CHAPTER 4 BASIC DESIGN

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4.1 Design Principle

In general, the GMP (Good Manufacturing Practice) is well known as one of the guidelines for planning or designing pharmaceutical manufacturing plants. This practice is originally purposed to provide requirements for manufacturing quality products in any field. In Japan, however, it is applied particularly to manufacture of pharmaceuticals including facilities, operative management and quality control. This does not only comply with the resolution of WHO, but goes with the world tendency. Viewed from the above, it is considered essential to design this projected Formulation Centre in Sri Lanka with due consideration for the concept of the GMP. The GMP provides that pharmaceutical facilities shall be designed mainly with the following two in mind.

(1) Consideration for layout

(2) Consideration for materials and construction/installation thereof

To establish the satisfactory layout plan, consideration will be given at least to the following.

a. To prevent cross contamination between the penicillin manufacturing zone and the general drugs manufacturing zone.

b. To house each process line of production equipment in a separate room so as to prevent cross contamination due to simultaneous manufacture of many kinds of pharmaceuticals.

c. To ensure cleanliness by appropriate installation of air-conditioning system and provide buffer zones (e.g., air shower room, pass room) to prevent direct air flow between manufacturing space and general space.

As for construction/installation materials, due attention will be paid at least to the following points.

a. To use materials free of rust and dust.

b. To use materials which can withstand washing.

c. To make room corners, connections of floor and wall, connections of wall and ceiling, window sill, etc. in such a manner as will minimise dust accumulation.

To be more specific, the following considerations will be given to the design of the Formulation Centre.

Circulation lines of persons and goods will be shortened as much as possible in order to enhance efficiency of production. Since the manufacture contemplated for this Formulation Centre includes granulating process which requires organic solvent, special consideration will be given to safety (e.g., explosion-proofing, fire-proofing) of machines, building structures and finishes, etc. In reply to the Sri Lankan request, the production zone will be planned so as to enable visitors to observe part of it. For this purpose, observation courses will be provided in such a manner that visitors will not contaminate the production zone.

To effect out energy saving, due attention will be paid to maximum use of natural ventilation and lighting in the building design and reduction of running cost in the mechanical and electrical design.

The grade of facilities and installations of the Formulation Centre will be determined not only in accordance with the GMP requirements, but by reference to the observations of the existing pharmaceutical manufacturing plants described in 2.2.4 "Observations on Private Pharmaceutical Manufacturers."

As for construction materials, every effort will be made to use local ones as much as practicable in order to reduce construction cost and facilitate maintenance after the completion. In addition, the quality and availability of local materials will be taken into account as necessary in terms of durability and compliance with the GMP.

In consideration of the fact that the present level of local personnel in pharmaceutical manufacturing is so low as to require training, production equipment to be installed in the Formulation Centre will be such as can be easily and effectively used to get to earliest stabilised production and, in addition, as can manufacture many kinds of pharmaceuticals with high flexibility to development of formulation. Analytical and other instruments and apparatuses will be selected with due consideration for maintainability

(e.g., availability of spare parts, after-sales service) in Sri Lanka and provided with a minimum of spare parts necessary for maintenance.

4.2 Outline of the Basic Design

4.2.1 Layout Plan

The project site is nearly rectangular in shape, measuring 185 m and 87 m approximately. The site area is about 1.6 hectares (4 acres). The planned facilities comprise functions of general drug manufacturing, penicillin manufacturing, administration, quality control, welfare, utilities, security, etc. The given area is not sufficient to provide a building for each of the functions including perimeter roads and spaces. Therefore, the number of buildings will have to be minimised to make effective use of the site.

In view of the above situation, building facilities of this Formulation Centre will consist of the Main Building appropriately containing various functions, the Utility Building and the Guardhouse. They will be arranged in the site on the following principles (See Fig. 4.1).

(1) The Main Building containing general drug manufacturing, penicillin manufacturing and administrative functions will be located in the east-to-west direction as a result of physical, technological and psychological studies on effective use of the narrow site, architectural view from the front road, clarification of approach, centralisation of utility equipment, circulation lines, etc. This location will be effective also in ventilation, protection from the sun, etc.

(2) In the Main Building, the administration zone will be placed between the penicillin manufacturing zone on the east and the general drug manufacturing zone on the west. Cross contamination in the building will be prevented by such complete separation of the two manufacturing zones. Space for future expansion will be left between the Main Building and the existing Store Complex. This is the reason why the penicillin manufacturing zone which absolutely refuses cross contamination has been laid on the east end where no expansion is possible in the future. The western zone of the Main Building will be planned so that connection with the future expansion can be made through the dirty area of the general drug manufacturing zone.

(3) The main gate will be positioned in front of the entrance of the Main Building. In consideration of the vehicle flow and the harmony with the existing Store Complex, the Main Building will be set back from the south road in such a way that the south wall surface can come into line with that of the Store Complex.

(4) The Utility Building will be placed in the north centre of the Administration Building so as to enable utility supply to the Main Buidling to be made at the shortest distance, and will be connected with the Main Building by two piping racks so as to secure a scenic view from the canteen on the ground floor of the Main Building.

(5) The Guardhouse will be positioned next to the main gate to check employees and visitors entering and leaving the Formulation Centre.

(6) The gate will be provided separately from that of the Store Complex of which the operating conditions such as working hours are different from those of the SPC.

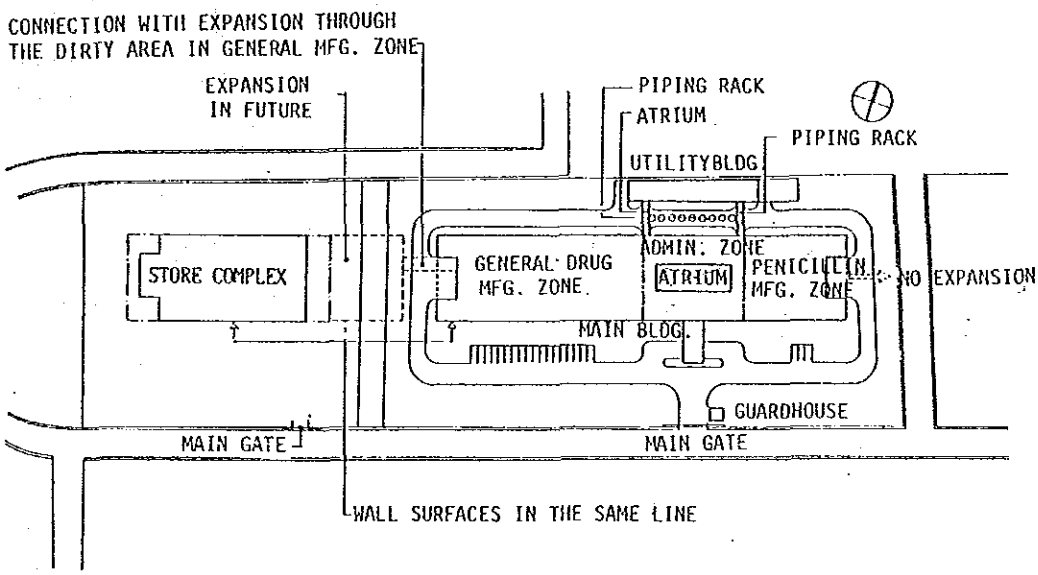


Fig. 4.1 Concept of the Layout Plan

4.2.2 Manufacturing Plan

(1) Basic Requirements

The basic manufacturing requirments are as described in 3.3.2 "Capacity and Scale of the Project."

(2) Pharmaceutical Specifications

From the available protocols and the discussion results with SPC, the pharmaceutical specifications of products are as delineated below:

1) Tablets

Size

Large	(16.0 to 14.0 mm dia.)	3 items	36.6-millon pcs./yr
Medium	(14.0 to 10.0 mm dia.)	7 items	127.4-million pcs./yr
Small	(Less than 10.0 mm dia.)	25 items	317.9-million pcs./yr

Type

Uncoated tablets	29 items	387.7-million pcs./yr
Sugar-coated tablets	3 items	92.1-million pcs./yr
Film-coated tablets	3 items	2.1-million pcs./yr

Identification

Tablets for the public sector will be marked in the course of tabletting so as to distinguish them from those for the private sector.

2) Capsules

Capsule size will be Nos. 1, 2 and 4 in the international size originated by Parke-Davis and Elanco in U.S.A.

3) Bottled Powder

The specified amount will be contained and sealed in standard 4 oz. brown bottles.

(3) Process Plan

The process system will be designed in compliance with the protocols taking local features, etc. into account. Fig. 4.2 shows the process flow prepared in accordance with the projected manufacturing requirements. Each of the processes is as briefly described below.

1) Preparation

This process is purposed to sieve and/or atomize materials in advance in order to facilitate the subsequent processes.

All materials received will be sieved for the purpose of removal of foreign matter and grading of particle size. They will be atomized as appropriate in order to make particle size uniform and pretreat colouring matter. Materials will be pneumatically conveyed to sieving machines so as to insure dustproofness and facilitate operation.

2) Weighing

This process is to weigh and take up necessary materials for every production unit.

Weighing will be carried out by two systems so as to prevent cross contamination which may be caused by manufacturing many items of pharmaceuticals. These systems will be devised in such a manner that they can be easily cleaned when the manufacturing item is changed. Materials will be transported mainly by putting containers on small-size pallets.

3) Granulating

This granulating process which is positioned as a preparatory stage of the tabletting process consists of granulating, drying, oscillating (size grading), etc.

Granulating will be performed mostly by a wet method and in part by a dry method, a spray method or a direct-mixing method.

Drying will be made by the use of a ventilating dryer and a fluid-bed granulator. Since organic solvent is used in part of the process, dryers will be of explosion-proof structure so as to cope with explosion and dust explosion.

Oscillating will be conducted in an airtight space because it produces a large amount of dust. Granulated matter will be pneumatically conveyed from an oscillator to a mixer which is located at a high point.

