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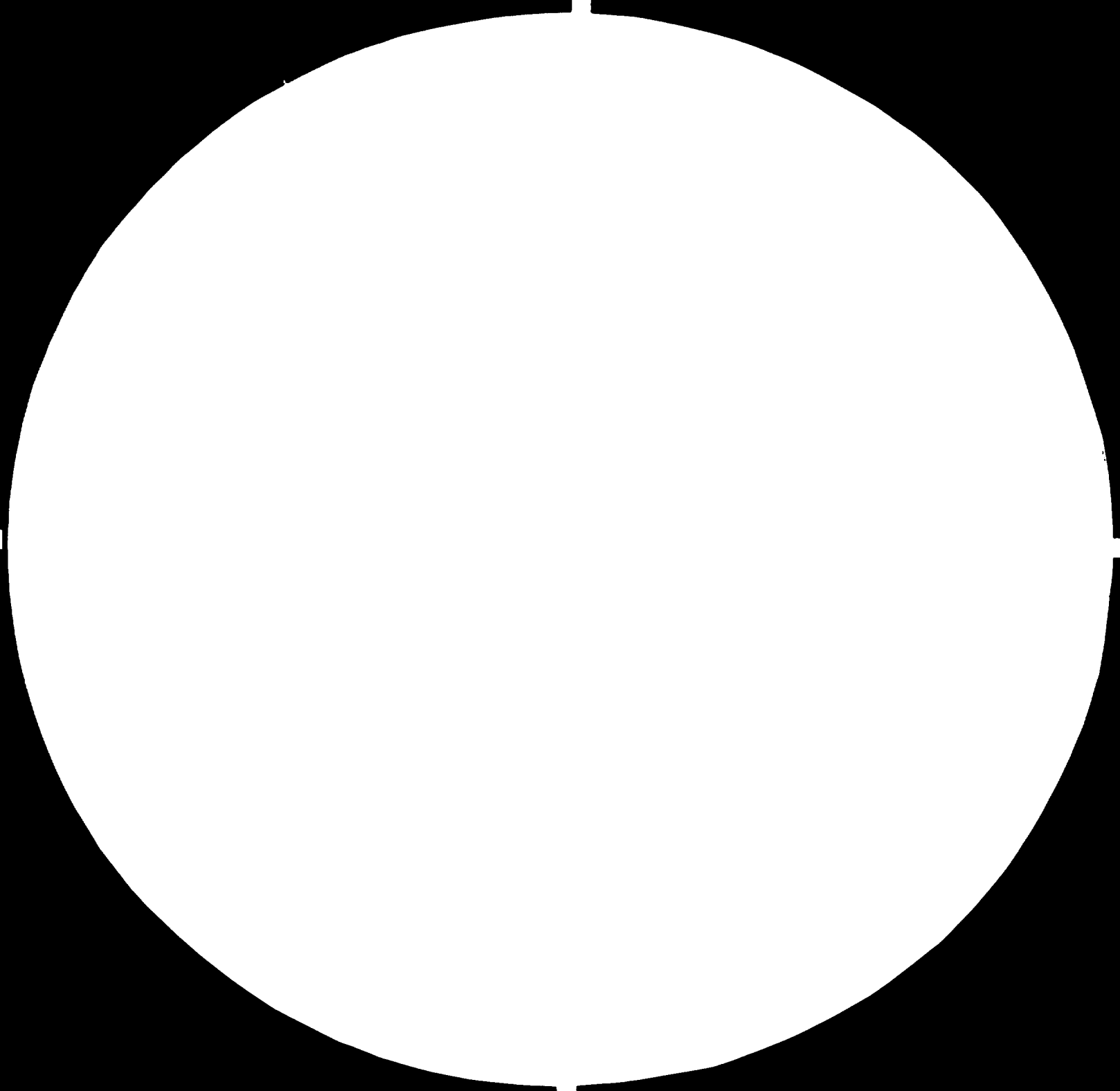
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2 June 1980

English

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EVALUATION OF EXISTING FACILITIES FOR
THE PRODUCTION OF PHARMACEUTICALS AT
GUYANA PHARMACEUTICAL CORPORATION AND
DESIGN OF NEW FILLING UNIT FOR
ANTIBIOTICS .

SI/GUY/78/801 .

. GUYANA .

Terminal Report *

Prepared for the Government of Guyana
by the United Nations Industrial Development Organization,
executing agency for the United Nations Development Programme

Based on the work of C.N. Chari, pharmaceutical industry advisor

United Nations Industrial Development Organization
Vienna

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SUMMARY

An assessment of the pharmaceutical products required by Guyana has been made. The existing facilities for the production of pharmaceutical products and Quality Control at Guyana Pharmaceutical Corporation have also been evaluated. The local production of pharmaceuticals meets about 19 per cent of the requirements of the country, while the balance 81 per cent is made up by imports in dosage form. On the basis of a modest annual rate of increase of 10 per cent in the per capita consumption of drugs, the annual requirement will go up to G\$30 million by 1983. If the local production were to meet 50 per cent of the projected demand, the value of production will go up to G\$18 million per year from the current annual level of G\$3.5 million. This indicates the growth potential for Guyana Pharmaceutical Corporation. A number of recommendations have been made with a view to upgrade the facilities and procedures to conform to International Good Pharmaceutical Manufacturing practice and efficient utilization of plant capacity. A unit has been designed for the encapsulation of antibiotics and the technology for encapsulation has been demonstrated.

1. Purpose of the Project

The purpose of the Project is set out in UNIDO job description indicated in Annex 1. The object of the present study is to evaluate the existing facilities at Guyana Pharmaceutical Corporation Limited (GPC) for the production of pharmaceuticals and design of a new filling unit for antibiotics.

2. Background Information

Guyana is bounded by Venezuela on the west, Suriname on the east, Brazil on the south and the Atlantic ocean on the north. The land is broken by large rivers. It rises gently from the sea to a region of undulating grass land, which in turn gives way to the emerald-green mountains inland. Its total area is 83,000 square miles. The country has a population of over 700,000. Georgetown, the capital, is on the mouth of the Demerara River. Guyana is a member of the Caribbean Community.

The State owned GPC located in Georgetown, is the only unit in the country engaged in the manufacture of pharmaceutical products. Besides, the Georgetown Hospital Dispensary prepares some ointments and tinctures for its use. There is also one private concern in Georgetown in the small scale sector producing Cough Syrup and disinfectants. The local production is confined to formulations from imported active ingredients and there is yet no production of bulk drugs within the country.

3. Guyana Pharmaceutical Corporation Limited

GPC is one of the thirty seven public sector Corporations under the control of Guyana State Corporation. The manufacturing activities of GPC cover toiletries, proprietary medicines and ethical medical products. Currently, GPC is diversifying its operations into the field of foods. GPC is also the sole importer of all drugs for Guyana.

The history of GPC dates back to the thirties, when a toilet lotion and a cough remedy were produced by the then Bookers Drug Stores. Subsequently, from 1945 to 1966 the latter concern was known as Bookers Manufacturing Drug Company Limited producing a wide range of proprietary medicines and toilet lotion. From 1966 onwards, the concern became a joint venture between Bookers and British Drug Houses, U.K., and was known as Booker B.D.H. Limited, which later became Carib Drug Company Limited. Guyana Pharmaceutical Corporation started operations in May 1976, when the Government of Guyana acquired from Booker McConnell Limited and Glaxo Holdings Limited the former Carib Drug Company Limited.

/the assets

Pursuant to a decision by the Government, GPC was charged with the responsibility for the implementation of a national drug policy. This resulted in the formation of the National Ordering Committee and the National Formulary Committee. The former consists of experienced pharmacists and is responsible for determining the national drug requirements, obtaining quotations and tenders from international pharmaceutical manufacturers and placing the necessary orders. The National Formulary Committee prepared and published the first National Formulary of Guyana in 1977 which reduced the large number of ethical drugs on the market to an essential list of 1146 dosage forms. The new policy aims at the integration of local manufacture with drug importation, so that there will be unified policy for the manufacture of pharmaceutical products based on National Formulary and the importation of Generic, Ethical drugs and Medical Supplies. During 1978, GPC undertook the total responsibility for the purchasing and distribution of all the drugs required in Guyana. Sales and other income during 1977 amounted to G\$13.4 million (1US\$ = 2.56 G\$ based on exchange rate prevailing in December, 1978) resulting in an after tax profit of G\$1.7 million. Out of the total sales, export sales contributed G\$5.08 million (approximately 40%). The Company employed 308 management and non-management staff at the beginning of 1977 and there are qualified and competent persons at various levels.

4. Requirement of drugs and pharmaceuticals

Drugs and pharmaceuticals required by Guyana are met partly by GPC and the balance by imports. The National drug bill in 1978 amounted to G\$19.5 million.

5. Imports of drugs and pharmaceuticals

As the information on the quantum of pharmaceutical products actually imported was not readily available, it was suggested that the tender enquiries for import pertaining to 1978 and 1979 be taken as the basis for computing the requirements. However, it will be appreciated that tender enquiries give only an indication of the anticipated requirements but do not necessarily reflect the items and the quantities actually imported or consumed in any given year. The information concerning antibiotics, intravenous infusions and solutions, injections and insulin extracted from the tender enquiries for 1978 and 1979 is given in Annex 2. It is understood that imports of pharmaceutical products during 1978 may amount to G\$15 million.

6. Local production of drugs and pharmaceuticals

Ethical medical products falling within the range of manufacture of GPC are shown in Annex 3 and proprietary medicines and toiletries in Annex 4. Ethical medical products in the form of Tablets actually produced during 1977 are indicated in Annex 5. The product mix in 1977 comprised approximately 80 per cent liquids (including toilet lotion, essences and OTC medical products), 12 per cent tablets and 8 per cent ointments by volume.

7. Availability of raw materials and packing materials

As regards raw materials, only sucrose and ethyl alcohol (95%) are available within the country. All the remaining raw materials and auxiliary materials required in production are imported. As far as packing materials are concerned, labels and cartons made from imported paper stock and wooden boxes are available locally. Glass and plastic containers are imported. A glass plant is expected to go on stream in June 1979 but it may produce bottles for domestic use in the initial phase.

8. Existing facilities for the production of pharmaceuticals

The facilities of GPC are located at LaPenitence and Kingston areas of Georgetown. Ethical medical products comprise mainly tablets and some liquids. The layout of the production area at LaPenitence indicating the disposition of major equipments is shown in Annex 6. The list of equipments there is given in Annex 7. There is a floor space of about 5000 sq. meters at LaPenitence. Part of the laboratories is located at Kingston covering about 600 sq. meters of floor space. The agency section handling the imported items is also located in Kingston occupying a floor area of about 2000 sq. meters. The hospital supplies section has a floor space of about 1100 sq. meters. Floor area of 322 sq. meters is available for encapsulation. There is a workshop with one lathe, a drilling machine and welding equipment primarily meant for maintenance. As regards utilities, there is an electric boiler with capacity of 160 lb/hr (50 PSI), one air conditioning unit of 15 ton capacity and another unit which has been out of commission.

