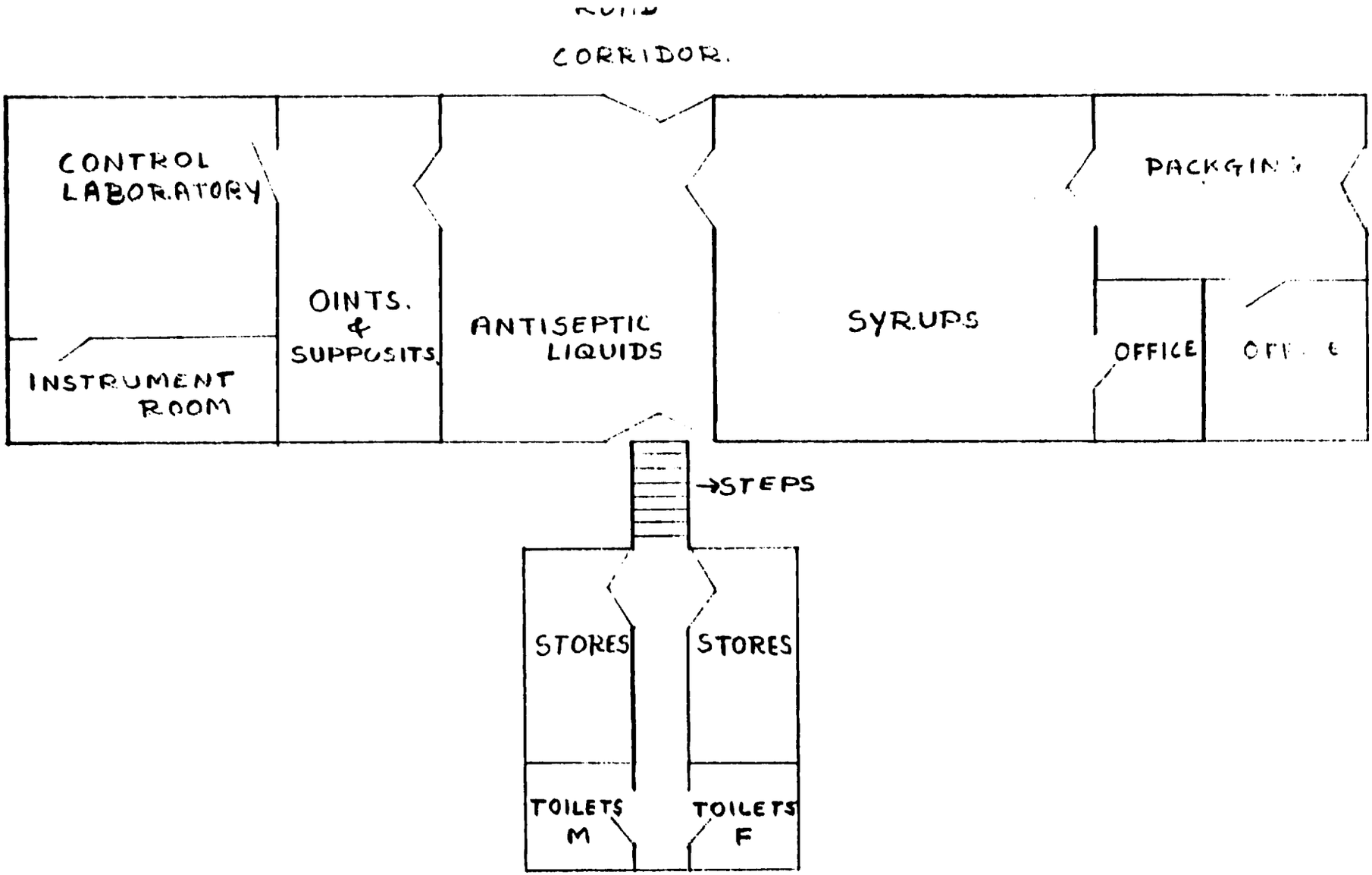
1 Chef de l'Unite (Pharmacien)
1 Comptable
1 Secretaire de direction
1 Dactylo
2 Chauffeurs
1 Agent d'entretien
1 Garcon des courses

B. PRODUCTION

1 Responsable de la production (Pharmacien)
1 Agent de maitrise (technicien en Sc. Pharm)
1 Dactylo
1 Chef de magasin
1 Ingenieur electromecanicien
1 Technicien en électronique
1 Technicien en mecanique
2 Blanchisseurs
2 Agents d'entretien
4 Manutentionnaires
1 Technicien pour l'eau
1 Technicien pour la pasee et la preparation
5 Conditionneuses
1 Technicien pour la sterilisation
3 Inspecteurs
4 Agents d'tequettage et emballage (2 homes + 2 filles)

C. CONTROLE DE LA QUALITE

1 Responsable de controle de la qualite (Pharmacien)
2 Techniciens chimistes
3 Techniciens microbiologiste et pyrogene
1 Agent pour l'animalerie



PRODUCTION UNIT FOR CENTRAL PHARMACY, YAOUNDE.