Except for the aforesaid pneumatic conveyance, materials in the process of granulating will be contained in stainless steel drums and transported by putting the drums on pallets (1.1 m x 1.1 m) sized to Japanese Industrial Standards (JIS).

4) Tabletting

In this process, granulated matter is moulded into tablets.

Each of tabletting machines will be housed in a room. Every batch of granulated matter will be tabletted by one machine. To make effective use of the tabletting machines, temporary storage space will be provided before and behind a tabletting machine room. Powder will be transported from a drum to a hopper of a tabletting machine by means of a drum converter and lift.

Tablets will be put in 30 litre drums and carried to the next stage by the use of standard size pallets.

5) Sugar Coating/Film Coating

This process is to apply coating to tablets for the purpose of prevention of deterioration, taste-masking, etc.

Sugar coating will be made in the sequence of protection, pasting, syrupping and polishing, taking five days for all the process. Syrup will be prepared in advance and put in reusable containers.

Film coating will be conducted by the spray method. Coating liquid will be dissolved in water before use.

Coating machines will be such as can be used for both sugar coating and film coating.

6) Packaging

Products will be packed in brown bottles or cans by the 100, 250, 500, 1,000 and 5,000 pieces depending on the kind of pharmaceuticals. Packaging will be made by the counting method for 100-pcs. and 250-pcs. units and the weighing method for 500- or larger pcs. units.

7) Transportation

Considering that many kinds of pharmaceuticals are manufactured by comparatively many processes, materials, in-process goods and products will be transported in the Formulation Centre mainly by the use of a forklift truck carrying drums on a pallet. Pneumatic (vacuum) system will be generally used for transportation to high places. For details, see Fig. 4.2.

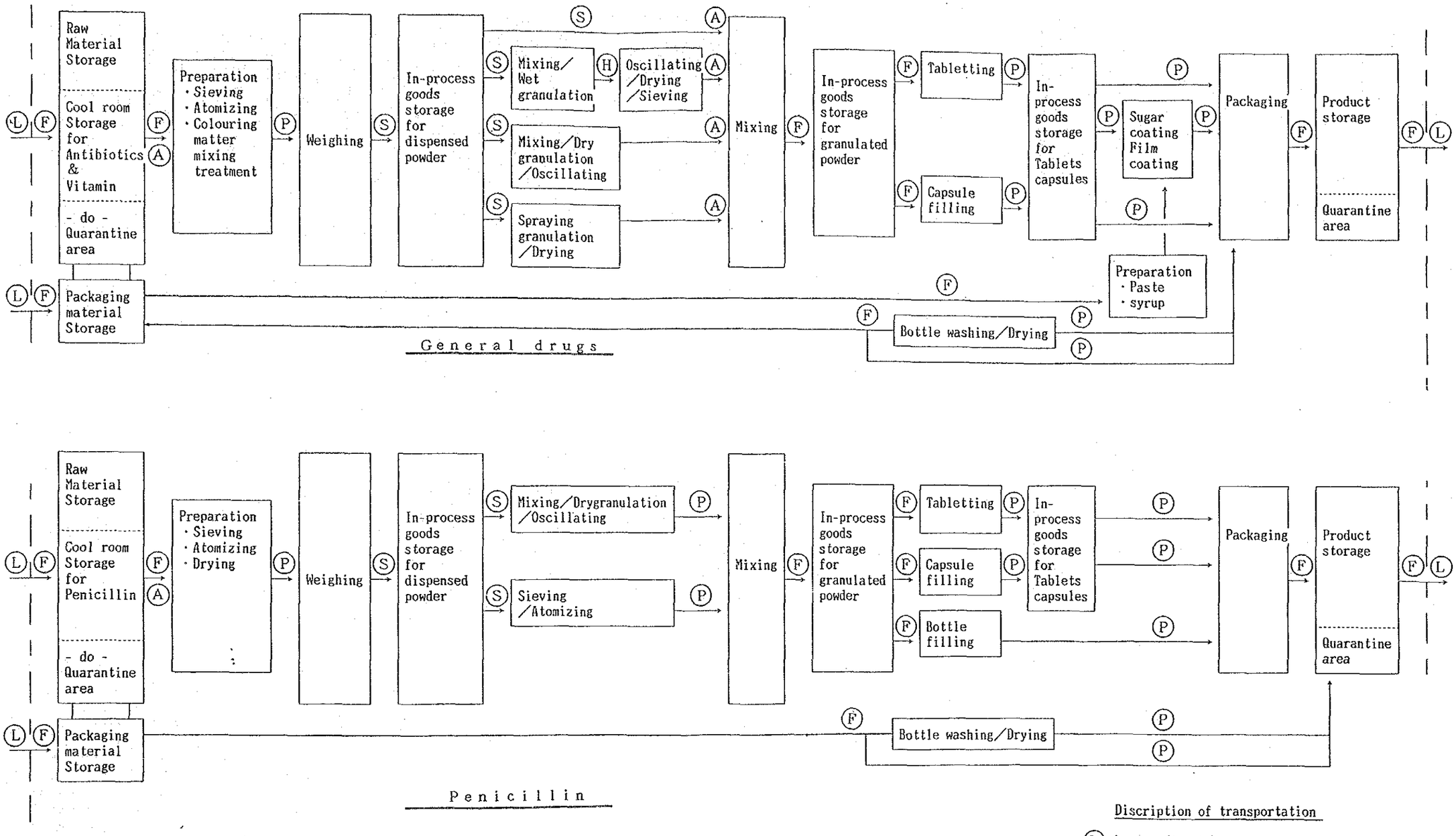


Fig. 4.2 Process Flow Diagram

Discription of transportation

- (L) Lorry (truck)
- (F) Forklift (standard size pallet)
- (P) Pallet truck (standard size pallet)
- (S) Pallet truck (small size pallet)
- (A) Pneumatic (Vacuum)
- (H) Handcart

4.2.3 Building Plan

(1) Size of Buildings

As for the size of rooms in the production department and the quality control (QC) and laboratory department, its approximate values have been preset on the basis of dimensions of production machines and QC/laboratory instruments, necessary operation area, amount of materials and products, etc., and then final values have been determined with due consideration for architectural aspects, such as standard size of building materials, adequacy to the layout plan, and module capable of standardising arrangement of doors and windows.

The size of rooms in the administration zone has been determined from dimensions of local furniture, circulation lines, local features of office work, etc.

The size of rooms in the Formulation Centre is as described below:

The Main Building

Room		Area (m^2)	Remarks
General Drug Mfg.	Pass Room	5.8	
	Pretreatment	86.4	Incl. Atomizing, Sieving and Temporary Storage
	Weighing	30.8	2 rooms
	Post-weighing Storage	15.4	
	Granulating (1)	12.6	
	Granulating (2)	17.3	
	Oscillating/Drying (1)	46.0	2 rooms
	Oscillating/Drying (2)	28.8	
	Dry Granulating	16.8	
	Sieving	12.6	

(to be continued)

(continued)

Room		Area (m^2)	Remarks
General Drug Mfg.	Oscillating/Mixing (1)	23.0	
	Oscillating/Mixing (2)	69.2	2 rooms
	Post-granulating storage	43.2	
	In-process Analysis	14.4	
	Tabletting	138.2	6 rooms
	Paste Preparation	28.8	
	Film Coating	51.8	
	Capsule Filling	23.0	
	Tablet Sorting	17.3	
	Custodial Closet	4.8	
	Packaging Preparation	9.6	
	Packaging	103.7	
	In-process Goods Storage	37.4	
	Product Storage	51.8	
	Unloading Office	9.6	
	Air Shower	12.5	
	Low Temperature Storage	34.6	Incl. Sampling Room
	Raw Material Storage	69.1	
	Office	17.3	
	Maintenance	23.0	
	Resting	34.6	
	Toilet	34.6	
	Laundry	17.3	
	Clothes Changing	115.2	
	Equipment Washing	34.6	
	Equipment Drying	13.0	

(to be continued)

(continued)

Room		Area (m^2)	Remarks
General Drugs Mfg.	Parts Store	28.8	
	Bottle Washing/Drying	13.0	
	Subtotal	1,345.9	
Penicillin Mfg.	Pass Room	11.5	
	Raw Material Storage	69.1	Incl. Low Temp. Storage and Sampling Room
	Pretreatment	40.3	Incl. Sieving, Atomizing and Temporary Storage
	Weighing	23.0	
	Granulating	17.3	
	Drying	23.0	
	In-process Analysis	17.3	
	Washing	17.3	
	Equipment Drying	17.3	
	In-process Goods Storage	34.6	
	Bottle Washing	17.3	
	Maintenance	11.5	
	Mixing	23.0	
	Tabletting	23.0	
	Capsule Filling	23.0	
	Tablet Sorting	17.3	
	Bottle Filling	23.0	
	Packaging	69.1	
	Product Storage	23.0	
	Parts Store	23.0	2 rooms
	Laundry	11.5	

(to be continued)

(continued)

Room		Area (m^2)	Remarks
Penicillin Mfg.	Unloading Office	8.6	
	Air Shower	8.6	
	Office	11.5	
	Resting	17.3	
	Toilet	25.9	
	Clothes Changing	83.5	
	Subtotal	682.1	
Administration	Entrance Hall	46.1	
	Anteroom	44.6	
	Office	83.5	For 14 occupants Incl. Copier Room
	Medical	18.2	
	Toilet	29.8	
	Canteeen	133.9	For 80 persons, on one shift
	Kitchenette	18.2	
	Conference Room (1)	74.4	For 20 persons
	Conference Room (2)	29.8	For 12 persons
	Anteroom	29.8	
	Manager	29.8	
	Physico-chem. Laboratory	89.3	
	Instrumentation	44.6	
	Biological Laboratory	44.6	
	Sample Storage	29.8	
	Laboratory	44.6	
	Subtotal	791.0	

(to be continued)

(continued)

Room		Area (m^2)	Remarks
Others	Machine	293.8	
	Staircases, Toilets, Hall	167.1	
	Corridors	941.2	
	Subtotal	1,402.1	
Total of the Main Building		4,229.8	

The Utility Building

Room	Area (m^2)	Remarks
Pump, Compressor, Boiler, Generator and Blower Rooms	226.7	
Napping Room	17.3	For one person
Storage	26.8	
Toilet, Corridor, etc.	23.0	
Total of the Utility Building	293.8	

The Guardhouse

Room	Area (m^2)	Remarks
Guard	9.0	Two men and one woman
Time Recorder	6.0	
Total of the Guardhouse	15.0	

(2) Layout

1) The Main Building

As already described in 4.2.1, the administration zone will be placed between the general drug manufacturing zone and the penicillin manufacturing zone. The main entrance will be located in the south centre of the administration zone, and loading/unloading points of the manufacturing zones will be positioned at the east and west ends of the building. An atrium will be made in the centre of the administration zone so as to insure natural ventilation and lighting under the severe natural environment having high temperature and humidity.