/a

There is a mixed bed deionizing column for water with a capacity of 900 lits/hr. There are small air compressors (one of 3 HP at 110PSI) for transporting liquids. Water is drawn from the city water supply system and amounts to 1.35 million litres per month. There are no facilities for effluent disposal and the effluent is discharged into a drainage canal adjacent to the plant. Power supply is available at 220V and 110V and power consumption is 180 KVA.

9. Consumption and demand for pharmaceutical products and prospects for future growth and export.

Based on the figures relating to the value of imports (G\$15 million) and local production of pharmaceutical products (G\$3.5 million) in Guyana in 1978, the per capita consumption of drugs and pharmaceuticals works out to G\$26.4 (US10.3.) during that year. Out of the requirements of drugs and pharmaceuticals in 1978, about 19 per cent was contributed by local production while about 81 per cent of the requirements was met through imports.

As far as the per capita consumption of drugs is concerned, the figure compares favourably with that obtained in more "advanced" countries amongst the developing countries although it is much less than that obtained in developed countries. However, a large proportion of drugs imported currently could be in the nature of OTC pharmaceutical products rather than essential drugs as such. By regulation of imports based on the National Formulary to generic ethical drugs, the imbalance can be reduced and with this, the import bill is likely to go down.

As regards the share of local production in the national drug bill, the figure is considerably less than that obtained in a number of developing countries. As the standard of living goes up and national health programmes gain momentum, the per capita consumption of drugs is bound to go up. In view of this, the future production programme of GPC may aim at meeting a larger proportion of the requirements of drugs of Guyana and to that extent become self reliant in this vital field as well as keeping pace with the normal increase in the population and per capita consumption of drugs.

/production of

Assuming that the consumption of pharmaceutical products increases at a modest rate of 10 per cent annually over the next five years, the National drug bill in 1983 may amount to G\$30 million. If local production is to meet at least 60 per cent of these requirements, as is the case with a number of developing countries, it will amount to G\$18 million. As Guyana is a member of the Caribbean Community and is currently exporting about 50 per cent of its proprietary medicines and cosmetics, there could be reasonable prospects for export of its ethical medical products. Export will also become necessary when GPC moves towards backward integration of its production to the manufacture of active ingredients from intermediates and basic chemicals in view of the limited local market and in order to ensure economically viable quantum of production. To attain a competitive position in the International market in the field of ethical medical products, it will be necessary to ensure efficient utilization of plant capacity and at the same time to upgrade facilities and procedures to conform to International Good Pharmaceutical Manufacturing practice. It is with this object that a number of recommendations are made in these areas here under.

10. Recommendations relating to the existing facilities for production of pharmaceuticals and Quality Control

Based on a review of the existing facilities for the production of pharmaceuticals and Quality Control, the following recommendations are made with a view to upgrade the facilities and procedures to conform to Good Pharmaceutical Manufacturing practice.

(a) Manufacturing premises and equipment

- (i) All processing equipment which may create problems of contamination of other drug products should be enclosed in their own cubicles and necessary environmental control equipment to regulate temperature and humidities installed. The types of equipment include tableting machines, granulating equipment, liquid manufacturing equipment etc.
- (ii) Detailed maintenance programmes should be drawn up which would permit the equipment to be dismantled after every production run for thorough cleaning and maintenance check. Instructions for cleaning and maintenance should be recorded in operational manuals and should be available in the specific work areas.

(b) Quality Control Department

- (i) It is gratifying to note that Quality Control Manual has been prepared in 1977. It is recommended that immediate steps be taken to fully implement the provisions contained therein and filling in the gaps particularly in the following areas:
 - Analysis of raw material samples should be carried out according to specifications
 - Controlling storage conditions and adhering to them
 - Check by Quality Control of packaging materials against the approved specimen in the Product Master Formula file
 - Designing a system for inspection of bottles, caps, cartons etc.
 - Each sample of bulk products should be tested according to all the pharmacopoeial or commercial specifications for finished products
 - The bulk product should only be released for packaging after certification of the lot and not on the basis of few tests. This applies to all the products and not only to active ingredients

(b) Quality Control Department Cont'd

- Each and every lot should be analysed completely and not lots at random
 - It is not clear what is meant by "water height is correct and not more than one month old". The suitability of water to be used should depend on its quality and not its age. Process water as well as deionized water should be tested to include microbiological analysis
 - Shelf Life testing includes all tests stipulated in the pharmacopoeia or the compendium as the case may be
 - Shelf Life tests should continue at least till the expiration date of the lot concerned
 - Action to be taken on the detection of faults should be stipulated e.g. suspending the use of the batch, recall of the batch etc.
 - Procedure for recall of batches should be laid down
 - Checks at various levels with respect to sanitation should be stipulated and these should be recorded
 - A record of factory inspection by Q.C. chemist should be maintained
- (ii) The Quality Control manual may be revised based on the above observations as well as recommendations contained in this report.
- (iii) Develop in-process manufacturing and packaging quality control procedures. These should include physical and chemical checks at various appropriate steps in the process
- (iv) Review and rewrite where necessary all manufacturing and testing procedures to ensure the maximum of GMP.
- (v) Strengthen the existing chemical and microbiological laboratories by the provision of necessary instruments and facilities including laminar flow cabinet for the microbiological laboratory
- (vi) Establish pharmacological testing facilities. Pending this, arrangements should be made to carry out the pharmacological testing at reputed laboratories elsewhere

- (b) (vii) Arrangements may be made to test check samples from new products proposed to be marketed at established laboratories outside. It is also desirable to test check random samples from current production at certain intervals at outside laboratories to ensure that the testing procedures in vogue are adequate.

(c) Raw Material and Packaging Material tests

- (i) Detailed specifications should be drawn for every raw material and packaging material including bottles, caps, cartons, labels etc. and every lot of these materials received should be tested against the given specifications. These should be updated at frequent intervals. Some progress has already been made on the raw material specifications
- (ii) Every batch of raw material and packaging material should be assigned a number on receipt at the plant and this receiving number should be entered on all documents relating to these materials.
- (iii) The storage conditions of raw materials and packaging materials should be reviewed to safeguard/any deterioration during storage

/against

(d) In Process Manufacturing and Quality checks

- (i) Review all manufacturing, packaging and testing procedures to ensure GMP.

(e) Finished product tests

- (i) The specifications against which all finished products are tested should be updated along with any revision of the compendial standards
- (ii) Pharmacopoeia reference chemical standard materials should always be available to compare raw materials and finished products for identity, potency and purity
- (iii) Every batch of finished product should invariably be tested according to label claim
- (iv) Each and all finished product tests for products listed in the compendia should be performed. It should not be left to the discretion of the analyst to eliminate some of the tests because these tests are not considered important

(f) Stability Testing

- (i) Periodic observations on physical appearance are made on reference samples of finished products. Whenever any defects are noticed, such lots should be subjected to finished product tests.

(f)

- (ii) Random lots from the reference samples should be subjected to finished product test at regular intervals, irrespective of the fact whether they exhibit any defects in physical appearance or not. These tests should also be sensitive enough to detect degradation by-products.
- (iii) All new products proposed to be marketed should be subjected to accelerated stability testing under temperatures up to about 60°C and relative humidities ranging between 50% and 90% and exposure to direct sunlight. The expiration dates stated on the label should be based on the stability studies.

Stability studies should also be conducted whenever changes are made in the production process, dosage form or packaging.

(g) Recall System

- (i) Procedures should be set up for recalling a defective lot of product from the market, where necessary
- (ii) Record keeping system should be organized to facilitate the tracing of each unit of a lot of product to the level of the retail pharmacy or hospital dispensary or field clinic.

(h) Complaints

- (i) All complaints relating to the finished product received from medical or pharmacy profession or the public should be registered and scrutinized by a technical committee comprising Production, Quality Control and Research and Development Managers. An analysis of the reference samples from the lot in question should be carried out to find out whether the defect could be traced to any deficiency in the manufacture or could be due to storage or handling outside
- (ii) Where a complaint refers to severe adverse reaction, further use of the lot should be stopped pending a detailed investigation.

(i) Records

- (i) The master formulation document should include:
 - the theoretical quantity of the batch size with the theoretical percentage deviation permitted, when the actual yield produced was compared with the theoretical yield
 - the date manufacture was started

(i) Cont'd

- the date manufacture ended
- the name of the quality control person checking the cleanliness of the equipment before production is initiated
- the name and standard quantity of each raw material used in the batch, with lot numbers
- the initials of the person weighing each ingredient
- the initials of the person checking the weight of each ingredient weighed by the operator above
- the initials of the person adding the measured raw material to the bulk mixing equipment
- the initials of the person checking the addition of each quantum of ingredient to the bulk mixing equipment
- special instructions such as protective wear for personnel; storage conditions for raw and bulk materials etc.
- complete manufacturing instructions in detailed step by step processing procedures including equipment to be used, mixing time, drying or melting temperature etc.
- the initials of each operator performing each step of the process
- the signature of a supervisor indicating that the processing operation was completed satisfactorily
- the signature of the Quality Control person who sampled the finished product
- the signature of the production person responsible for ensuring that the equipment used in the manufacturing process was cleaned according to written instructions
- the signature of the Q.C. person checking that the equipment used has been cleaned satisfactorily
- the signature of the Quality Control and Production personnel releasing the bulk for packaging with date shown
- name of the product to be packaged
- date packaging started
- the source of the bulk
- the container size, type and colour
- the type of drying agent and filler
- the type of cap and liner
- the type of closer seals
- packaging parameters such as the position of the label

(ii) The product information record should include:

- name of product
- ingredient or ingredients and the standard to which they conform
- chemistry and pharmacology
- indications which should include any abstracts from pharmacological or medical publications
- contraindications
- toxic effects, adverse reactions and precautions
- treatment of toxic effects
- storage conditions
- units per packaged dosage form
- recommended dosages

(iii) The above records should be reviewed and up-dated periodically. The review of this documentation should be closely integrated with other activities to upgrade GMP and checking system in sanitation, maintenance of premises, equipment, product information, self inspection programmes etc.

(j) Samples

- (i) Samples should be drawn by Quality Control personnel according to the sampling procedure specified for each lot of finished product
- (ii) Samples should be kept in environmentally controlled locations. A sufficient quantity of units of each lot of product should be kept so that all the tests required for that product can be repeated at least three times. Samples should be complete final packaged dosage forms meeting all the company's requirements

(k) Imported raw materials and finished dosage forms

- (i) A certified copy of the certificate of analysis for each lot of product imported should accompany the product as a part of the shipping document
- (ii) All finished products should be packaged in light resistant containers, well sealed against humidity
- (iii) All products with known stability problems should carry expiration dates on the label and the product should not be used after that date
- (iv) The premises in which the products are stored should be environmentally controlled to ensure stability of the product

- (v) Raw material storage: There should be five distinct areas properly segregated as follows:
 - received but not sampled
 - under test
 - approved
 - rejected
 - crossed expiration date
- (vi) Lots rejected and those which crossed the expiration dates should be promptly disposed off to avoid mixup.
- (vii) Hazardous chemicals and inflammable materials including packing materials should be stored separately, where adequate fire prevention and fire fighting facilities are available
- (viii) Hygroscopic materials should be segregated to avoid contamination

(l) Sanitation

- (i) Precise clean-up procedures in detail should be laid down for work areas including walls, floors and sinks. The procedures should specify the type of disinfectant to be used, the concentration and how often the disinfectants are to be applied
- (ii) Clean working garments should be worn by all the personnel. Head covers should be mandatory in all manufacturing areas. Street shoes should not be worn as such in the manufacturing areas - either separate shoes should be worn or the street shoes should be suitably covered.
- (iii) Periodic health check-up of all employees particularly those working in the production area should be carried out

(m) Training

- (i) Seminars or short term training courses may be organized for senior and middle management to exchange ideas to upgrade GMP
- (ii) Senior management may be sent abroad to visit plants performing according to international GMP
- (iii) Subscribe to publications on GMP such as the Gold and Green Sheets of U.S. FDA, the Federal Register of the USA and similar publications of the Governments of U.K., Germany and Sweden to acquaint themselves with the changes in quality assurance management procedures.