RAK/JULY 1982

SCALE 1cm = 1m.

APPENDIX II/2a

PRODUCTION PROGRAMME (Annual)

I.	SYRUP AND ORAL LIQUIDS	
1.	Chloroquine syrup	25,000 litres
2	Paracetamol syrup	10,000 "
3.	Piperazine syrup	20,000 "
4.	Diphenhydramine Exp. syrup	20,000 "
5.	Codeine syrup	5,000 "
6.	Sulphadimidine syrup	10,000 "
7.	Vitanin B - complex syrup	10,000 "
	T O T A L	100,000 litres
II.	ANTISEPTIC LUTIONS	
1.	Chlorpylenol solution	35,000 Litres
2.	Mercurochrome solution	20,000 "
3.	Cetrimide solution	30,000 "
4.	Tincture iodine	10,000 "
5.	Dakins solution	5,000 "
6.	Benzyl benzoate lotion	10,000 "
	T O T A L	100,000 Litres
III.	OINTMENTS AND CREAMS	
1.	Hydrocortisone with neomycin cream	100 Kilograms
2.	Tetracycline ointment	700 "
3.	Clioquinol ointment	200 "
	T O T A L	1,000 Kilograms
IV.	SUPPOSITORIES	
1.	Glycerine	50,000
2.	Aminophylline	50,000
3.	Visceralgine	75,000
4.	Paracetamol	40,000
5.	Anti-haemorrhoidal	50,000
6.	Phenylbutazone	35,000
	T O T A L	300,000

APPENDIX II/2b

LIST OF RAW MATERIALS

	NAME	Estimated Price per kg, f.o.d CFA
1.	Chloroquine Phosphate	10,000 F
2.	Paracetamol	2,500 F
3.	Piperazine Hydrate	1,000 F
4.	Diphenhydramine HCl	5,000 F
5.	Ammonium Chloride	500 F
6.	Codeine Phosphate	120,000 F
7.	Sulphadimidine	3,000 F
8.	Vitamin B_1	10,000 F
9.	Vitamin B_2	Not known
10.	Vitamin B_6	12,000 F
11.	Vitamin B_{12}	1,800 F per gram
12.	Nicotinamide	Not known
13.	Chroloxylenol	4,000 F
14.	Cetrimide	2,500 F
15.	Neomycin sulphate (sterile)	Not known
16.	Hydrocortosone Acetate	250 per gram
17.	Iodine	5,000 F
18.	Benzyl Benzoate	2,000 F
19.	Tetracycline HCl	10,000 F
20.	Aminophylline	3,000 F
21.	Phenylbutazone	4,000 F
22.	Clioquinol	7,000 F
23.	WITEPSOL base for suppositories	prices already supplied
24.	White Soft Paraffin	500 F

(ii)

25.	Liquid Paraffin	1000 F
26.	Sugar (prevailing price in Cameroon)	200 F
27.	Methyl Paraben	2200 F
28.	Bismuth Sub-gallate	Not known
29.	Visceralgin	Not known

APPENDIX II/3a

LIST OF EQUIPMENT

I SERVICES AND UTILITIES

1.	Electricity (triphasic)	already available
2.	Gas	butagaz
3.	Water	already available
4.	Air conditioning)	to be provided as
5.	Air extractor fans)	normal complement
6.	Laboratory benches)	of a building
7.	Demineralised water unit to produce 50 litres/hour	US $10,000 CFA3,300000

II SYRUPS

		US $	CFA
1.	Syrup kettle, capacity 500 litres with electric heating, stainless steel with stirrer	10,000	3,300,000F
2.	Mixing tank, 500 litres stainless steel with stirrer	5,000	1,650,000F
3.	Filter press unit with pump	5,000	1,650,000F
4.	Pump, small ½ h.p.	1.000	330,000F
5.	Storage tank, stainless steel 500 litres	4,000	1,320,000F
6.	Weighing scales, capacity 100 kg	2,000	660,000
7.	PH meter	1,000	330,000
8.	Mobile stirrer	1,000	330,000
9.	Semi automatic machine for filling & labelling	10,000	3,330,000
10.	Miscellaneous jars, containers etc polypropylene	1,000	330,000
	TOTAL	40,000	13,200,000