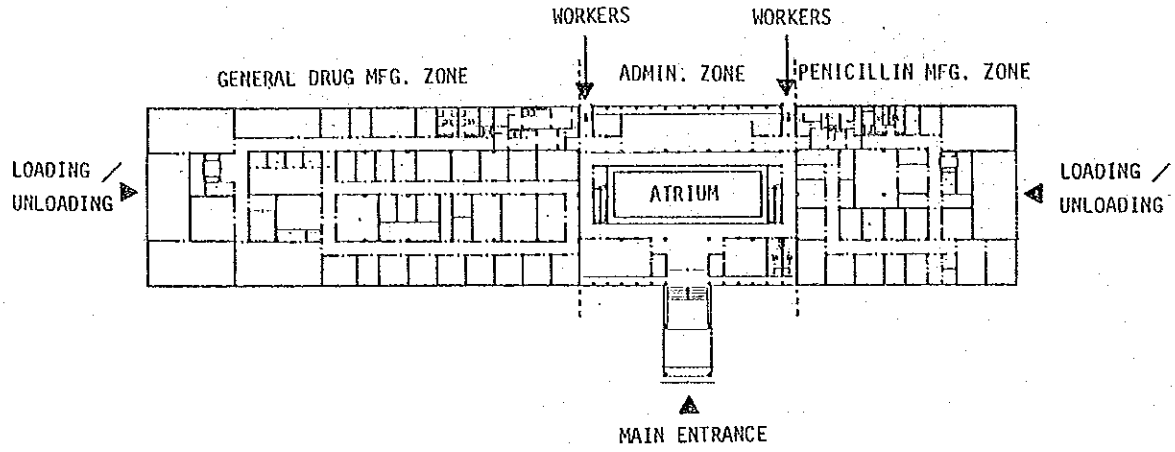


Fig. 4.3 Plan of the Main Building

The administration zone will be divided into the southern part and the northern part by the atrium. In the southern part, entrance, offices, etc. will be placed on the ground floor and manager room, conference room, etc., on the first floor. In the northern part, such welfare functions as canteen and medical room will be laid on the ground floor and QC functions such as laboratories, on the first floor. All these rooms will be connected by the galleries surrounding the atrium.

Observatory windows will be provided in partition walls between the administration zone and the manufacturing zone so that visitors can see the manufacturing process not changing their clothes.

In the manufacturing zone, buffer area consisting of such air locks as air shower rooms, pass rooms, etc. will be provided between areas different in cleanliness. Rooms of the manufacturing zone will be functionally laid out to the manufacturing process so as to make personal and goods circulation lines as short as possible.

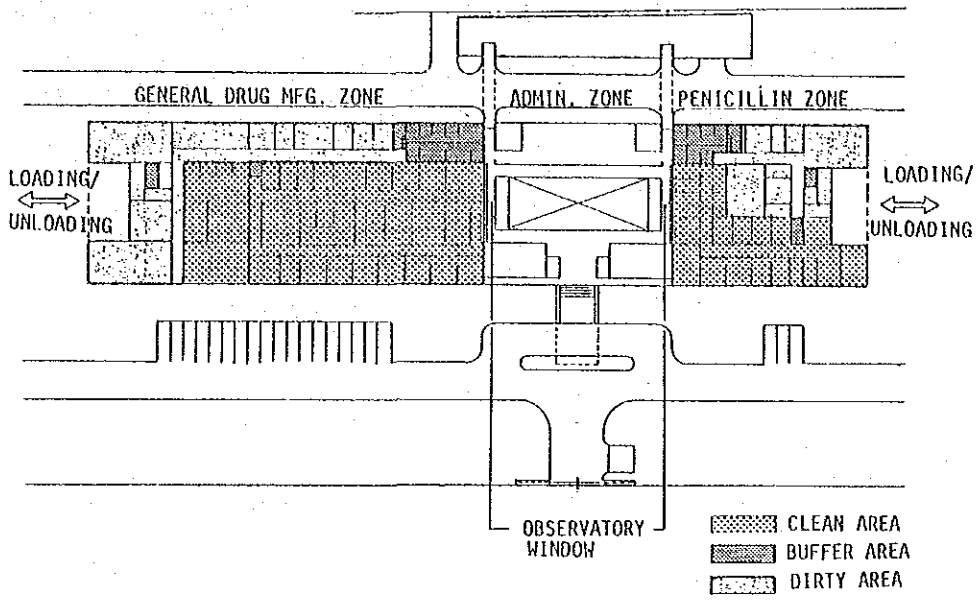


Fig. 4.4 Divisions of Cleanliness

Most of the manufacturing processes will be installed by a closed system, and so there is little fear of interior contamination by dust. Therefore, cleaning of floors in the manufacturing zone will be made by mop wiping. A sink for mops will be installed in the custodial closet. Neither faucets nor floor drains will be provided in any manufacturing room, except for the equipment washing room and the paste preparation room.

The 2.4 m x 2.4 m basic module will be adopted for this building so as to facilitate arrangement of production equipment, standardisation of building materials, effective installation of building service equipment, corridor width, repetitions of room dimensions, etc. The adoption of basic module will produce high flexibility to change of partition, etc. In the manufacturing zone, exterior walls will be of wall columns spaced 2.4 m. To make effective use of the interior spaces and minimise dust accumulation, the interior wall surfaces will be flush with columns ribbed on the exterior side. In

the administration zone, columns will be spaced 2.4 m on the perimeter, and windows will be set back from the column line so as to produce protection from strong sunbeam and heavy rainfall and effect out the energy saving. Spacings of interior columns will be taken as 7.2 m, three times the basic module, considering that the 3.6 m module produced by halving the column spacing will be economically and functionally useful in the administration and laboratory zones.

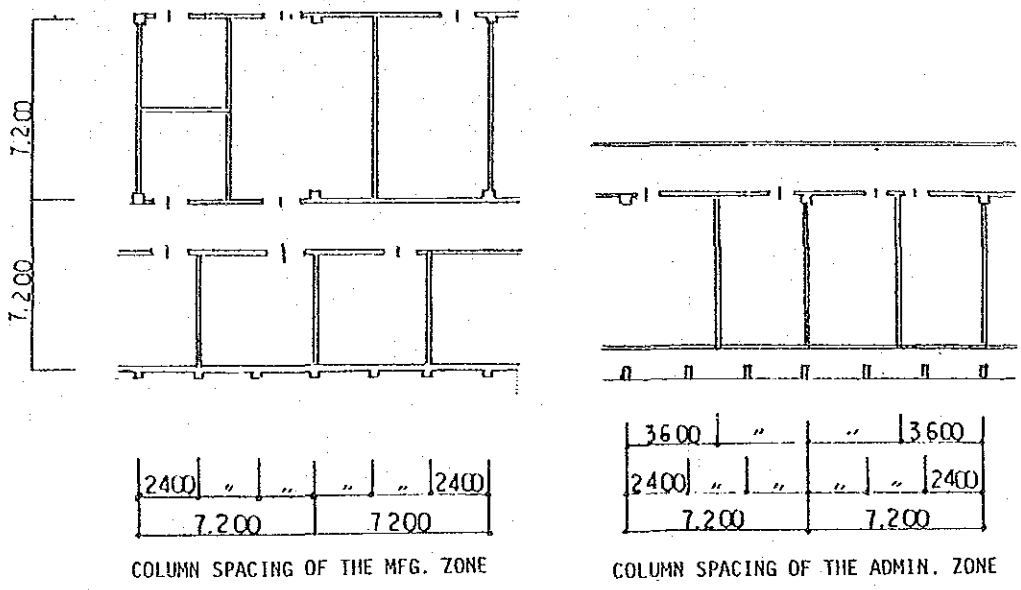


Fig. 4.5 Module Plan

2) The Utility Building and the Guardhouse

The Utility Building will have one storey and comprise a pump room, a compressor room, a boiler room, a generator room, a machine room, a napping room for nocturnal guard, an exterior toilet for truck drivers and external workers, a storage for external work and a waste treatment facility. In addition, the power receiving/transforming equipment to be installed on the part of Sri Lanka and the incinerator will be provided in the building. Such intensive allocation of various facilities has resulted from consideration for shortening of service lines among the facilities, reduction of construction costs, effective use of the site area, creation of large landscaping area and so on.

Service lines from the Utility Building will be led to the Main Building by two piping racks. These piping racks will be used also as canopies for the north entrances to the Main Building and the entrances to the Utility Building. And, landscaping considerations will be given to the space between the Main Building and the Utility Building so as not to spoil view from the canteen on the ground floor of the Main Building.

The Guardhouse will be of one storey consisting of a guard room and a time recorder room.

(3) Sectional Plan

1) The Main Building

Ceiling height of the manufacturing zone is determined from the height of equipment to be installed. In this building, ceiling height will be classified into two types: 3.5 m and 2.7 m. Storey height will be 5,750 mm with consideration for the ceiling height, ducting/piping space above ceiling, beam depths, maintenance, flexibility in future, etc.