- (iv) In collaboration with the concerned Ministries and Guyana University, a programme in pharmaceutical technology, quality assessment or quality control management and quality control principles may be built into the curricula of the relevant university faculties
- (v) In plant quality control and quality assurance programmes should be designed for the training of all personnel

(n) Bioavailability

- (i) It is recommended that bio-availability studies be carried out on all new ethical medical products, where bio-availability is an important factor. It is learnt that at present there are no facilities for carrying out such studies within the country. It would then be necessary to conduct such studies in reputed institutions abroad
- (ii) Similarly it is desirable to carry out bio-availability studies on ethical medical products currently in production, where necessary to ensure their competitive position in the market particularly the export market

(o) Product Development

At this stage when the company is endeavouring to assume a bigger share of the total market for pharmaceutical products, it will be necessary to branch into new lines and launch a number of new products in the near future. Product Development can become a limiting factor in this regard. At present there are skeleton staff and limited facilities for this purpose, and these have to be strengthened to attain the objective within a reasonable period of time. Additional facilities considered necessary for the Product Development unit are indicated in Annex B.

(p) General

1. All instruments and weighing machines should be calibrated and checked at regular intervals
2. Drying oven should not be used for storage of products. This may result in the degradation of the product apart from damaging the equipment running for days continuously
3. Electrical wiring should be properly shielded. Exposed wiring particularly in wet areas can be highly hazardous
4. Humidograph should be used for recording relative humidity. These records should accompany process data sheets
5. Microbiological laboratory should be modified as suggested to ensure optimum conditions. Laminar air flow cabinet should be provided for carrying out microbiological tests
6. Norms should be fixed for deionized water including microbial counts. This water should be tested periodically and may be used only when it fully complies with specifications

7. Norms should be fixed for microbial counts on plates exposed in production areas, which should be tested at frequent intervals. Production operations should be discontinued when the area does not conform to stipulated norms and area decontaminated
 8. Limits should be fixed on the extent of microorganisms present in non-parenteral products to ensure GMP and finished products should be tested to conform to this
 9. All electrical equipments, accessories and lights used in areas where inflammable and explosive materials are handled should conform to the required flame proof and explosion proof classification
- Concentration of explosive gases in such areas should be monitored regularly.

11. Formulation of Antibiotics

Antibiotics constitute one of the most important groups amongst drugs and pharmaceuticals consumed in any country and this is also the case with Guyana. The formulation of antibiotics at GPC at present is confined only to oxytetracycline base in the form of tablets and that too to a limited extent. An examination of the requirements of drugs and pharmaceuticals shown in Annex 2 reveals that there is significant demand for various antibiotic formulations in non-parenteral as well as parenteral dosage forms. In view of this, it is prudent to take up the formulation of antibiotics in non-parenteral dosage form to start with. The logical step in this regard appears to be encapsulation of antibiotics. In fact, GPC has not so far embarked upon encapsulation of any drug. Amongst the antibiotics to be taken up for encapsulation, the obvious choice is for Ampicillin, Tetracycline and Chloramphenicol in that order, based on the demand pattern. Any facility for the manufacture of antibiotic and steroid encapsulated products should be specially designed to separate these types of products from other encapsulated dosage forms. This process also calls for a highly sophisticated technology, very rigid in-process quality controls with regard to different parameters.

(a) Encapsulation of Antibiotics

The steps involved in filling antibiotics in hard gelatine capsules are described below:

- a. Inspection of empty capsules
- b. Sieving
- c. Powdering, where necessary
- d. Blending
- e. Granulation, where applicable
- f. Drying followed by sieving where necessary
- g. Filling and Sealing
- h. Dedusting
- i. Inspection
- j. Packing

A brief description of the process is given below:

According to the Master Formulation card, the raw materials are weighed and sieved to eliminate extraneous matter coming from container etc. The materials are powdered, where necessary. The materials are then thoroughly blended in a mixer. Where granulation is required, granulating solution is added and the wet mass is passed through granulator. Wet granules are dried in a drying oven under controlled conditions of temperature.

The powder/granules are then passed through sieve, where necessary. The batch is then filled in the capsule filling machine after adjusting the weight. The filled capsules are regularly checked for weight variation. The filled capsules are then dedusted to remove powder adhering to the sides. Thereafter, the capsules are visually inspected and defective capsules removed. The inspected capsules are filled in containers with the help of a mechanical counter or strip packed in laminated aluminum foil. When they are filled in glass or plastic containers a wad of surgical cotton is put and a silica gel bag is also inserted where the material is hygroscopic as in the case of Ampicillin. Strict in-process and quality control tests should be carried as described earlier. After the batch is released by Q.C., the containers are labelled after printing the batch number, manufacturing date, expiry date etc.

A number of precautions should be taken while handling antibiotics including the following in particular:

- Walls, floors, ceiling of rooms shall be smooth, impermeable avoiding shedding or accumulation of dust or other particles; shall be washed and disinfected at frequent intervals. Germicidal paints should be used
- Fittings and equipments shall be minimum for work in progress and where possible should be capable of being serviced outside of room
- Equipment should be cleaned and checked. Equipment must be free from contamination
- Pyrogen free water should be used
- Sanitation programme should be worked out including cleaning of walls, ceiling and equipment after manufacturing
- Antibiotics are potent substances and operating personnel must wear masks and gloves
- containers, equipment and accessories used for one antibiotic should not be used for handling another antibiotic or drug to avoid cross contamination. In the course of normal cleaning and washing procedures; it may not be feasible to free the equipment completely from contamination. Very minute traces of antibiotics such as penicillin and ampicillin and their degradation products are known to cause severe adverse reactions. So every care should be taken to avoid cross contamination which can occur due to various factors such as air supply, personnel, equipment, containers, premises, clothing etc.
- Traffic in and out of areas where antibiotics are handled should be through air-locks, where the personnel put on special clothing, gloves, masks, shoes etc., they decontaminate their hands in an antiseptic solution (such as 70 per cent Isopropyl alcohol or hexachlorophene soap). Air curtains are provided in air locks to dedust the personnel, materials and equipment entering air locks

- Air conditioning with controlled humidity and temperature is provided. The relative humidity should be around 50 per cent and temperature about 25°C. The conditions for storage and handling of capsules are 25°C and about 45 per cent relative humidity
- A positive pressure should be maintained in the granulation and filling areas (not less than 10 air changes per hour)
- Empty gelatin capsules on prolonged storage are highly sensitive to the effect of high temperature
- In the granulation and filling rooms where the powder is exposed, relative humidities should preferably be less than 50 per cent
- No recirculation of air should be carried out when the air handling system serves different rooms handling more than one antibiotic to avoid cross contamination
- The air handling system should be provided with prefilters and after filters to trap dust and antibiotic powders. Passage of air around ultraviolet lights will kill viable organisms
- Detailed instructions should be issued for the maintenance of air handling system, change of filter elements, disposal of filter elements etc to avoid cross contamination
- Environmental control tests should include monitoring the extent of sterility of the areas by exposing petriplates and taking swabs of equipments at frequent intervals.
- Prior to the introduction of a new product on the market, tests for safety and bioavailability studies should also be carried out besides pharmacopoeial tests for finished products.
- Persons with known history of allergy may not be permitted to work in these areas
- Periodic medical examination of all persons working in these areas should be carried out
- Instructions should be prominently displayed in working areas.
- Special characteristics of different antibiotics, their toxic effects and precautions to be taken are described in standard publications.² Some of these are mentioned below:
 - 1) Ampicillin, anhydrous: Soluble in 170 of water, almost insoluble in alcohol, acetone, chloroform, ether and fixed oils. Absorbs insignificant amounts of moisture at 25° at relative humidities up to about 80 per cent but under damper conditions it absorbs significant amounts.

Toxic effects: As for benzyl penicillin, allergic reactions such as pruritus, skin rashes, erythema, fever, and anaphylactic oedema may occur in sensitized persons. Diarrhoea, nausea,

2. Extra Pharmacopoeia, Martindale. 27th Ed., 1977

vomiting and abdominal pains have occurred. Superinfections of the gastro-intestinal tract have been reported.

Precautions: Ampicillin is contra-indicated in patients known to be sensitive to penicillin and it should be used with caution in patients with known history of allergy.

Store at a temperature not exceeding 25° in air tight containers.

11) Tetracycline Hydrochloride

Storage: should be kept in a well-closed container protected from light. It darkens on exposure to strong sunlight in a moist atmosphere.

111) Chloramphenicol

Store in airtight containers. Protect from light.

Precautions Chloramphenicol is contra-indicated in patients with a history of hypersensitivity or toxic reactions.

(b) Design of unit for encapsulation of antibiotics

- i) Ampicillin: The requirement of ampicillin capsules during 1978 and 1979 is given in Annex 2. From this, it can be seen that the current annual demand for ampicillin capsules of 250 mg, amounts to about 5 million capsules and that for capsules of 500 mg about 300,000 capsules. Based on the demand projection made, the requirements may go up to nearly twice these quantities within the next five year period. In view of this, the design of the encapsulation unit for ampicillin is based on an annual capacity equivalent to 11 million capsules of 250 mg each (both sizes put together)

Capacity 11 million capsules per year (230 working days) 48,000 capsules per day approximately. Average weight of capsule: 300 mg
14,4 kg/day
72 kg/week

For half of the above capacity, the batch size for one week is 36 kg/day

Premises: GPC has recently constructed four rooms with a total floor area of about 322 sq meters. Of course, this space would have been adequate for a considerably bigger capacity. However, on account of reasons stated earlier, formulation of tetracycline or chloramphenicol cannot be taken up along with ampicillin in the same premises. Further at present there is no separate room for storing empty gelatin capsules at the required temperature and humidity. In view of this, one room is proposed to be used for the storage of empty gelatin capsules and ampicillin bulk.

The proposed lay out of the premises is shown in Annex 9 and is outlined below:

- A. Storage of empty gelatin capsules and ampicillin bulk. Inspection of empty capsules.
- B. Preparation of batch for filling. (Inflammable solvents are handled. Necessary precautions as stated earlier should be taken).
- C. Encapsulation, dedusting and inspection of filled capsules.
- D. Packing and storage of finished product.

The function of air-locks, regime for the personnel working in the premises, meters for air conditioning, in-process and quality control checks etc. have been described in detail earlier. These have also been explained to the concerned personnel.

Equipment

The list of equipments required is given in Annex 10.