III	ANTI-SEPTIC LIQUIDS	US $	CFA
	1. Two mixing tanks, stainless steel 500 litres each with one stirrer for each	10,000	3,300,000 F
	2. Two pumps, each ¼ h.p.	3,000	990,000 F
	3. Semi automatic filling machine for bulk containers	5,000	1,650,000F
	TOTAL	18,000	5,940,000 F

IV	OINTMENTS AND SUPPOSITORIES		
	1. Mixer Homogeniser with bath for heating, electrically operated, with stirrer and tilting device, stainless steel, capacity 50 litres	15,000	4,950,000F
	2. Filling and closing machine for aluminium tubes complete with pump, semi-automatic	5,000	1,650,000F
	3. Semi-automatic labelling machine	2,000	660,000F
	4. Machine, automatic, for mixing filling and closing of suppositories like Dott. Bonapace model B P-4V	10,000	3,330,000F
	TOTAL	32,000	10,560,000F

V	CONTROL LABORATORY	US $	CFA
1.	Polarimeter	2,500	825,000 F
2.	Two Magnetic stirrer/heater	1,000	330,000 F
3.	Water bath, 6 holes concentric rings	1,000	330,000 F
4.	Drying oven, medium	2,000	660,000 F
5.	Vacuum drying, medium	3,000	990,000 F
6.	pH meter	1,500	495,000 F
7.	Semi-micro balance	2,000	660,000 F
8.	Analytical balance ± 0.1 mg	4,000	1,320,000 F
9.	Refractometer	1,000	330,000 F
10.	Vacuum pump	2,000	660,000 F
11.	Refrigerator	500	165,000 F
12.	Spectorophotometer UV and Visible Range 200 - 1000 nm	6,000	1,980,000 F
13.	Muffle furnace 1200°C	5,000	1,650,000 F
14.	Melting point apparatus, Electrothermal	1,000	330,000 F
15.	Centrifuge, laboratory	1,000	330,000 F
16.	Constant Temp. Water Bath	4,000	1,320,000 F
17.	Titration assembly	1,000	330,000 F
18.	TLC Assembly, Gelman Kit	1,000	330,000 F
19.	Electric heaters (s)	500	165,000 F
20.	Miscellaneous glassware	2,000	660,000 F
		43,000	14,190,000 F

TOTAL COST OF EQUIPMENT FOR PHARMACEUTICAL PROJECT

		US $	CFA
I	Services and utilities	10,000	3,300,000F
II	Syrups	40,000	13,200,000F
III	Antiseptic liquids	18,000	5,940,000F
IV	Ointments and suppositories	32,000	10,560,000F
V	Control laboratory	43,000	14,190,000F
	TOTAL	143,000	47,190,000F
	+ 10% accessories and spares	14,300	4,719,000F
	GRAND TOTAL	157,300	51,909,000 F
		-	52,000,000 F

APPENDIX II/3b

LISTE DES OUVRAGES

1. Pharmacoppe Francaise, edition le plus nouvelle
2. British Pharmacopeia, 1980 volumes I et II
3. Martindale's Extra Pharmacopeia, 27eme edition
4. British Pharmacopeial Codex, 1973
5. British Pharmacopeial Codex, 1979
6. Pharmacopee europeene, volumes I, II et III
7. Pharmacopee europeene, supplement aux volumes II et III
8. Pharmacopeia Helvetica VI, tome I, II (A-H), II (I-Z) et III
9. Pharmacopee Internationale, 1'OMS, volumes I et II
10. United States Pharmacopeia 1980, XXeme edition et National Formulary XVeme edition
11. La Pharmacopee senegalaise traditionnelle, plantes medicinales et toxiques, par J. Kerharo et J. G. Adam, editions Vigot Freres
12. Practical Pharmaceutical Chemistry, 3eme edition, volumes I et II, par Beckett, Athlone Press Londres
13. Identification of Drugs, volumes I et II par E. G. C. Clarke, The Pharmaceutical Press, Londres
14. Analytical Microbiology, volumes I et II par Fredrick Kavanagh, Academic Press, New York
15. The Quantitative Analysis of Drugs par D. C. Garratt, Chapman and Hall Ltd.
16. DIFCO Manual of Dehydrated Culture Media 9 eme edion, DIFCO Laboratories, USA
17. Pharmacology and Therapeutics par I. A. T. Mtulia, Nairobi, Kenya