Level of the ground floor will be 750 mm above the design ground level. This level will be the same as that of the loading/unloading platforms and high enough to keep the interior from being flooded by heavy rain and subjected to damp from the soil. In order to prevent backflows in piping, the level of underfloor piping will be placed above the ground level.

The manufacturing zone will have no windows in principle because part of materials dislikes exposition to ultraviolet rays contained in daylight and windows have adverse effects on maintenance of cleanliness and energy saving.

Utility space for piping, ducting, fan rooms, etc. to be required by future change of production equipment will be provided on the roof of the manufacturing zone.

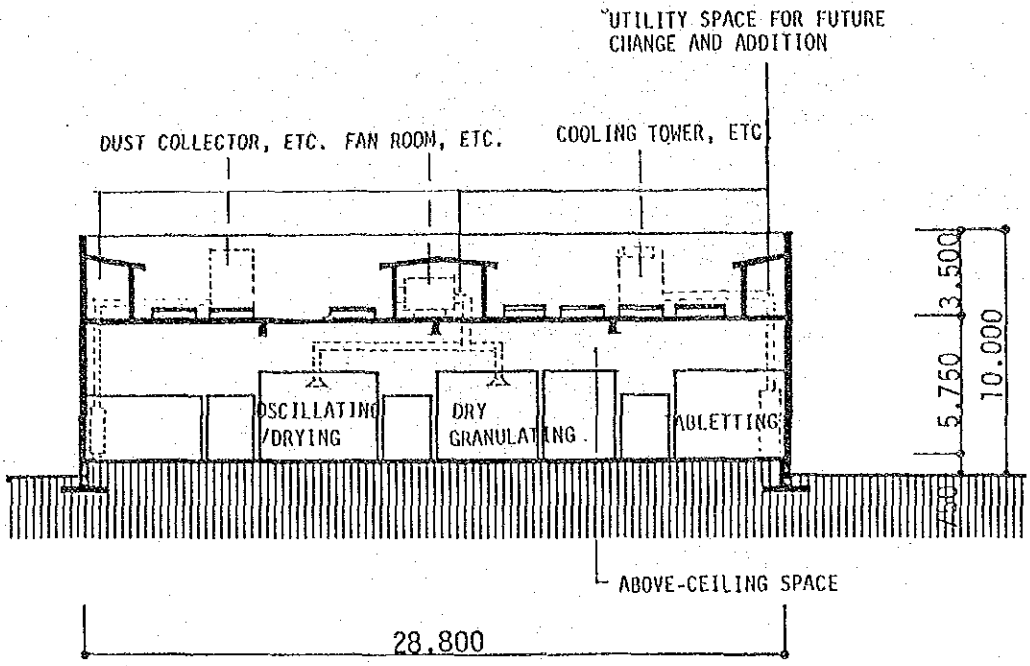


Fig. 4.6 Section of the Manufacturing Zone

Ceiling height of the administration zone will be taken as 3.0 m in order to make natural ventilation more effective. Storey height will be 4,400 mm on both the ground floor and the first floor. The gallery around the atrium and the verandah-like recess on the perimeter will function as protection from the sun and rainwater, producing the atmosphere of tropical architecture.

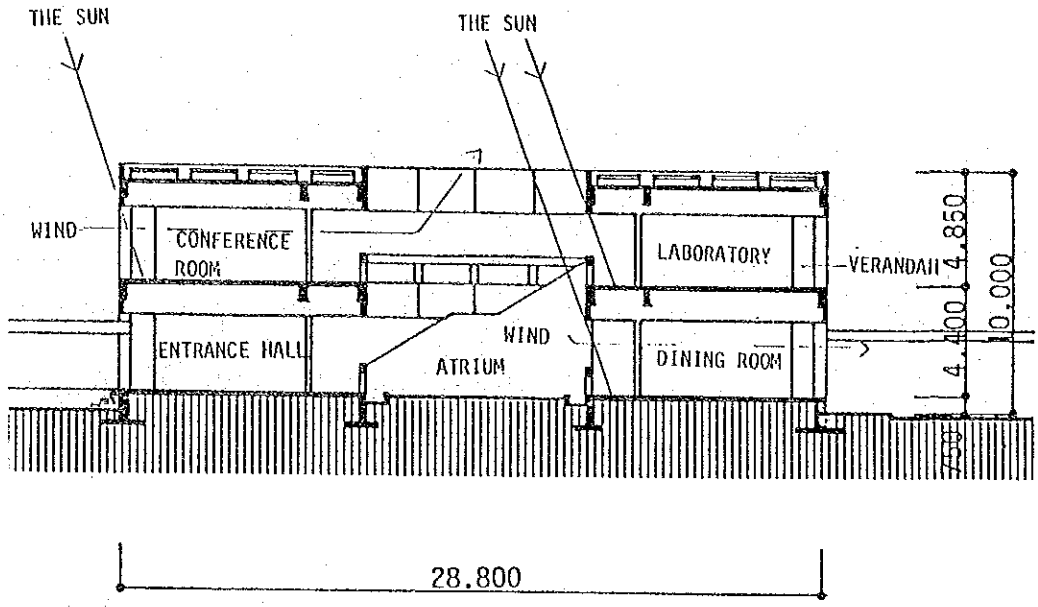


Fig. 4.7 Section of the Administration Zone

The manufacturing zone and part of the administration zone must be air-conditioned. To reduce the running energy of air-conditioning system, insulation materials will be put in walls and roofs as much as practicable. In addition, corrugated asbestos cement boards will be laid on roofing with air space between them for the purpose of protection of waterproofing layer and energy saving.

2) The Utility Building and the Guardhouse

The Utility Building will have a storey height of 4,600 mm and the ground floor level of 100 mm above the design ground level in view of dimensions of equiment to be installed. An elevated water tank rising 19 m above the design ground level will be provided over the Utility Building. A 40 ton water reservoir (also for fire fighting) and a 20 ton tank for waste water after backwash will be provided in the foundation.

The Guardhouse will be about 2,500 mm in storey height and have architectural view harmonious with that of the main gate.

(4) External Work

1) Road and Car Park

A roundabout will be provided in front of the entrance of the Main Building so as to facilitate traffic movement to any destination in the Formulation Centre. The road will surround the Main Building having service approaches to platforms of the two manufacturing zones and the Utility Building. The road will be a paved road having a width of 7.0 m in front and 6.0 m on the back, east and west sides.

A car park having a capacity of about 20 vehicles will be placed on the south of the Main Building.

2) Stormwater Drainage

Stormwater will be led to ditches and culverts in the Formulation Centre and discharged into gutters outside of the premises.

3) Piping Rack

Two piping racks constructed of steel will be provided between the Main Building and the Utility Building.

4) Main Gate and Flag Poles

The main gate will be located on the south of the site, fronting the entrance of the Main Building. Flag poles will be erected near the main gate on the south of the Main Building.

(5) Structural Plan

1) Principles

The structural plan of the Formulation Centre will be drawn out on the following principles.

a) The main structure is made of reinforced concrete with rigid frame and part of exterior walls are of in-situ reinforced concrete.

b) The buildings is structurally divided as appropriate by expan-

sion joints in order to cope with drying shrinkage of concrete, thermal stress and differential settlement of foundations.

c) According to the soil investigation report, the depth of 6 m to 7 m below the ground surface is occupied by comparatively soft alternating layers of clay and sand underlain by very hard soil. The clayey soil layers are weakly consolidated. Therefore, preloading by about 1 m high fill with rolling compaction should be applied for the purpose of improvement of the upper clayey soil layer and increase of bearing capacity of the surface layer. (See Appendix 5.)

d) Foundations will be made of reinforced concrete independent or continuous footings resting directly on soil.

e) Construction will be executed by using local materials and practice as much as possible.

2) Design Standards

The structural design will be in principle carried out in compliance with British Standards (BS). When deemed necessary, standards set forth by the Architectural Institute of Japan (AIJ) will be applied.

a) Loads

BS CP3 Chapter V "Loading"
Part 1 Dead and Imposed Loads (1967)
Part 2 Wind Loads (1972)

b) Reinforced Concrete

BS CP110 : 1972 "The Structure Use of Concrete"

c) Steel

BS 449 : 1969 "The Structure Use of Steel in Building"

3) Design Loads

Design loads will be preset in compliance with British Standards and, if necessary, the design standards set forth by AIJ.

a) Dead Loads

Reinforced concrete : 2.45 t/m^3
Steel : 7.85 t/m^3
Concrete block : 1.9 t/m^3

Loads of other materials will be calculated according to actual use.

b) Live Loads

Fundamental live loads will be determined as follows from BS CP3 Chapter V "Loading" Part 1 (1967).

Table 4.1 Live Load Conditions

Position	Uniformly Distributed Loads (kgf/m^2)	Concentrated Loads (kgf)
Roof	77	92 (on 125 mm square)
Stairs and Stair Platform	Stairs : 365 Stair platform : 510	Nil
Toilet	204	Nil
Office	255	275 (on 300 mm square)
Machine Room	408	To actual use
Corridor	Same as those of connecting room	

c) Thermal Loads

Since the buildings will be provided with expansion joints and yearly and daily temperature changes are small, thermal loads will be disregarded.

d) Wind Loads

Wind loads will be taken as 75 miles/hr or 33.3 m/sec.

e) Seismic Loads

Such earthquakes as would adversely affect building structures have never occurred in this area of Sri Lanka. Therefore, seismic loads will be disregarded in the structural design.

(6) Electrical Plan

1) Power Receiving/Transforming System

Power will be led in from CEB 33 kV line existing on the south of the site, and transformed to 3 ϕ 4 W 400 V/230 V 50 Hz by a transformer to be installed in the Utility Building by CEB. Electrical work after the main switch on the secondary side of the transformer will be carried out by the user. The electrical work will be planned and designed in compliance with BS and, if necessary, JIS.