11) Tetracycline Hydrochloride

The requirement of tetracycline hydrochloride capsules during 1978 and 1979 is given in Annex 2. It can be seen from this, that the current annual demand for Tetracycline capsules of 250 mg amounts to about 5 million capsules. Based on the demand projection, the requirement may go up to about 10 million capsules in the next 5 year period. In the light of above, the design of the encapsulation unit for Tetracycline hydrochloride is based on a capacity of 10 million capsules of 250 mg each.

Capacity 10 million capsules/year (230 working days)
 44,000 capsules/day approximately
 Average weight of capsule: 30 mg
 13.2 kg/day
 66.0 kg/week

For half of the above capacity, the batch size for one week is 33 kg/day.

Premises: The premises for Tetracycline should be segregated from that used for ampicillin. The layout of the premises is similar to areas C and D indicated in Annex 9.

- C - Inspection of empty capsules
 Blending where necessary
 Filling and dedusting. Inspection of filled capsules
- D - Packing and storage of finished product

The functions and different parameters are similar to what was indicated under encapsulation earlier.

Equipment: The List of equipment required is given in Annex 11.

iii) Chloramphenicol

The requirement of chloramphenicol capsules during 1978 and 1979 is shown in Annex 2. From this it is observed that the current annual demand for chloramphenicol capsules of 250 mg amounts to about 1 million capsules. According to the demand projection, it will go up to about 2 million capsules within the next five years. As the demand is not significant, the premises and equipment described under Tetracycline could possibly be used after discontinuation of filling Tetracycline and after ensuring that there is no possibility of cross contamination due to any factor whatever.

iv) Technology for Encapsulation

The process for the granulation and filling of ampicillin (anhydrous) on the semi-automatic capsule filling machine was demonstrated in the Product Development unit. In all seven experimental batches were prepared and filled capsules met with B.P. tests for content of ampicillin, assay and disintegration. Other tests are in progress.

v) Based on the discussions of the recommendations with the management, the encapsulation project has been divided into three phases as indicated below along with the estimated cost of equipment:

Phase I Automatic filling of ampicillin capsules and bulk packing.

Semi-automatic filling of tetracycline and chloramphenicol capsules and bulk packing.

Improvised air conditioning in rooms. Minor additions to the laboratories.

Estimated cost of equipments US\$ 225,500.

Phase II Automatic strip packing of ampicillin capsules.

Automatic dedusting.

Additional facilities for the laboratories to take up systematic work.

Estimated cost of equipment US\$ 84,000.

Phase III Automatic strip packing of tetracycline and chloramphenicol capsules.

Installation of central air-conditioning equipment

Establishment of pharmacological laboratory on an experimental basis.

Estimated cost of equipment US\$ 382,700.

12. Pharmaceutical Products for Veterinary Use

The present requirements of pharmaceutical products for Veterinary use along with the anticipated requirements are indicated in Annex 12. The requirements in respect of non-parenteral antibiotics are rather small and these could easily be met from the facilities described under Chapter 11. Similar is the situation with regard to tablets which could be supplied from the existing production facilities.

13. Intravenous infusions, solutions and injectables

It can be seen from Annex 2 that there is a significant demand for intravenous infusions and solutions. There is also a sizeable demand for injectables but this covers a large number of products and the quantum required in the case of any particular product is rather small. GPC has recently carried out a feasibility study on intravenous fluids project. Based on going prices, the investment was found inefficient and the economic viability of the project was stated to depend on the export market. There could also be other considerations such as the attainment of self sufficiency in essential pharmaceutical products such as intravenous infusions. In view of this, it is recommended that GPC may consider taking up the production of intravenous infusions. This will enable them to build up the necessary infrastructure and skills to take up subsequently the production of injections in liquid as well as solid form.

The drug and chemical bond premises at Kingston appears to be suitable for locating the unit for the manufacture of intravenous infusions and injections.

14. Oral Rehydration Salts

The current requirement of Oral rehydration salts (O.R.S.) is stated to be about 25,000 standard packages per year. There could also be prospects for export to neighbouring countries. The production of O.R.S. is simple and consists of weighing, mixing and packaging of the pulverized components. All the raw materials and packing materials will have to be imported.

15. Other pharmaceutical products

- (a) Medicinal plants: GPC has undertaken experimental cultivation of thyme, lemon grass etc. on one acre plot.
- (b) Opootherapeutics from animal waste: Based on a recent UNIDO survey, the quantity of pancreas available in Guyana is not adequate to take up commercial production of insulin. In view of this, it is recommended that arrangements be made to deep freeze pancreas, export to neighbouring countries and receive in return crystalline insulin in bulk and formulate into dosage form.

ANNEX I

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

JOB DESCRIPTION

SI/GUY/78/801

Post Title: Pharmaceutical Adviser

Duration: 1 Month

Date Required: As soon as possible

Duty Station: Georgetown, Guyana

Purpose of Project: To evaluate the existing facilities for the production of pharmaceuticals and design of a new filling unit for antibiotics.

Duties: The expert, in co-operation with the Guyana Pharmaceutical Corporation Limited will carry out the following:

1. To evaluate the existing facilities in the Guyana Pharmaceutical Corporation Limited plant.
2. To study the production methods and quality control measures in G.P.C.
3. To review the quality and quantity of drugs being imported.
4. To prepare a list of antibiotics which could be produced locally.
5. To prepare a list of other drugs which could be produced in the available facilities.
6. Based on the above findings, the expert will prepare a design for the new antibiotics filling unit as well as prepare a list of equipment and other facilities required for the production of new items and to improve the technology of the existing products.

Qualifications:

Pharmacist, Chemist or Chemical Engineer, with extensive experience in production, establishment and quality control of antibiotics.

Language:

English

Background
Information:

The Guyana Pharmaceutical Corporation Limited (G.P.C.) has been under Government ownership and control for the last 15 months, during which time a National Drug Policy has been evolved, the principal features of which are the rationalization of the importation of drugs and the planned development of the local pharmaceutical manufacturing industry. GPC would like to use available natural resources for the production of drugs. Currently, tablets and golenicals are being produced by G.P.C. and they would like to take up the production of antibiotic formulations.

SCHEDULE OF WORK OF MR. C.N. CHARI

December, 1978	Arrival in Georgetown, Guyana
December 4, 1978	Discussions with officials of UNDP and GPC Review of existing facilities at GPC
December 5, 1978	Review of Quality Control, GPC
December 6, 1978	Review of facilities of GPC at La Penitence
December 7, 1978	Discussions with Technical Staff
December 9 - 22, 1978	Demonstration of the process of granulation and encapsulation of antibiotics in Product Development Unit Discussions on Proposed Lay-out
December 13, 1978	Visit to the Laboratory of Government Analyst and discussions on proposed layout of anti- biotic filling unit
December 15, 1978	Discussions with Technical Staff
December 21, 1978	Discussions with Resident Representative, UNDP
December 21, 1978	Discussions of Draft Terminal Report with Technical Staff
December 27, 1978	Departure from Georgetown

ANNEX 2

REQUIREMENT OF PHARMACEUTICAL PRODUCTS 11) ANTIBIOTICS

<u>Description</u>	<u>Pack Size</u>	<u>Tender 1978 Quantity</u>	<u>Tender 1979 Quantity</u>
Ampicillin Caps. 250 mg	500's	10,000 bots.	10,000 bots.
Ampicillin Caps. 500 mg	100's	3,000 bots	3,000 bots.
Doxycycline Hyd. Caps 100 mg	100's	60	
Tetracycline Hyd. Caps 250 mg	1000's	5,000	5,000 bots.
Erythromycin Caps. 250 mg	100's	20	
Lincomycin Hcl. Caps 500 mg	100's	500	500
Chloramphenicol Caps. 250 mg	1000's	1,000	1,000 bots.
Rifampicin Caps. 150 mg	100's	200	
Rifampicin Caps. 150 mg	1000's	50	
Cloxacillin Caps. 250 mg	100's	20	
Cloxacillin Caps. 250 mg	250's		20
Cephaloridine Caps. 250 mg	100's	100	
Cephaloridine Caps. 500 mg	100's	50	
Cephalexin Caps. B.P. 250 mg	100's	470	470
Cloxacillin Caps. 250 mg	500's		2,000 bots.
Amoxycillin Caps. 250 mg	500's		200 bots.

- 1) Source: Guyana Pharmaceutical Corporation Ltd; National Ordering Committee tender enquires for imported pharmaceutical products.

LIST OF ITEMS PURCHASED — CARICOM BULK PURCHASING
1979

1.	Ampicillin Capsules 250 mg	-	10,000 bcts. x 500
2.	Ampicillin Capsules 500 mg	-	3,000 bcts x 100
3.	Ampicillin Suspension 125mg/5ml	-	5,000 bcts. x 100 ml
4.	Ampicillin Suspension 250mg/5ml	-	Nil
5.	Ampicillin Injection 250 mg	-	12,000 vials x 5 ml
6.	Ampicillin Injection 500 mg	-	3,000 vials
7.	Tetracycline Capsules 250 mg	-	5,000 bcts. x 1,000 caps.
8.	Tetracycline Suspension 125mg/5ml	-	1,000 bcts. x 4.5 litres 6,000 bcts. x 60 ml
9.	Tetracycline Injection I.M. 100 mg	-	3,000 vials
10.	Tetracycline Injection I.V. 250 mg	-	Combination order as at 9 above
11.	Tetracycline Eye Ointment	-	2,500 tubes
12.	Tetracycline Eye Drops	-	1,000 vials
13.	Chlorpropamide Tablets 250 mg	-	4,000 bcts. x 1,000
14.	Diazepam Caps/Tabls 2 mg	-	800 bcts. x 500
15.	Diazepam Caps/Tabls 5 mg	-	1,000 bcts. x 100 2,000 bcts. x 500 1,000 bcts. x 1,000
16.	Diazepam Injection 5mg/ml	-	10,000 amps x 10 mg 10,000 amps x 20 mg
17.	Injection Procaine Penicillin 3 Mega Units	-	Not Required
18.	Injection Procaine Penicillin 4 Mega Units	-	100,000 vials
19.	Injection Procaine Penicillin 0.4 Mega Units	-	50,000 vials
20.	Soluble Penicillin G Sodium Injection 0.5 Mega Units	-	Nil
21.	Soluble Penicillin G Sodium Injection 1.0 Mega Units	-	50,000 vials
22.	Penicillin G Potassium Suspension 125mg/5ml	-	1,000 bcts. x 60 ml
23.	Penicillin G Potassium Suspension 250mg/5ml	-	Nil