(ii)

18. Merck Index, Merck & Co, New Rahway, Jersey, USA

CATALOGUES

1. GALLENKAMP, Angleterre
2. KARL KOLB Allemagne Occidental
3. KOTTERMANN Allemagne Occidental
4. FISCHER, U.S.A.
5. PROLABO, France

APPENDIX II/4

TRAINING PROGRAMME

A. PRODUCTION

1. Production Management including production planning procurement of equipment, raw and packing materials, warehousing, sales and distribution, finance control and personnel matters.

2. Pharmaceutical technology including basic knowledge of pharmacy, chemistry and pharmaceutical techniques, equipment and processes for the production and packing of syrups, antiseptic liquids, ointments and creams and suppositories, precautions observed in production operations and enforcement of Good Manufacturing Practices and pharmaceutical quality control and maintenance repair of equipment and machinery.

B. QUALITY CONTROL

1. Laboratory Management, including documentation and record-keeping, interpretation of results and decision making and procurment of laboratory equipment and reagents, finance control and personnel matters.

2. Pharmaceutical Analysis as follows:-

a) General Physical methods including pH, specific gravity, solubility, polarimetry, refractometry and viscosity

b) Chemical Purity and its control, including limit tests

c) Techniques of volumetric analysis, including acid alkali, oxidation,- reduction, non-aqueous, complexiometric, iodometric argentometric titrations.

(ii)

d) Extraction methods e.g. alkaloidal assays

e) Practical Gravimetric Analysis

c) Column, Paper and Thin Layer chromatography

g) Visual and Photo-electric colorimetry

h) Ultra-violet spectrophotometry including instrumentation

APPENDIX II/5

JOB DESCRIPTION

Post Title : Pharmaceutical Adviser (Production and Quality Control)

Duration : 12 months

Duty Station : Yaounde, Cameroon

Date Required: April, 1983

Purpose of Project: To instal and commission a unit for local production of pharmaceuticals at the Central Pharmacy, Yaounde, United Republic of Cameroon

Duties : With the assistance of Ministry of Health in Cameroon, the Adviser will carry out the following tasks:-

1. To prepare for the implementation of Phase I of the project in the production of syrups, antiseptic liquids, ointments and creams and suppositories.
2. To check the equipment and raw materials received or on order and propose supplementation of additional equipment where necessary.
3. To receive, check and instal the equipment.
4. To check and supervise the building alterations in the production and quality control premises at the Central Pharmacy and advise further alterations if required.
5. To finalise the list of products to be made in Phase I of the project and plan requisite production programme for the same on a monthly basis.

6. To draft and finalise methods of manufacture of each product and organise procedures and methods for testing of the products.

7. To organise the training programme of counterpart senior personnel and impart training on-the-job to the technical personnel.

8. To draft and enforce a Guide to Good Manufacturing Practices for the Unit.

9. To commission the Plant.

10. To plan for the implementation of Phase II of the project for the manufacture of tablets and capsules, oral rehydration salts and expansion of quality control. This will include preparing line diagrams of new premises and giving specifications for construction, preparation of lists of equipment and raw materials, and making proposals for further training of counterpart personnel.

11. To undertake such other duties as are connected with the project in agreement with the Government of Cameroon.

Qualifications : Industrial Pharmacist or Pharmaceutical Chemist with actual extensive experience in pharmaceutical industry and expertise in production and quality control.

Language : English or French, with working knowledge of the other.

Background Information :

Cameroon, with a population of over 8.5 million has a budget allocation of CFA 2,500,000,000 F equivalent to dollars about 7.5 millions, has a constant and rising demand for pharmaceuticals required for its hospitals and health centres. The drugs are purchased by the Central Pharmacy in the Ministry of Health.

It is intended to produce drugs in two phases: Phase I includes the production of syrups, disinfectants, ointments and suppositories and setting up of a Quality Control Laboratory; Phase II includes the expansion of the above production, with the addition of production of tablets, capsules and oral rehydration salts and extension of quality control laboratory. Phase I will be located in the existing premises of the Central Pharmacy. For Phase II, new premises will be planned.

Cameroon has a sufficeint number of pharmacists, who will require training in production and quality control.

-o-o-o-o-o-