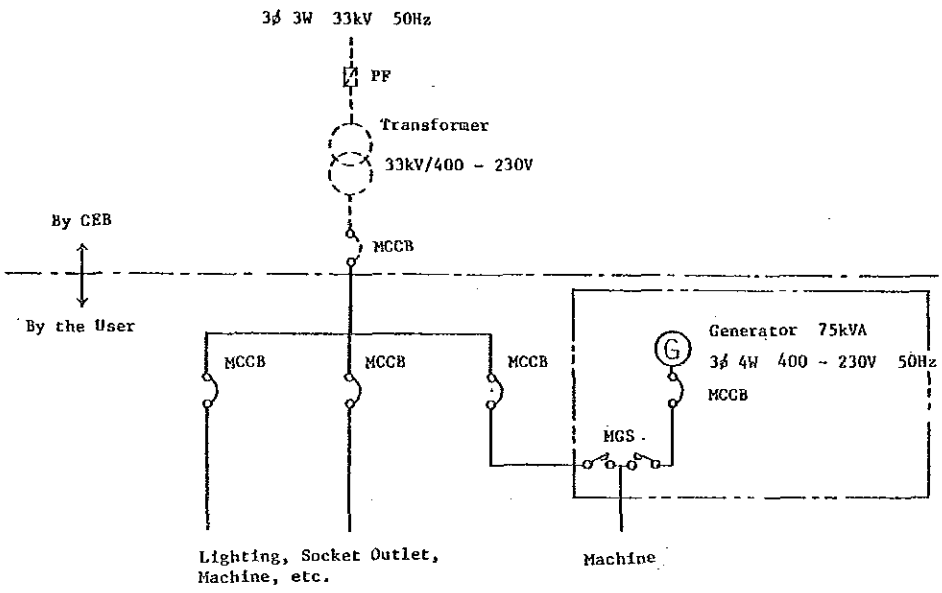


Fig. 4.8 Skeleton Diagram of Power Receiving/Transforming System

Loads of the Formulation Centre will be roughly estimated as follows totalling to 900 kVA.

Lighting and socket outlets	100 kVA
Air-conditioning and ventilation	460 kVA
Water supply and sewerage	80 kVA
Manufacturing	260 kVA
Total	900 kVA

2) Emergency Generator

A fire water pump and necessary production equipment (e.g., sugar coating pan) will be backed up by an emergency generator at the time of power failure.

3) Main Lines

Power of 3 ϕ 4 W 400 V/230 V 50 Hz will be supplied from the main switch on the secondary side of the transformer (to be installed by CEB) to production and lighting panel and air-conditioning and plumbing power panel.

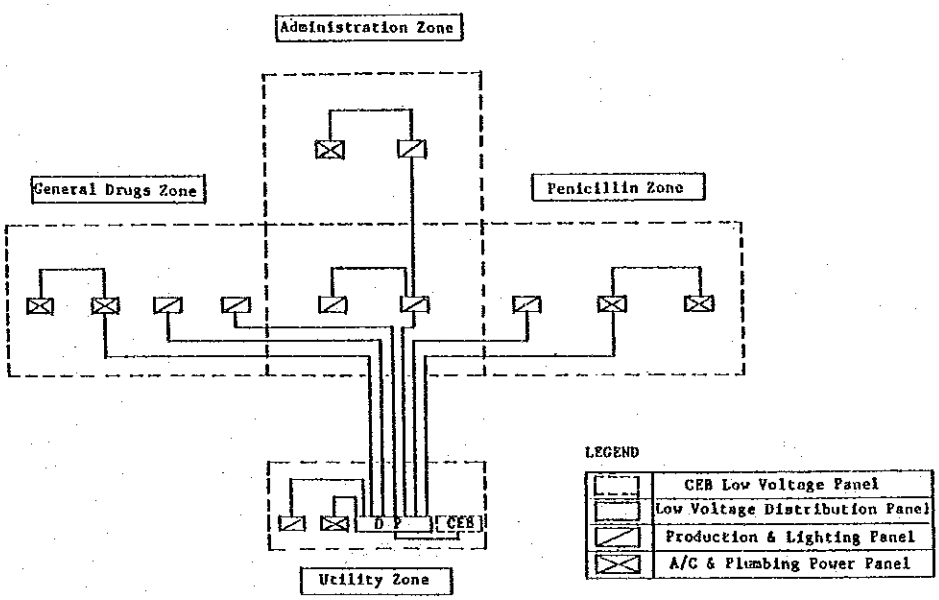


Fig. 4.9 Main Line Diagram

4) Power Circuit

The following two types of power will be supplied to water supply equipment, air-conditioners, ventilating machines, utility equipment and production equipment through respective control panels.

3 ϕ 3 W 400 V 50 Hz
1 ϕ 2 W 230 V 50 Hz

5) Lighting and Socket Outlets

a) Lighting

Lighting will be mainly made with fluorescent lamps and partly with incandescent lamps. Power for lighting will be 1 ϕ 2 W 230 V 50 Hz and emergency batteries will be housed in lighting fixtures as necessary. Rooms or areas will have the following illumination intensities.

Manufacturing Zone	300 to 400 luxes
QC Room	300 to 400 luxes
Office	300 to 400 luxes
Storage	50 to 100 luxes
Machine Room	50 to 100 luxes

b) Socket Outlets

Socket outlets will be provided in the manufacturing zone, offices, etc.

6) Telephone System

The portion from the telephone main cable to the main terminal boards in the Formulation Centre will be undertaken by the Regional Telecommunication Engineer's Office. Cabling, conduiting and equipment installation after that portion will be carried out by the user. A small exchange and about 20 telephone instruments will be installed.

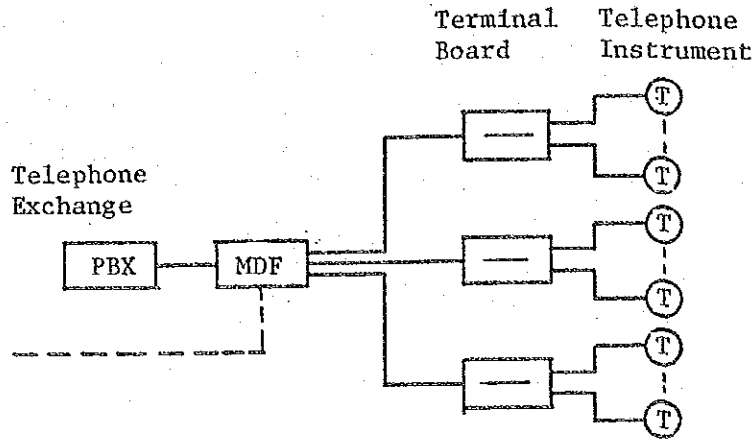


Fig. 4.10 Telephone System Diagram

7) Intercommunication System

Interphone instruments will be provided between necessary places.

8) Fire Alarm System

Fire alarm bells and push buttons therefor will be provided in the buildings. When fire is detected, all the bells will be rung by pushing a button and at the same time fire alarm will be indicated on the fire alarm panel on the ground floor of the administration zone.

(7) Air-conditioning and Ventilating Plan

1) Design Conditions

Outdoor and indoor conditions will be set as follows:

Outdoor

Dry bulb temperature : 33 ^{o}CDB
Relative humidity : 75 %RH

Indoor

Table 4.2 Indoor Conditions

Zone	Dry Bulb Temp. (°CDB)	Relative Humidity (%RH)
Manufacturing	23 to 25	60 or less
QC	25 to 27	Not controlled
Low-temp. Storage (General Drugs)	15 or less	Not controlled
Low-temp. Storage (Penicillin)	25 or less	Not controlled

2) Zoning and Method of Air-conditioning

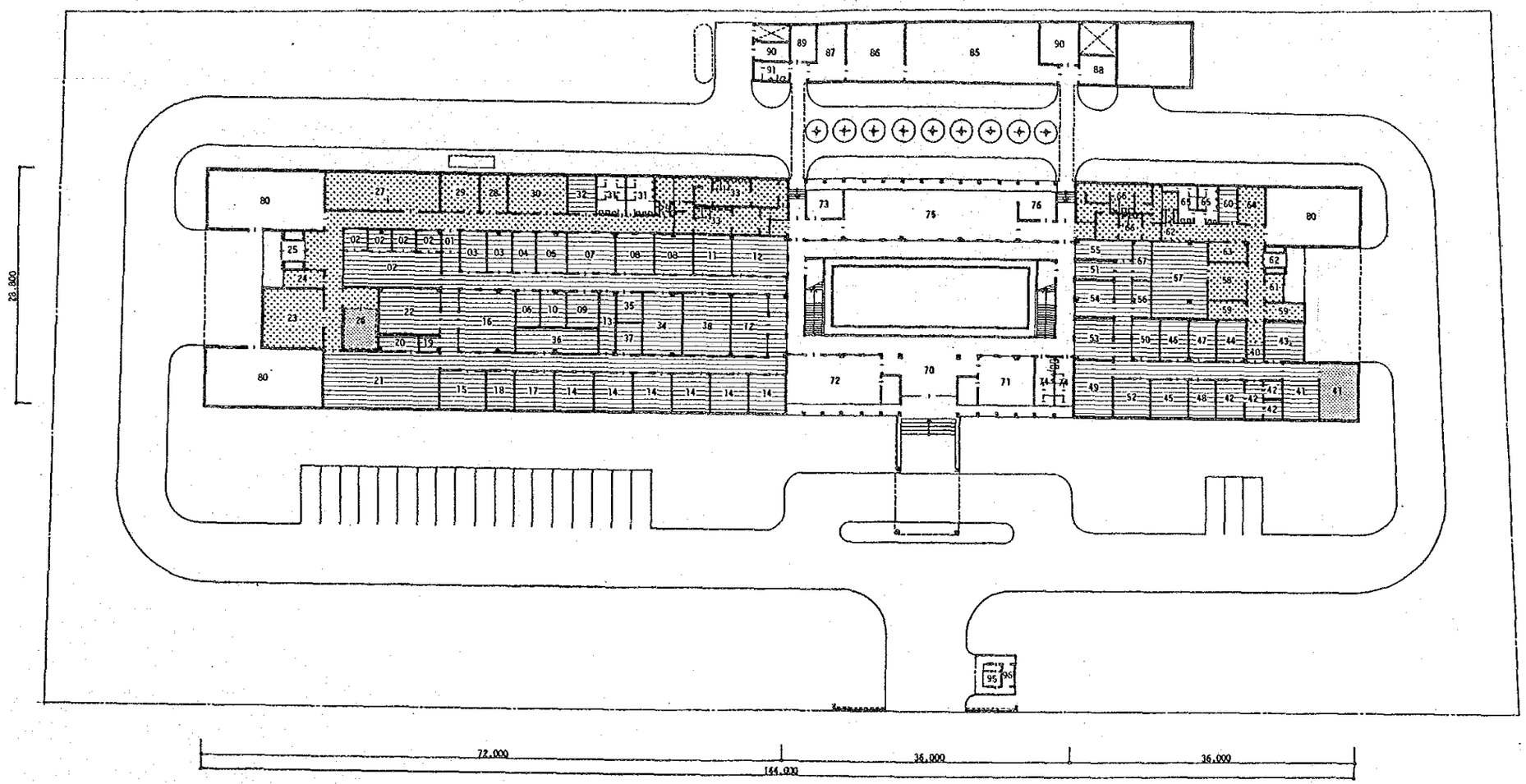
Air-conditioning systems for the general drug manufacturing zone and the penicillin manufacturing zone will be completely separated from each other. Air-conditioning will be made by centralised single duct system. Air filters of air-conditioners will be selected according to the required cleanliness.