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24.	Insulin Soluble 40 i.u/ml	- Nil
25.	Insulin Soluble 80 i.u/ml	- Nil
26.	Insulin Soluble 100 i.u/ml	- 15,000 vials x 10 mls
27.	Insulin Protamine Zinc 40 i.u/ml	- Nil
28.	Insulin Protamine Zinc 80 i.u/ml	- Nil
29.	Insulin Protamine Zinc 100 i.u/ml	- 1,500 vials x 10 ml
30.	Insulin Zinc Suspension (Lente) 40 i.u/ml	- Nil
31.	Insulin Zinc Suspension (Lente) 80 i.u/ml	- Nil
32.	Insulin Zinc Suspension (Lente) 100 i.u/ml	- 35,000 x 10 ml
33.	Insulin Zinc Suspension Semi-Lente 40 i.u/ml	- Nil
34.	Insulin Zinc Suspension Semi-Lente 80 i.u/ml	- Nil
35.	Insulin Zinc Suspension Semi-Lente 100 i.u/ml	- Nil
36.	Tablets Chlorpromazine 25 mg	- 500 bts. x 500
37.	Tablets Chlorpromazine 50 mg	- 2,000 bts. x 500
38.	Tablets Chlorpromazine 100 mg	- 2,660 bts. x 1,000
39.	Injection Chlorpromazine 50mg/2ml	- 12,500 vials
40.	Tablets Aspirin 300 mg	- Local
41.	Tablets Methyldopa 250 mg	- 2,000 bts x 1,000 150 bts x 100
42.	Tablets Frusemide 40 mg	- 1,000 bts x 250 500 bts x 1,000
43.	Injection Frusemide 20mg/2ml	- 1,000 bxs. x 5 amps.
44.	Chloramphenicol Caps. 250 mg	- 1,000 bts x 1,000
45.	Chloramphenicol Suspension 125mg/5ml	- 8,000 bts x 60 ml 300 bts x 4.5 litre
46.	Chloramphenicol Succinate Injection	- 1,500 vials
47.	Metronidazole Tabs. 200mg	- 500 bts. x 250
48.	Clordiazepoxide Caps/Tabs 5mg	- 2,000 bts. x 500

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49.	Chlordiazepoxide Caps/Tabs 10 mg	-	2,000 bots. x 500
50.	Chlordiazepoxide Caps/Tabs 25 mg	-	500 bots. x 1,000
51.	Bendofluazide Tablets 5 mg	-	500 bots. x 500
52.	Oral Polio Vaccine	-	1,500 vials x 20 dose vials
53.	Triple Vaccine (DPT)	-	5,000 x 10 ml vials
54.	Phenylbutazone Tabs. 100 mg	-	2,000 bots. x 1,000 1,000 bots. x 100
55.	Phenylbutazone Tabs. 200 mg	-	300 bots. x 100
56.	Dextrose 5% in Water 1000 ml	-	35,000 litres
57.	Dextrose 5% in Water 500ml	-	6,000 bags
58.	Dextrose 5% in Water 250ml	-	Nil
59.	Dextrose 4.3% Sod. Chloride 0.18% 1000 ml	-	Nil
60.	Dextrose 4.3% Sod. Chloride 0.18% 500 ml	-	550 bags
61.	Sodium Chloride 0.9% (Normal Saline) 1000 ml	-	29,000 bags x 1,000 ml
62.	Sodium Lactate Compound (Hartmann's Solution) 1000 ml	-	20,000 bags
63.	Sodium Lactate Compound (Hartmann's Solution) 500 ml	-	5,000 bags
64.	Sodium Lactate Compound (Hartmann's Solution) 250 ml	-	5,000 bags
65.	Dextrose 5% in Normal Saline 1000ml	-	30,000 bags
66.	Dextrose 5% in Normal Saline 500 ml	-	50 bags
67.	Tetanus Toxoid (Adsorbed)	-	25,000 vials x 10 ml
68.	Diphtheria and Tetanus Vaccine (D.T.)	-	1,500 vials x 10 ml
69.	Sodium Chloride 0.9% (Normal Saline) 500 ml	-	8,500 bags x 500 ml

2) INTRAVENOUS INFUSIONS and Solutions

<u>Description</u>	<u>Form</u>	<u>Size</u>	<u>Tender 1978 Quantity</u>	<u>Tender 1979 Quantity</u>
Dextrose 5% in water	Inj.	1000 ml 250 ml	35,000 12,000	
Dextrose 5% in 0.09 % Sodium Chloride	Inj.	1000 ml 500 ml	30,125 2,000	
Dextrose 10% in water	Inj.	500 ml bots.	7,500	
Dextrose 20% in water	Inj.	500 ml 50 ml	2,000 15,000	2,000 bags 5,000 amps.
Dextrose 50% in water (50 ml)	Inj.	50 ml bots.	1,500	
Normasol M 900 cal		1000 ml	440	
Potassium Chloride 20mg/10ml	Inj.	box of 5 Amps.	2,000	
Sodium Bicarbonate	Inj.	50 ml bots.	2,000	
Sodium Chloride 0.90 % (0.15 mm per ml)	Inj.	1000 ml 500 ml	29,000 0,750	
Normal Saline		250 ml 50 ml	1,000 500	
Sodium Lactate	Inj.	500 ml	4,000	
Sodium Lactate Compound	Inj.	1000 ml 500 ml 250 ml	3,750 12,500 12,500	
<u>Combination:</u>				
Sodium Lactate 0.29-0.33% W/V	Inj.	1000 ml.	1,250	1,250 bags
Calcium Chloride 0.018 - 0.022 W/V		500 ml	2,500	
Potassium Chloride 0.027 - 0.33% W/V		250 ml	1,250	
Sodium Chloride 0.57 - 0.63 % W/V		250 ml		1,500 bags

<u>Description</u>	<u>Form</u>	<u>Size</u>	<u>Tender 1978</u> <u>Quantity</u>	<u>Tender 1979</u> <u>Quantity</u>
Water for Injection - Sterile	Inj.	2 ml Amps.	25,000	
		5 ml Amps	30,000	
		10 ml Amps	50,000	
		20 ml Amps	30,000	

<u>Description and Pack Size</u>	<u>Tender 1978 Quantity</u>	<u>Tender 1979 Quantity</u>
Dextrose 5% in water in 500 ml bags	1000 bags	6,000 bags
Dextrose 5% N/S in 500 ml bags	50 bags	50 bags
Half Strength Darrows Solution 500 ml	3,000 bags	6,000 bags
Full Strength Darrows Solution in 1 L	4,000 Litres	4,000 Litres
Dextrose 5% in water in Litres	18,000 Litres	35,000 Litres
Dextrose 5% in Normal Saline in Lits.	7,500 Litres	30,000 Litres
Dextrose 5% in Normal Saline in 500 ml		2,000 L Bags
Dextrose 5% in Normal Saline 0.45%	1,000 Litres	2,000 L Bags
Dextrose 20% in water in Litres	1,200 Litres	1,200 bags
Dextrose 10% in Normal Saline	500 Litres	1,200 L bags
Dextrose 50% in water X 500 mls	1,200 bts.	1,200 bags
Dextrose 10% in water X 1000 mls	1,200 Litres	1,200 L bags
Dextrose 10% in water X 500 mls		2,500 bags
Sodium Chloride 0.18% X 1000 mls	50 Litres	50 bags
Dextrose 4.3% in N/Saline 0.18%	1,500 Litres	
Dextrose 4.3% in N/Saline X 250 ml		10,000 bags
Dextrose 4.3% in N/Saline X 500 ml		500 bags
Sodium Chloride 0.9% X 1000 mls	25,000 Litres	29,000 bags
Sodium Chloride 0.9% X 500 mls	500 bags	8,500 bags
Sodium Chloride 0.9% X 250 mls		1,000 bags
Sodium Chloride 0.9% X 50 mls		500 bags
Sodium lactate 1/6 Molar X 1000 mls	100 Litres	1,000 L bags
Sodium Lactate 1/6 Molar X 500 mls		100 bags

INJECTABLES IMPORTED THROUGH N.L.C.C. TENDER (1978)

<u>INJECTABLES</u>		<u>QUANTITIES</u>
Digoxin Injection	- 0.5 mg	2,500 amps.
Glyceryl Trinitrate	- 20 mg	100 amps.
Propranolol Hcl.	- 1 mg/ml	150 amps.
Sodium Nitropruside BP		500 amps.
Hydralazine	- 20 mg	1,250 amps.
Meteraminol Bitartrate	- 10 mg	150 boxes x 12 amps.
Noradrenaline	- 4 mcg	150 boxes x 6 amps.
Nikethamide		10 boxes x 100 amps.
Aminophylline	- 250/10 ml	6,000 amps.
Ephedrine Injection BP		56 boxes x 100
Phenylbutazone Injection		250 amps.
<u>Combination:</u>		
Ergotamine Tartrate		
Caffeine Hydrate 100 mg		100 boxes x 100 amps.
Cyclizine Hcl. 50 mg		
(eg. Cafergot, Migril)		
Chlorpromazine Hcl.	- 50 mg/2ml	12,500 amps.
Diazepam	- 10 mg	24,000 amps.
Diazepam	- 20 mg	10,000 amps.
Fluphenazine Decanoate	- 25 mg/ml	1,250 vials
Prochlorperazine Maleate	- 12.5 mg	200 boxes x 10 amps.
Trifluoperazine	- 1 mg/ml	600 amps.
Cloxacillin	- 250 mg	400 vials.
Methicillin	- 1 g/vial	9,000 vials,
Procaine Penicillin	- 2 mega Unit/ vial	20,000 vials
Procaine Penicillin	- 4 mega Unit	100,000 vials
Procaine Penicillin	- 0.4 mega Unit	500 vials x 50 vials.
Seclomycin		6,000 vials.
Triolonen		10,000 vials
Carbenicillin	- 1 g	200 vials
Genorin	- 1 g vial	400 vials.
Kanamycin Sulphate	- 1 g/2 ml	1,000 vials.

<u>INJECTABLES</u>		<u>QUANTITIES</u>
Streptomycin Sulphate	- 1 g	400 x 25's
Oxytetracycline	- 100 mg/ IM/IV Inj.	900 vials.
Tetracycline Hcl.	- 100 mg/IM/IV	5,000 vials
Chloremphenicol Inj.	- 1 g	1,500 vials
Chloroquine Phosphate		125 amps.
Quinine Dihydrochloride	- 300 mg	190 amps.
Dimercaprol	- 50 mg/m/2ml	300 boxes x 10 amps.
Penicillamine		100 vials
Pralidoxine Mesylate	- 1 g/20 ml	3,000 vials
Promazine Hyd.	- 100 mg/2 ml	4,000 amps.
Peraldehyde	- 5 mls	200 amps.
Dimenhydrinate	- 50 mg/1 ml	702 amps. x 5 c.c.
Phenytoin Sodium	- 250 mg/5 ml	1,000 amps.
Phenobarbitone Sodium	- 25 mg/1 ml	4,000 amps.
Senztropine Mesylate	- 2 mg	500 amps.
Gallamine Triethiodide		800 boxes x 10 ml
Orphenadrine Citrate	- 100 mg	2,004 amps.
Suxamethonium Bromide	- 67 mg/vial	6,000 amps.
Suxamethonium Bromide	- 335 mg/vial	2,000 amps.
Scoline Injection	-	2,000 amps.
Neostigmine Methylsulph	- 0.5 mg/ml	400 amps.
Neostigmine Methylsulph	- 2.5 mg/ml	1,800 amps.
Atropine Sulphate	- 600 mcg/ml (1ml amps)	20,000 amps.
Atropine Sulphate	- 600 mcg/ml (10 ml amps)	10,000 amps
Kelamine Hyd.	- 10 mg/ml	350 vials.
Kelamine Hyd.	- 50 mg/ml	1,000 vials.
Methohexiton Sodium	- 50 mg/vial	300 vials
Thiopentone Sodium	- 5 g/vial	1,500 vials
Thiocentone Sodium	- 1 g/vials	1,500 vials
Lignocaine Inj. - Plain 1/2	- 30 m/vial	4,000 vials
Methotrexate	- 20 mg/vial	150 vials