The low-temperature storages which have to be air-conditioned around the clock will be equipped independently with air-cooled air-conditioners.

In the administration zone, the rooms for QC section, conference rooms and other rooms where overtime work is apt to be done will be cooled by air-cooled air-conditioners. The canteen and general offices will not be air-conditioned, but equipped with ceiling fans.

Table 4.3 Methods of Air-conditioning

Zone/Area		Air-conditioning Method
General Drugs	Clean Area 1	Centralised single duct
	Clean Area 2	do.
	General Area	do.
	Low-temp. Storage	Air-cooled air-conditioner
Penicillin	Clean Area	Centralised single duct
	General Area	do.
	Lower-temp. Storage	Air-cooled air-conditioner
Admini-stration	QC Area	do.
	Manager Room, etc.	do.



GENERAL DRUGS MANUFACTURING
01 PASS ROOM
02 PRETREATMENT
03 WEIGHING
04 POST-WEIGHING STORAGE
05 GRANULATING (1)
06 GRANULATING (2)
07 OSCILLATING/DRYING (1)
08 OSCILLATING/DRYING (2)
09 DRY GRANULATING
10 SIEVING
11 OSCILLATING/MIXING (1)
12 OSCILLATING/MIXING (2)
13 IN-PROCESS ANALYSIS
14 TABLETTING
15 *PASTE PREPARATION*
16 FILM COATING
17 CAPSULE FILLING
18 TABLET SORTING
19 CUSTODIAL CLOSET
20 PACKAGING PREPARATION
21 PACKAGING
22 IN-PROCESS GOODS STORAGE
23 PRODUCT STORAGE
24 UNLOADING OFFICE
25 AIR SHOWER
26 LOW TEMP. STORAGE
27 RAW MATERIAL STORAGE
28 OFFICE
29 MAINTENANCE
30 RESTINVG
31 TOILET
32 LAUNDRY
33 CLOTHES CHANGING
34 *EQUIPMENT WASHING*
35 EQUIPMENT DRYING
36 PARTS STORE
37 BOTTLE WASHING/DRYING
38 POST-GRANULATING STORAGE

PENICILLIN MANUFACTURING
40 PASS ROOM
41 RAW MATERIAL STORAGE
42 PRETREATMENT
43 WEIGHING
44 GRANULATING
45 DRYING
46 IN-PROCESS ANALYSIS
47 EQUIPMENT WASHING
48 EQUIPMENT DRYING
49 *IN-PROCESS GOODS STORAGE*
50 BOTTLE WASHING
51 MAINTENANCE
52 MIXING
53 TABLETTING
54 *CAPSULE FILLING*
55 TABLET SORTING
56 BOTTLE FILLING
57 PACKAGING
58 PRODUCT STORAGE
59 PARTS STORE
60 LAUNDRY
61 UNLOADING OFFICE
62 AIR SHOWER
63 OFFICE
64 RESTING
65 TOILET
66 CLOTHES CHANGING
67 FILLING ROOM

ADMINISTRATION
70 ENTRANCE HALL
71 ANTEROOM
72 OFFICE
73 MEDICAL
74 TOILET
75 CANTEEN
76 KITCHENETTE

OTHERS
80 MACHINE

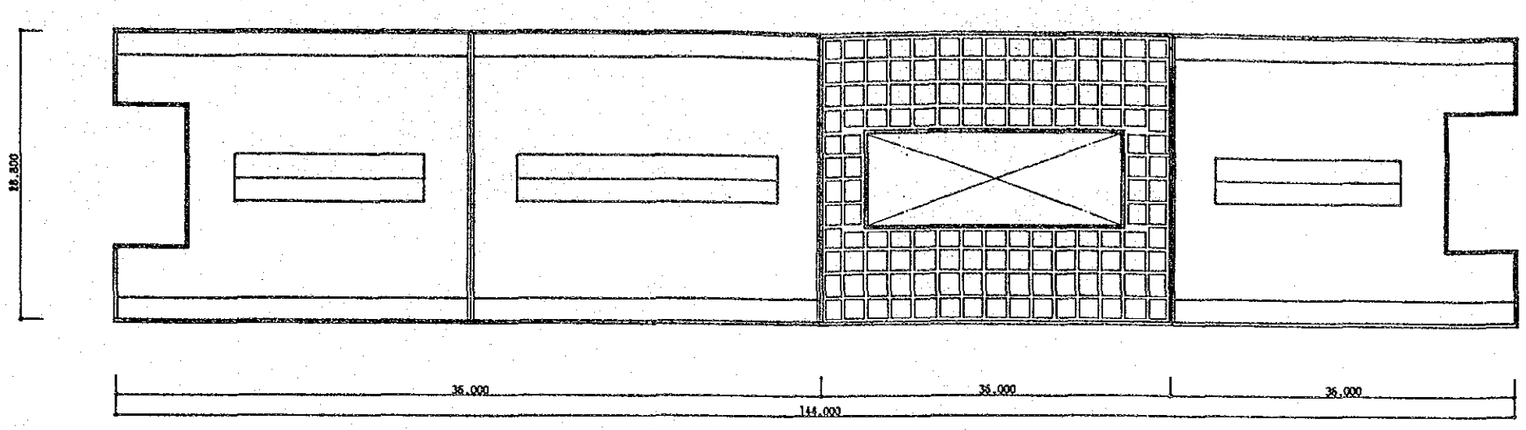
UTILITY BUILDING
85 PUMP, COMPRESSOR ROOM
86 BOILER ROOM
87 GENERATOR ROOM
88 BLOWER ROOM
89 *MAPPING*
90 STORAGE
91 TOILET

GUARDHOUSE
95 GUARD
96 TIME

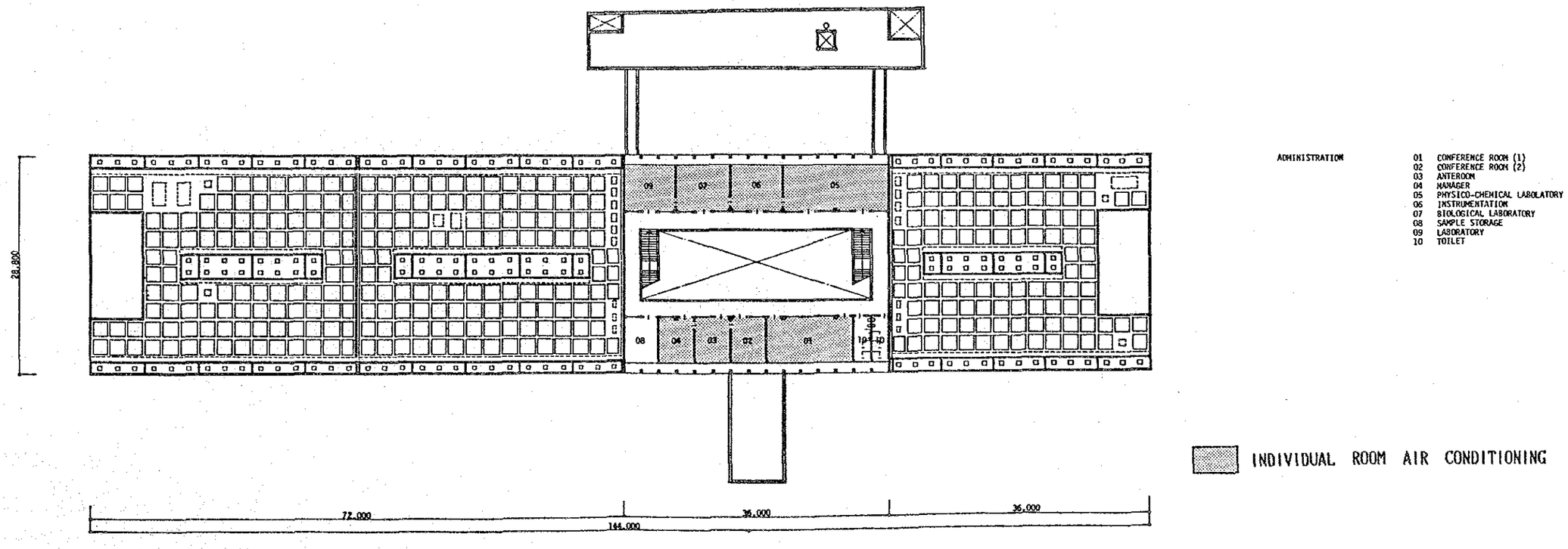
GROUND FLOOR PLAN

CLEAN ZONE
DIRTY ZONE
INDIVIDUAL ROOM AIR CONDITIONING

Fig. 4.11 Zoning Plan for Air-Conditioning System (on the Ground Floor)



ROOF PLAN



1st FLOOR PLAN

Fig. 4.12 Zoning Plan for Air-Conditioning System (on the 1st Floor)

3) Heat Sources

Chilled water generated by water-cooled water chilling units will be supplied to each of air-conditioners. Steam for reheaters in air-conditioners will be generated by a steam boiler, which will be combinedly used for steam supply to the production equipment.

Air-conditioning systems for the low-temperature storage and other specially-conditioned facilities will be operated by an independent air-cooled air-conditioner.

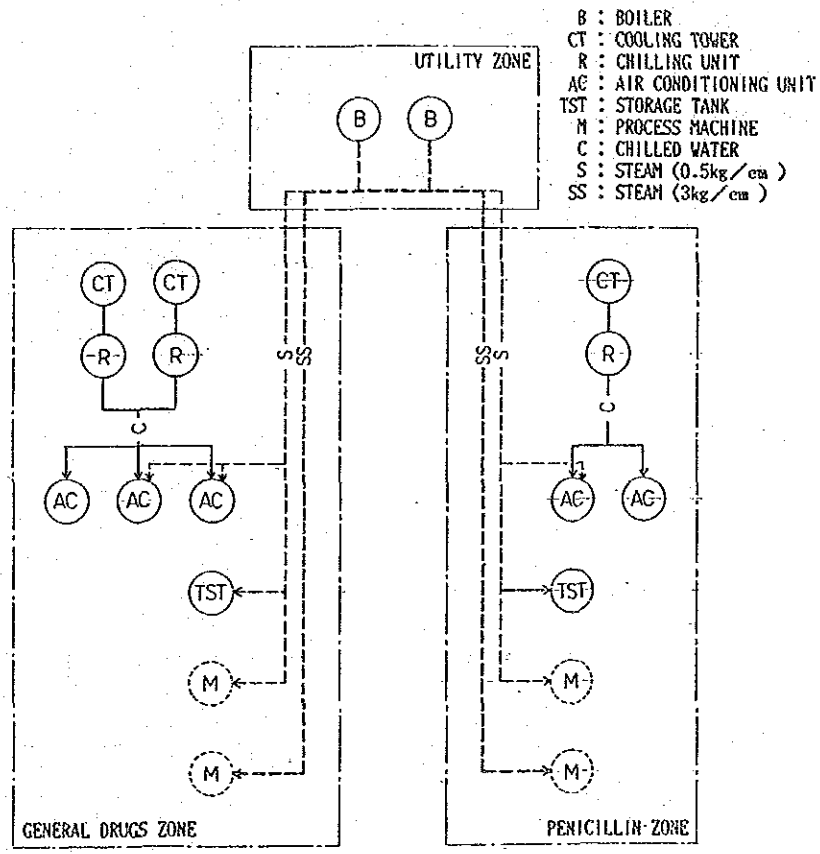


Fig. 4.13 Heat Source Flow

4) Ventilation System

Areas where high temperature heat, offensive smell, gas, etc. are generated will be mechanically ventilated and, if necessary, exhaust air will be treated. Outdoor air or pretreated air will be supplied to production equipment as necessary.

(8) Plumbing and Utility

1) Water Supply System

Municipal water will be received from the 100 ϕ main laid under the south road and once stored in a water reservoir. The stored municipal water may suffer deterioration in quality. Therefore, that water will be pumped up to an elevated tank after filtration and disinfection and supplied to use points by gravity. Deionized water for process use will be supplied to a water distilling unit, etc. by forced circulation. The daily amount of water to be supplied is assumed as follows:

Type of Water	Daily Amount (m^3/day)
Domestic water	15
Process water	10
Make-up water for cooling tower	35
Others (e.g., filter backwash water)	20
Total	80

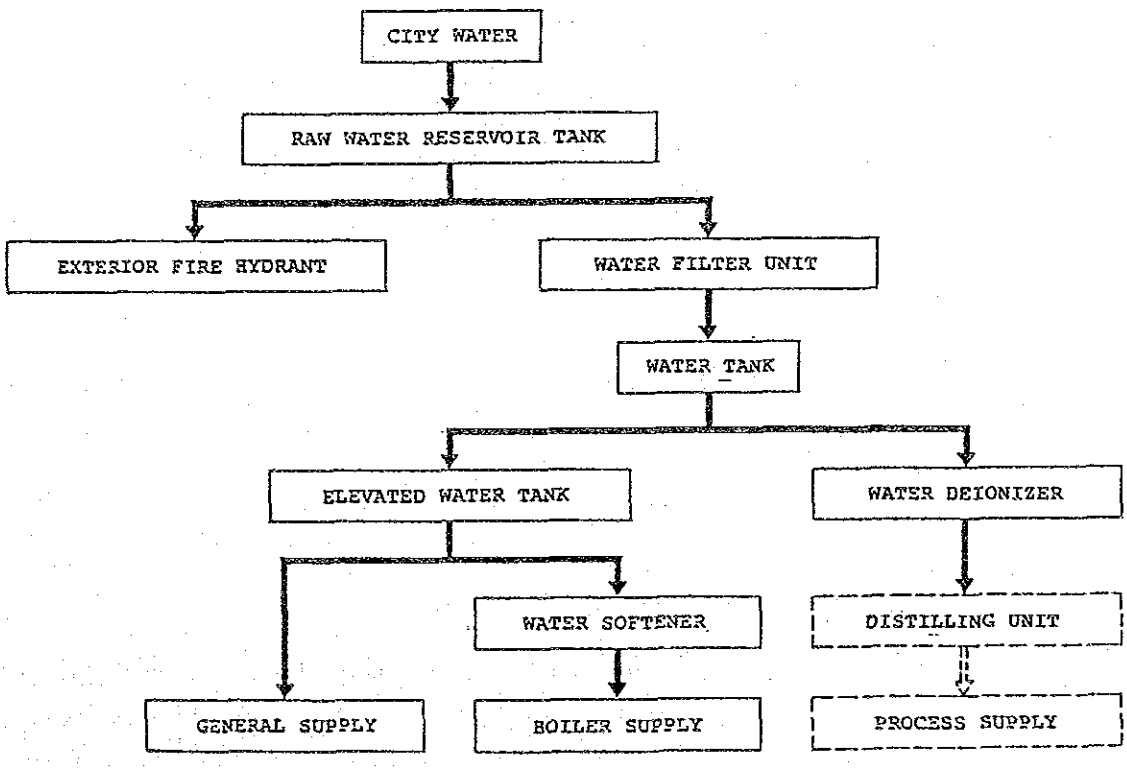


Fig. 4.14 Water Supply Flow

2) Sewerage System

The sewerage system will deal with the following five kinds of sewage and waste water.

a) Soil water
b) Waste water from domestic area
c) Waste water from water deionizer
d) Process waste water with high suspended solids (SS)
e) Process waste water with low SS

Before treatment, the waste water from water deionizer will be neutralized and the process waste water with high SS will be stored in a sedimentation tank. All the aforesaid sewage and waste water will be biologically treated and discharged into the gutter outside of the premises. The treatment system will be designed so that the effluent quality can be within 30 ppm in BOD in accordance with the tolerance limits provided in the National Environment Act of Sri Lanka (See Appendix 4).

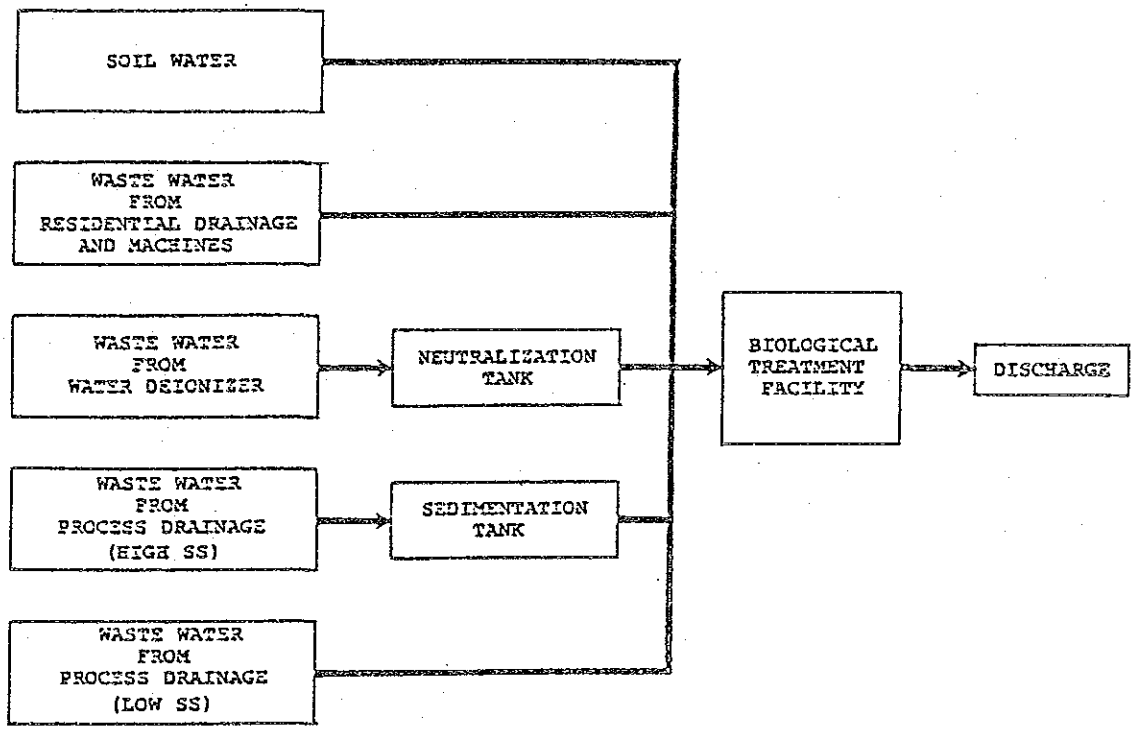


Fig. 4.15 Sewerage Flow

3) Gas

Gas from cylinders will be supplied to water heaters, burners in the QC section, etc.