<u>INJECTABLES</u>	<u>QUANTITIES</u>
Dexamethasone - 5 mg/ml IV	3,400 vials
Hydrocortisone - 100 mg	20,000 vials
Hydrocortisone - 250 mg	5,687 vials
Hydrocortisone Intra Articular	500 vials
Insulin Soluble - Beef - 100 U/ml	10,000 vials
Insulin Soluble - Pork - 100 U/ml	5,000 vials
Insulin Protamine Zinc - 100 U/ml	1,500 vials
Insulin Zinc Susp. (Lente)- 100 U/ml	36,000 vials
Sulphated (Insulin High Purified)	1,000 vials
Ampicillin Injection - 250 mg/5ml vial	11,500 vials
Ampicillin Injection - 500 mg	5,600 vials
Ampiclox - 500 mg	2,500 vials
Ampiclox Neo Natal	900 vials
Benzathine Penicillin G - 1.2 mega U/vial - 4 ml	3,000 vials x 50
Benzathine Penicillin G - 2.4 mega U/vial - 4 ml	10,000 vials x 50
Benzathine Penicillin G - 6.33	4,000 vials x 50
Benzyl Pencillin G - 1 mega U/vial	50,000 vials
Lignocaine 1% with Adrenalin - 30 ml vials	2,000 vials
Lignocaine 2% Plain - 30 ml/vial	6,000 vials
Lignocaine 2% with Adrenalin - 30ml vials	4,000 vials
Lignocaine 4% - 30 ml/vails	300 vials
Octocaine Inj. 2% - 1.8 cc Tube	8,000 tins x 50 cartridges
Octocaine Inj. 2% with Epinephrine - 1 - 100,000	8,000 tins x cartridges
Tubcurarine Chloride - 15 mg/ml	6,000 amps.
Gonaplex - 10 cc Inj.	1,000 vials
Conjugated Estrogens - 25 mg	250 vials
Hydroxy Progesterone Hexanoate - 25 mg/ml	3,000 amps.
Ergometrine Maleate - 500 mcg/ml	750 boxes x 100 amps.
Oxytocin (Pitocin Cytocinon - 10 U/ml	100 boxes x 100 amps.

INJECTABLES

QUANTITIES

Combination:

Ergometrine Maleate - 500 mcg Oxytocin - 5 U/ml (ec. Syntonetrine)	500 boxes x 100 amps.
Fruzenide - 10 mg/ml	13,000 amps
Calcium Gluconate - 10% W/V 5 ml amps	5,600 amps.
Calcium Gluconate - 10% W/V 10 ml amps 10% W/V	11,260 amps.
Heparin Sodium - 5,000 U/10 ml	300 amps.
Heparin Sodium - 10,000 U/ml	380 amps.
Heparin Sodium - 25,000 U/ml	550 amps.
Phytomenadione - 10 mg/ml amps.	7,500 amps.
(eg. Phytomenadione - 1 mg/ml amps.	5,000 amps.
Human Fibrogen - 1 g	133 bots.
Protamine Sulchate - 50 mg/5ml	200 amps.
Potassium Chloride - 20 mg/10 ml	2,000 boxes x 5 amps.
Sodium Bicarbonate - 50 ml	500 vials
Water for Injection - 2 ml amps.	25,000 bots.
Water for Injection - 5 ml amps.	10,000 bots.
Water for Injection - 10 ml amps.	10,000 bots.
Water for Injection - 20 ml amps.	10,000 bots.
Methyl Prednisolone Acetate (Depo Medral) - 5 m/vials	1,250 vials
Methyl Prednisolone Acetate (Intra Articular) - 5 ml	100 vials
Calcium Folinete - 3 mg/ml	50 boxes x 6 amps.
Cyclophosphamide - 100 mg/vial	300 vials
5 - Fluorouracil - 250 mg/5ml	100 amps.
Tuberculin (PPD) (Contains 2 T.U. - 0.1 m in 20 ml vials)	10 pkts. x 25 vials.
Tuberculin (PPD) (Contains T.U. 100,000 1 ml vials)	75 vials
Chlorpheniramine Maleate - 10 mg	175 boxes x 100's

<u>INJECTABLES</u>		<u>QUANTITIES</u>
Adrenalin EP	1-1,000 amps/1.0 ml	35,000 amps.
Morphine	- $\frac{1}{2}$ gr	200 amps.
Morphine	- $\frac{1}{4}$ gr	100 amps.
Pethidine	- 1 ml/50 mg : amps.	1,000 boxes x 100 amps.
Pethilorphan	- 1.25 mg - 1 ml amp	1,000 boxes x 100 amps.
Pethidine	- 2 ml/100 mg	600 boxes x 100 amps.
Pethilorphan	- 2 ml amps	1,000 boxes x 100 amps.
Nepenthe	- 15 mls	50 vials x 15 mls
Nepenthe	- 0.5 mls	80 boxes x 5 amps.
Diemorphine Hyd. Inj.	- 5 mg	40 boxes x 5 amps.
Hyoscine Butylbromide	- 20 mg/ml (30 amps bxs)	1,200 amps.
Hyoscine Butylbromide	- 20 mg/ml (6 amps box)	5,490 amps.
Propantheline Bromide	- 30 mg/ml (25 amps box)	3,750 amps
Alupent Inj.	-	6,000 amps.
Amylobarbitone Sodium	- 50 mg/vial	1,000 amps.
Baralgin Inj.	- 5 ml (5 amps box)	5,000 amps.
Carbachol	- 0.25 mg/ml (5 amps box)	1,800 amps.
Carbachol	- 2.5 mg/ml (5 amps box)	5,000 amps.
Methoxyprogesterone Acetate (Decot Provera)	- 150 mg/ml	3,000 amps.
Primodos Forte		3,000 amps.
Progesterone	- 10 mg/ml (100 amps box)	600 amps.
Progesterone	- 10 mg/ml (100 amps box)	600 amps.

<u>INJECTABLES</u>		<u>QUANTITIES</u>
Cynocobamine	- 100 mcg (1 ml amps.)	4,000 amps.
Cynocobamine	- 1000 mcg 10 ml amps.	4,000 amps.
Iron Dextran Complex	- 50 mg/ml 20 mls	3,750 amps.
Iron Dextran Complex	- 50 mg/ml 5 mls	12,500 amps.
Iron Dextran Complex	- 50 mg/ml 2 mls	10,000 amps.
Thiamine Hcl.	- 50 mg/ml	5,000 amps
Thiamine Hcl.	- 100 mg/ml	5,000 amps.
Vit. B Complex (Parentrovite) H.P./I.V		1,200 prs. amps.
Vit. B Complex (Parentrovite) H.P./I.M		1,560 prs. amps.
Vit. B Complex (Parentrovite) Maintenance I.M		2,000 prs. amps.
Actinomycin D	- 0.5 mg	150 vials
Cytosine Arabinoside	- 100 mg	300 amps.
Rubidomycin Hcl.	- 20 mg	150 vials
Thiotepa	- 15 mg	150 vials.
Vincristine Sulchate	- 10 mg	150 vials
Vinblastine Sulchate	- 10 mg	150 vials
Testosterone Proopionate	- 10 mg	750 amps.
Testosterone Propionate	- 25 mg	750 amps.
Testosterone Propionate	- 50 mg	750 amps.
Erythromycin (E. Mycin)	- 50 mg/ml	300 vials
Lincomycin Hcl.	- 500 mg/2 ml	2,000 amps.
Gentamycin Sulchate I.M	- 40,000 U/ 5 mls	100 vials
Amphotericin B	- 10 mls	100 vials

5) Insulin

<u>Description</u>	<u>Form</u>	<u>Pack Size</u>	<u>Tender 1978 Quantity</u>
Insulin Soluble (Beef)	Inj.	Vials	8,000
Insulin Soluble (Pork) 100 v/ml	Inj.	Vials	1,500
Insulin Protamin Zinc	Inj.	Vials	36,000
Insulin Zinc Suspen. (lentg) - 100 v/ml	Inj.	Vials	10,000
Insulin High Purified	Inj.	Vials	

ANNEX 3

Ethical Medical Products in the Manufacturing Range of GPC

ITEM	POTENCY	UNIT PACKING
Aspirin Tabs. B.P.	300 mg	1000's bot.
Aspirin Tabs. B.P. Pink	300 mg	1000's bot.
Aspirin Tabs. B.P. Yellow	300 mg	1000's bot.
Aspirin-Codeine Tabs. B.P.	400 mg Aspirin, 8 mg Codeine Phosphate	1000's bot.
Aspirin-Caffeine Tablets B.P.	350 mg Aspirin; 30 mg Caffeine	1000's bot.
Becotabs (Vitamin B Tabs. Compound B.P.C.)	1 mg Thiamine Hydrochloride; 1 mg Riboflavine 15 mg Nicotinamide	2000's bot.
Becoforte Tabs. (Vitamin B Tabs. Compound, Strong B.P.C.)	5 mg Thiamine Hydrochloride; 2 mg Riboflavine 2 mg Pyridoxine Hydrochloride; 20 mg Nicotinamide	2000's bot.
Citrovite	Each 5 ml contains 3000 i.u. Vitamin A 800 i.u. Vitamin D 5 mg Vitamin B ₁ 1 mg Riboflavine 0.5 mg Pyridoxine Hydrochloride 10 mg Nicotinamide 50 mg Ascorbic Acid	2 L bot.
Ephedrine hydrochloride Tablets B.P.	30 mg	1000's bot.
Ephedrine Hydrochloride Tablets B.P.	60 mg	1000's bot.
Folic Acid Tabs. B.P.	5 mg	500's bot.
Magnesium Trisilicate Compound B.P.C.	250 mg Magnesium Trisilicate; 120 mg Dried Aluminium Hydroxide Gel	500's bot.
Paracetamol Tabs. B.P.	500 mg	1000's bot,

ANNEX 3

Ethical Medical Products in the Manufacturing Range of GPC

ITEM	POTENCY	UNIT PACKING
Pectolin	Each 30 ml contains 6.5 mcg Hyoscine Hydrobromide 103.2 mcg Hyoscyamine Sulphate 19.3 mcg Atropine Sulphate 16.2 mg Phenobarbitone 6.0 g Light Kaolin	150 ml bot. 2 L bot.
Pectomycin	Each 30 ml contains 255 mg Streptomycin Sulphate 2.1 g Sulphaguanidine 6.5 mcg Hyoscine Hydrobromide 103.2 mcg Hyoscyamine Sulphate 19.3 mcg Atropine Sulphate 16.2 mg Pheno- barbitone 6.0 g Light Kaolin	150 ml bot. 2 L bot.
Phenobarbitone Tablets B.P.	30 mg	1000's bot.
Phenobarbitone Tablets B.P.	60 mg	1000's bot.
Fipercite (Piperazine citrate Elixir B.P.C.	750 mg Piperazine hydrate per 5 ml	2 L bot.
Prednisolone Tablets B.P.	5 mg	100's bot.
Sulphadiazine Tablets B.P.	500 mg	1000's bot.
Sulphadiazine Tablets B.P.	500 mg	1000's bot.
Sulphaguanidine Tablets B.P.C.	500 mg	500's bot.
Vitamin B ₁ Tabs B.P.	3 mg	2000's bot.
Vitamin B ₁ Tabs B.P.	10 mg	2000's bot.

PROPRIETARY MEDICINES AND TOILETRIES IN THE MANUFACTURING RANGE OF GPC

<u>PRODUCTS</u>	<u>SIZE</u>	<u>NORMAL PACKING - DOZS</u>
Alcosulph Cream	42 gm	1
Alcosulph Lotion	2 oz	3
Alcosulph Lotion	4 oz	3
Ferrol Compound	6 oz	2
Ferrol Compound	16 oz	1
Ferrol Plain	6 oz	2
Ferrol Plain	16 oz	1
Nutrophos	6 oz	2
Nutrophos	16 oz	1
Children's Whizz	150's	3 1/3
Whizz Co. Tabs.	25's	3
Whizz Co. Tabs.	200's	40 boxes
Codol Compound	6 oz	2
Codol Compound	16 oz	1
Buckleys J & J Rub	1 oz	16
Buckleys J & J Syrup	100 ml	3
Buckleys Mixture	100 ml	3
Buckleys Mixture	200 ml	3
Buckleys White Rub	25 gm	12
Buckleys White Rub	60 gm	6
Canadian Healing Oil	2 oz	3
Beef, Iron & Wine	6 oz	2
Beef, Iron & Wine	16 oz	1
Dr. John's W.P. C/Syrup	2 oz	3
Ractor's R/Worm Rem.	1/2 oz	3
Shoo	100 ml	3
Radway's Ready Relief	2 oz	3
Mustacreme	2 oz	3
Robert's Cough Syrup	6 oz	2
Robert's Cough Syrup	100 ml	3
Robert's Baby C/Syrup	100 ml	3
Kellogg's Asthma Rem.	1 1/2 oz	3

<u>PRODUCTS</u>	<u>SIZE</u>	<u>NORMAL PACKING - DOZS</u>
Pectolin	100 ml	3
"	2 lt	$\frac{1}{2}$
Shielding Oil	2.5 cc	3
" "	10 cc	2
Vitone Plus	6 oz	2
" "	16 oz	1
Pipercite	100 ml	3
Viking	150 ml	3
"	300 ml	2
Livogen	150 ml	2
"	300 ml	1
Limacol Talc Powder	70 gm	

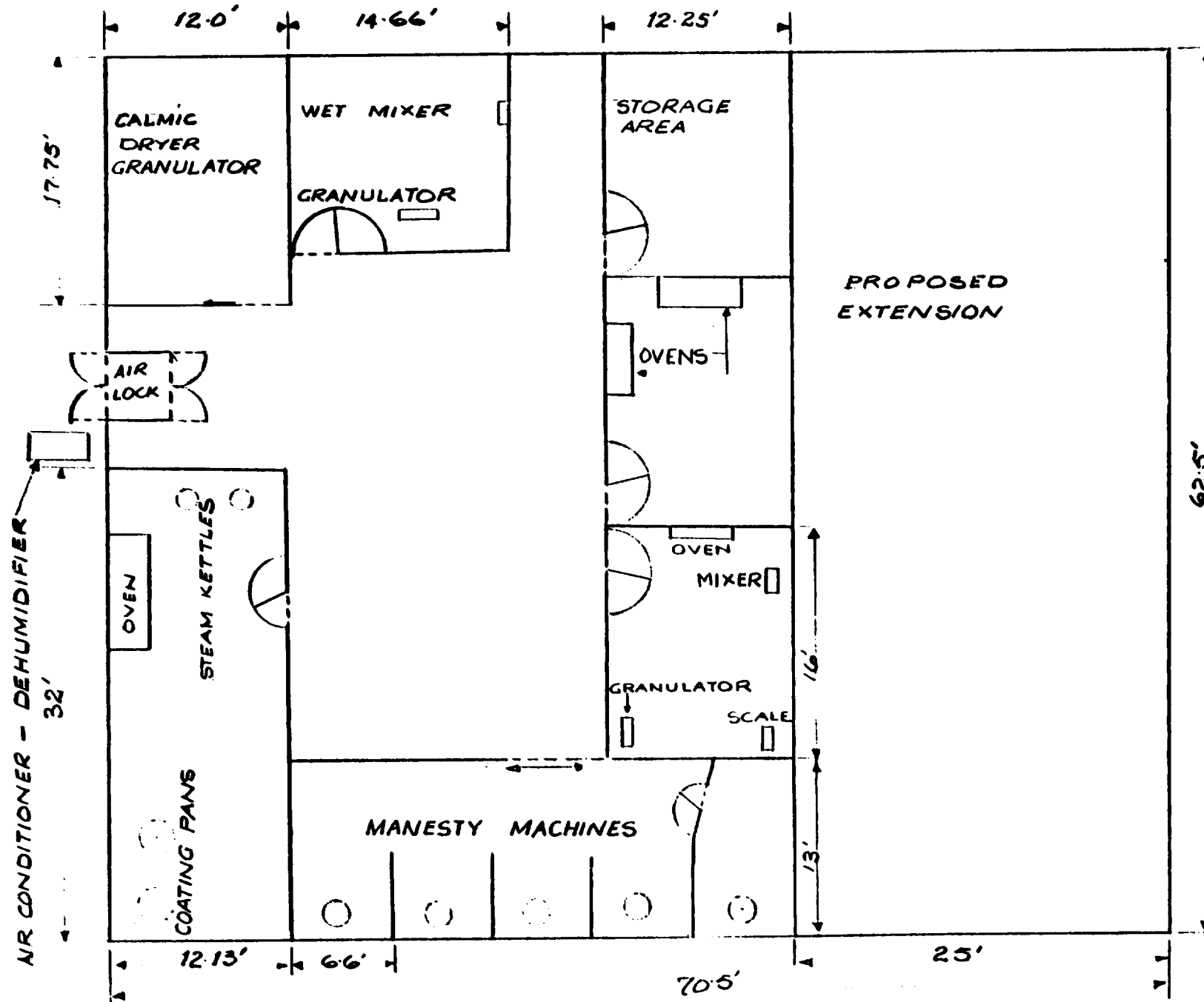
VERIPURE ESSENCES

Essence Almond	100 ml	3
" "	6 oz	2
" "	2 lt	$\frac{1}{2}$
Essence Mixed	100 ml	3
" "	6 oz	2
" "	2 lt	$\frac{1}{2}$
Essence Pear	100 ml	3
" "	6 oz	2
" "	2 lt	$\frac{1}{2}$
Essence Pine	100 ml	3
" "	6 oz	2
" "	2 lt	$\frac{1}{2}$
Essence Vanilla	100 ml	3
" "	6 oz	2
" "	2 lt	$\frac{1}{2}$
Vanco Vanilla Conc. (1-7)	2 lt	
Vanco Vanilla Conc. (1-7)	45 gin	

<u>PRODUCTS</u>	<u>SIZE</u>	<u>NORMAL PACKING - DBZS</u>
Bay Rum Plain	300 ml	2
Limacol Plain	100 ml	3
" "	250 ml	2
" "	500 ml	1
Limacol Mentholated	100 ml	3
" "	250 ml	2
" "	500 ml	1
Limacol Stick Deodorant	60 gm	3
" " "	55 gm	1
Smell - G - Pine	2 oz	3
"	100 ml	3
"	300 ml	2
"	500 ml	1
"	2 lt	$\frac{1}{2}$
"	45 gln	
Industrial Pine Dis.	45 gln	
Methylated & Surgical Spts.	45 gln	
" " "	under 45 gln	
" " "	80 oz	
" " "	2 lt	

ETHICAL MEDICAL PRODUCT TABLETS PRODUCED by GPC in 1977

<u>PRODUCT</u>	<u>QUANTITY</u>
Becotabs Forte	764,000
Becotabs Mild	1,936,000 + 4,713,000
Children's Aspirin	226,650
Sulphadimidine	8,625,000
Codeine Aspirin Tabs.	3,775,000
Phenobarbitone Tabs. 60 mg	2,018,500
Aspirin Tabs.	8,389,000
Antacid Tabs.	762,000
Paracetamol Tabs.	2,566,000
Oxytetracycline	336,000 - Film Coated
Whizz (Analgesic without Codeine)	154,240
Whizz (Analgesic with Codeine)	14,093,575
Senatogen Tabs.	1,691,640 Sugar Coated
Prednisolone 5 mg	388,700
Ascorbic Acid 300 mg	360,000
Sulphaguanidine	677,000
Total	<u>51,476,305</u>



SCALE: 1 IN. REP. 9 FT.

DIAGRAM SHOWING LAYOUT OF TABLET DEPARTMENT

ANNEX 7

LIST OF EQUIPMENTS IN TABLETTING DEPARTMENT OF GPC

<u>Description</u>	<u>Quantity</u>	<u>Capacity</u>
Manesty 16 head Tablet Machine	5	125 m/year
Dry Powder Mixers	3	45 kg each
Wet Mixers	1	45 kg
Rotorgran (Granulators)	2	20 /hr
Comminuting Mills	2	60 kg/hr
Drying Ovens	3	60 kg each
Foiling Machines for Tablets	2	15,000 /hr each
Tablet Counter/Filler	1	Variable speed.
Coating Pans for Sugar Coating	2	225,000 per operation
Celmic - Granulator/Film Coating Machine	1	Variable

List of Equipments in Liquids Department of GPC

<u>Description</u>	<u>Quantity</u>	<u>Capacity</u>
Fibre Glass Mixing Tanks	2	3,700 Litres each
" " " "	2	2,500 " "
Stainless Steel Mixing Tanks	2	4,000 " "
" " " "	6	1,200 - 1400 Litres each
" " " "	2	2,500 Litres each
" " " "	4	360 " "
Glass Lined " "	12	360 " "
Syrup Filter Meta Filter	1	200 L/hr
Disc Type Filters (Seitz Werke & Farrow Jackson)	6	Variable
S/S Pumps	2	800 L/hr
Vortex Mixer (Peter Silver & Sons)	3	Stainless Steel
Guisti Mixers	4	" "
Demineralit Plant (Beioniser)	1	for water treatment
Steam Jacketed Kettles	6	60 kg - 300 kg

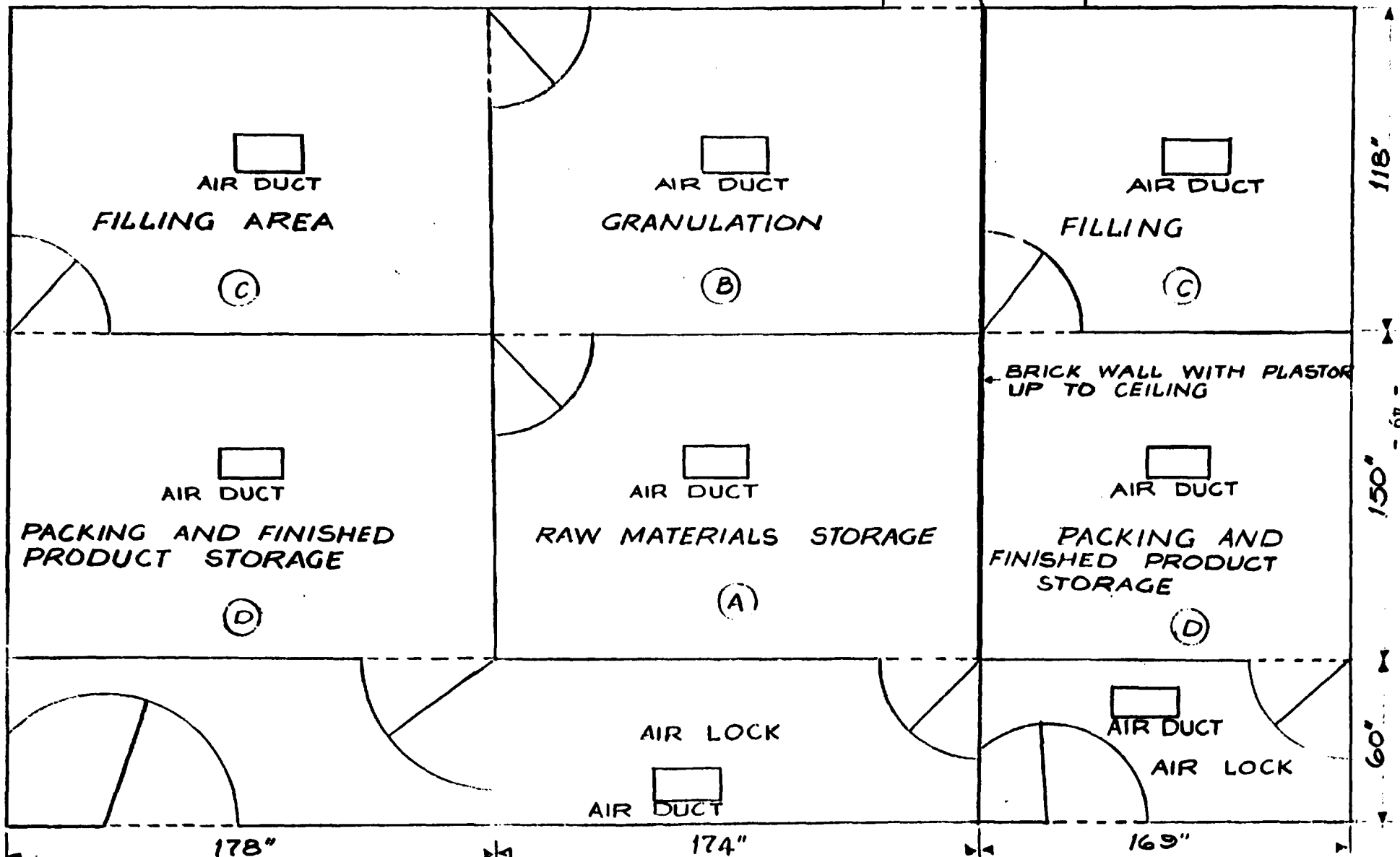
ANNEX 8

Additional facilities required for
Product Development

<u>DESCRIPTION</u>	<u>QUANTITY</u>	<u>Price FOB/US\$</u>	<u>Phase</u>
pH meter Beckman	1	1,000	I
Polarimeter	1	3,000	
Colorimeter, electric. Coleman	1	2,000	
Laminar flow cabinet	1	6,000	I
Laboratory autoclave horizontal 1/2m ³ , rectangular	1	3,000	
Millipore or sartorius for sterility	1	3,000	I
Large incubator for sterility and other tests 75 x 65 x 100 cm	1	2,000	
Small incubators 50 x 40 x 40 cm, to be used at various temperatures from 15-80°C	2	2,000	
Oven for dry heat sterilization, medium size	1	1,500	
rough balance, range 0.1 - 700 g, with compensation tare	1	500	
Hand filling capsule machine (Bonapace)	1	4,000	
Tablet machine for laboratory. Erweka with punches of different diameter 6-13mm, flat and concave	1	12,000	I
Experimental coating pan, stainless steel, complete with accessories (monesty)	1	1,500	III
Mixer, stainless steel, for pastes, small size, laboratory type, Erweka	1	3,000	
Ointment tube filling machine by hand, Erweka	1	4,000	
Constant temperature laboratory ovens ranging up to 150°C	1	1,000	
Muffle furnace (up to 2000°C)	1	2,500	III
Climatic chamber capable of giving different degrees of temperature and humidity to be varied according to requirements in carrying out accelerated stability tests	1	18,000	I
Tablet hardness tester, Erweka	1	3,000	
Unit for testing of pyrogen complete with rectal electrodes (12) to be used for rabbits	1	25,000	III
Cages for mice, stainless steel	1 unit	2,000	
Cages for rabbits	10	1,500	III
Movable carriers for cages for rabbits each for 3 cages	1	100	III
Movable carriers for cages of mice each for 10 cages	1	100	III
Homogeniser	1	3,000	

Annex 9

EMERGENCY EXIT →



DRAWING SHOWING NEW ARRANGEMENT OF CAPSULING ROOMS.

0 12 24 36 48 96 144
SCALE IN INCHES

LIST OF EQUIPMENT REQUIRED FOR ENCAPSULATION
OF AMPICILLIN

(Capacities indicated in the report)

<u>Description</u>	<u>Quantity</u>	<u>Price 1/ FOB/US\$</u>	<u>Pha</u>
1. Mixer Reference - cadmach, Ahmedabad, India - Manesty, Liverpool, U.K.	1	10,000	.
2. Oscillating granulating machine with a complete set of stainless steel sieves	1	8,000	
<u>References</u>			
- Manesty Machines, Liverpool			
- Erweka granulating machine Erweka apparate ben GMBH D - 6056 Hensenstamm Ottostrasse 20-22 P.O. Box 1326, W. Germany			
- Cadmach, Ahmedabad, India			
3. Double cone mixer for dry powders	1	18,000	II
<u>References</u>			
- Turbula Mixer, Model "Schatz" Willi A. Bachofen, Basel 5 Switzerland			
- Morandi, Italy via) Nicole d'Apulia 10 - 20/25 MILANO			
- Messrs. Metzsch Fiennal technik GMBH D - 8672 SELB, W. Germany			
Jorgen Jorgensen, Maskinfabrik A/S 65 Prags Boulevard 2300 Copenhagen 8 Denmark			
4. Automatic hard gelatin capsules filling, output 150 capsules/min (compression filling with accessories for filling other sizes		20,000	.
<u>Reference</u>			
- Zanasi Franco Nigris and Co via Settembrini 1-Milano cadmach Ahmedabad, India			

1/ Prices are approximate and are based on the value of US\$ in June 1978.

<u>Description</u>	<u>Quantity</u>	<u>Price</u> ^{1/} <u>FOB/US\$</u>	<u>Phase</u>
5. Automatic dedusting and polishing machine for hard gelatine capsules - Erweka	1	8,000	II
6. Vacuum shelf dryer with accessories and vacuum pump - Manesty	1	30,000	
7. Strip Sealing Machine - Uhlman Joseph Uhlman AG Fabrik Moderner Verpackungs Machinen 7958 Landohein, W. Germany Postfach 380, Uhlandstrasse - 12	1	50,000	II
- Holfiger and Karg Waiblingen bei Stuttgart, W. Germany			
- Strunk and Co. Colonne, W. Germany			
8. Platform scale range up to 100 kg	1	6,000	
Pan balance 10 kg	1		
Pan balance 1 kg	1		
<u>Reference</u>			
- Avery, London, U.K. - Bizerba - Waagen GmbH and Co. K.G. A - 1232 WIEN, Mosati gasse Postfach 67, Austria			
9. Mortar and pestle - 1 Kg capacity	1	500	
10. Semi-Automatic capsule filling machine (300 capsules) for hard gelatin capsules (in lieu of automatic capsule filling machine)	2	5,000	
With built-in electromagnetic vibrator with opening and closing devices for capsules, along with change parts for 4 sizes of capsules			
- Dott Bonapace, Italy - Associated capsules, Bombay, India			
11. Electrical batch counter for filling capsules 25 - 1000 pieces - King Co. U.K.	1	5,000	
12. Air showers, class 100	2	10,000	
13. Air conditioning and humidity control unit (Room air conditioners)	1	150,000 (10,000)	III I

1/ Prices are approximate and are based on the value of US\$ in June 1978.

List of Equipments required for
Encapsulation of Tetracycline Hydrochloride

(Capacity indicated in the report)

<u>Description</u>	<u>Quantity</u>	<u>Prices</u> ^{/1} <u>FOB/US\$</u>	<u>Phase</u>
1. Mixer - Blender	1	10,000	
<u>Reference</u>			
- Manesty,			
- Cadmach	1		
2. Oscillating granulating machine with a complete set of stainless steel sieves.	1	8,000	
<u>References</u>			
- Manesty			
- Erweka			
- Cadmach			
3. Semi-automatic capsule filling machine, 300 sockets for hard gelatin capsules with built-in electro-magnetic vibrator with opening and closing devices for capsules and change parts for 4 sizes of capsules.	2	5,000	
- Dott Bonapace			
- Associated Capsules.			
4. Automatic dedusting and polishing machine for capsules.	1	8,000	II
- Erweka			
5. Strip sealing machine	1	50,000	III
- Uhlman			
- Hofliger and Kerg			

REQUIREMENTS OF PHARMACEUTICAL PRODUCTS FOR VETERINARY USEa) Present Requirements

<u>Description</u>	<u>Dosage</u>	<u>Quantity</u>
<u>Antibiotics:</u>		
Tetracyclines	250 mg & 500 mg Caps.	10,000 each
Ampicillin	- do -	10,000 "
Chloremphenicol	- do -	10,000 "
Streptomycin		
<u>Sulfas</u>		<u>1 Annum</u>
Sulfadimidine	0.5 gms & 5 gms	20,000 & 15,000
Sulfaguanidine	- do -	20,000 & 10,000
Sulfamezathene	- do -	30,000 & 8,000
Sulfathalazole	- do -	20,000 & 5,000
Sulfaguinoxaline Soluble		1,200 lbs
Sulfatriads	- do -	20,000 & 12,000
Sulfanilamide Powder		1,200 lbs
Sulfamezathene Soln.	12.5% & 33%	200 gals each
<u>Antibiotics / Sulfas Combinations</u>		
Chloremphenicol / Sulfa	0.5 gm & 5 gm	
Sulfa / Strec	- do -	

b) Anticipated Requirements

<u>Antibiotics</u>	<u>Strength</u>	<u>Quantity Annam</u>
Tetracyclines	50 & 100 mg/ml	100,000 ml
Chloremphenicol	100 & 250 mg/ml	90,000 ml
Ampicillin	100 & 200 mg/ml	100,000 ml
Streptomycin	50 & 100 mg/ml	3,000 x 1 dose vials.
Penicillin	300,000 iu/ml	5,000 x 1 dose vials.
Fen / Strep	300,000 iu + 5mg/ml	50,000 ml

Sulfas

Suorenil (Sulfamezathene)	25%	200 x 30 ml bts.
Sulfa + Chloremphenicol	?	500 x 50 ml bts.