4) Hot Water

Hot water will be made in a hot water storage receiving heat source from steam, and supplied to pan washing, etc. by a centralised forced circulation method.

Hot water to a sink in the resting rooms, etc. will be supplied independently of local water heaters.

5) Steam

Steam generated by a high-pressure steam boiler will be supplied to production equipment, hot water storage and air-conditioners. The boiler will be burnt by auto diesel oil which will be used also for the emergency generator.

6) Compressed Air

Compressed air made by a screw type air compressor will be supplied to production equipment, etc. after dehumidification.

7) Cooling Water

Cooling water will be produced by a cooling tower and circulated for a water distilling unit.

8) Vacuum System for Drainage

Vacuum will be made by a water-sealing vacuum pump and used for suction drainage of a sugar coating pan, etc.

9) Incineration

An incinerator will be provided for incineration of general waste.

10) Fire Fighting System

No laws concerning fire fighting are put in force in Sri Lanka. The following fire extinguishing provisions will be installed by reference to the fire law of Japan.

Outdoor fire hydrant	For the whole buildings
Fire extinguisher	For the whole buildings
Large fire extinguisher	For the boiler room, the generator room, etc.

(9) Plan of Construction Materials

As briefly described in 4.1 "Design Principle," use of construction materials will be planned bearing the following points in mind.

- Every effort shall be made to use local materials as much as possible in order to reduce construction cost and facilitate maintenance for a long time.

- Portions related to the pharmaceutical process shall be as a rule made of materilas meeting the GMP requirements. That is, these materials and construction shall be free of rust and dust, have washable strength and minimise dust accumulation. In particular, flooring materials shall have sufficient chemical resistance and ductility resisting a floor crack.

- Exterior portions shall be finished with durable materials so as to withstand strong sunbeam and heavy rain featuring the tropics. Additionally, since the Formulation Centre is sited near the seaside, exterior metal parts shall be made of stainless steel and aluminium resistant to briny air. If the use of ferrous materials is not avoided, they shall be galvanised or multi-coated with anticorrossive paint so as to prevent injury from salt.

- To facilitate replacement and repairs, materials and equipment shall be standardised ones so far as circumstances permit.

1) Principal Exterior Finish

Roof	:	Corrugated asbestos cement board on urethane resin waterproofing
Wall	:	Sprayed-on tile-like coating on concrete
Doors/Windows	:	Aluminium, wood, steel or stainless steel frame and sash

2) Principal Interior Finish

Manufacturing Room (incl. Corridors)

Floor	:	Urethane resin coating
Wall	:	Asbestos calcium silicate board, paint finished
Ceiling	:	Asbestos calcium silicate board, paint finished

General Administrative Room

Floor	:	Terrazzo block
Wall	:	Mortar, paint finished
Ceiling	:	Rockwool acoustic board

Corridor in General and around Atrium

Floor	:	Terrazzo block
Wall	:	Sprayed-on tile-like coating on concrete
Ceiling	:	Rockwool acoustic board

Quality Control Room

Floor	:	Terrazzo block on base coated with urethane resin
Wall	:	Gypsum board, paint finished
Ceiling	:	Gypsum board, paint finished

Storage

Floor	:	Concrete, paint finished
Wall	:	Painted on concrete
Ceiling	:	Gypsum board, paint finished

Machine Room

Floor : Concrete, painting finished

Wall : Concrete block with face joint; in part glass wool with glass cloth

Ceiling : Rockwool sprayed on concrete

Toilet

Floor : Mosaic tile on base coated with urethane resin

Wall : Semiporcelain tile

Ceiling : Asbestos calcium silicate board with paint finish

3) Structural Materials

a) Concrete Strength

Grade	Compressive Strength at 28 days (kgf/cm^2)	Use
B15	153	Blinding concrete
B30	306	Column, girder, foundation, slab, ground slab

b) Reinforcing Bar

Reinforcing bars will comply with BS 4449: 1978 "Hot Rolled Steel Bars for the Reinforced Concrete," or they will be JIS SD35 products or equivalent.

c) Structural Steel

Structural steel will be JIS SS41 products or equivalent.

4) Principal Materials for Electrical and Mechanical Work

a)	Wire	PVC-insulated wire
b)	Cable	Cross-liked insulated PVC seathed cable
c)	Conduit	PVC cable, thin-walled conduit
d)	Water pipe	PVC lining steel pipe
e)	Hot water pipe	Copper pipe
f)	Sewer pipe	PVC pipe
g)	Fire water pipe	Galvanised steel pipe
h)	Compressed air pipe	Stainless steel pipe
i)	Purified water pipe	Stainless steel pipe
j)	Chilled water pipe	Galvanised steel pipe
k)	Cooling water pipe	Galvanised steel pipe, PVC lining steel pipe
l)	Steam pipe	Steel pipe

4.2.4 Equipment

(1) Production Equipment

Production equipment to be installed in the Formulation Centre has been selected on the basis of the descriptions given in 3.3.2 "Capacity and Scale of the Project." In selecting them, due attention has been paid to safety, durability and stability. To be more specific, the following points have been taken into consideration.

- To cope with manufacturing of many and various kinds of drugs, production equipment shall have multi-purpose functions.

- Production equipment shall be of as simple construction as possible in order to reduce troubles during the initial run.

- Since part of the granulating process includes use of a small amount of organic solvent, the relevant portion shall be provided with explosion-proof equipment and construction.

- Sri Lanka is climatologically characterised by high temperature and humidity. In particular, high humidity adversely affects stable operation of production equipment. Therefore, production equipment shall be constructed in such a manner that use of high-level electronic parts and ferrous materials in ready-rusting portions is avoided.

The principal kinds and numbers of equipment to be installed in the Formulaiton Centre are as shown below.

	General Drugs	Penicillin
(1) Pretreatment/Weighing		
Siever for raw material	2	1
Pneumatic conveyor (Vacuum type)	2	1
Atomizer	1	1
Atomizer (Small type)	1	1
On-floor scale (Large type)	3	1
On-floor scale (Small type)	3	1
Table top scale	2	1
Balance	2	1
(2) Granulating		
Roller compactor	1	1
Fluid-bed granulator	1	-
Converter for the above	1	-
Planetary mixer	2	-
Ventilating dryer	2	1
Siever for granule	1	-
Oscillator	4	2
Conical mixer	2	-
Drum mixer	1	1
Pneumatic conveyor (Vacuum type)	5	-
On-floor scale	3	1
(3) Tabletting		
Tabletter for large size	1	-
Tabletter for medium size	2	-
Tabletter for small size	3	1
Punches and dies (for each item)	L.S.	-
Deduster for tablets	6	1
Table top oscillator	1	1
On-floor scale	6	1
Balance	6	1

(to be continued)

(continued)

	General Drugs	Penicillin
(4) Sugar Coating/Film Coating		
Sugar Coating Pan	5	-
Spraying unit for film coating	L.S.	-
On-floor scale	1	-
Syrup mixing stirrer	1	-
Paste mixing stirrer	1	-
Colouring syrup mixing stirrer	1	-
Paste/syrup tank	6	-
Lifting stirrer	1	-
Hot water bath	1	-
Filtering apparatus	1	-
On-floor scale	1	-
Platform scale	1	-
Table top scale	1	-
Balance	1	-
Water distilling unit	1	-
(5) Packaging		
Visual inspector (Sorting belt)	1	1
Table top scale	6	2
Manual sealer	2	1
Label paster	3	1
Label stamper	L.S.	L.S.
Heat sealer	1	-
(6) Bottle Washing/Drying		
Jet washer	1	1
Ventilating dryer	1	1
(7) Capsule Filling		
Capsule filler	1	1
Deduster for capsule	1	1
On-floor scale	1	1
Balance	1	1

(to be continued)

(continued)

	General Drugs	Penicillin
(8) Powder Bottling		
Table top scale	-	2
Manual Sealer	-	1

(2) Non-production Equipment and Implement Plan

Selection of non-production equipment and implements for the Formulation Centre has been made basically in the same manner as that of production equipment and implements. Additionally, the following matters have been taken into consideration.

- Instruments for analytical use shall be selected with the local availability of maintenance service in mind.

- Furniture to be provided in the manufacturing zone shall be made of steel, etc. so that no dust can be produced.

The principal kinds and numbers of non-production equipment and instruments are as listed below.

1) Transportation Equipment

a) General

Pallet truck	9
Storage battery forklift truck	3
Pallet rack	L.S.
Drum porter	3
Synthetic resin pallet	L.S.
Stainless steel drum	L.S.
Steel can	L.S.
Container	L.S.
Dolly	L.S.
Small pallet	L.S.
Container converter	1

Drum converter	3
Drum lift	9

b) Miscellaneous

Dust collector	L.S.
Vacuum cleaner	L.S.
Dehumidifier	L.S.
Hopper and container	L.S.
Workbench and desk	L.S.
Stool	L.S.
Step	L.S.
Dust-protective cover	L.S.
Sieve	L.S.
Storage cabinet	L.S.
Shelves	L.S.

2) In-process Instruments

Thickness measuring apparatus	L.S.
Thermometer/hygrometer	L.S.
Hardness tester	2
Sample atomizer	2
Micrometer	4
Flyability tester	2
Electronic balance	4
Moisture determinator	4
Set of standard size sieve	2
Disintegrator	2
Stop watch	L.S.
Sugaredness meter	1
Repose angle tester	2

3) Maintenance and Other Equipment

Sink	4
Basket	L.S.
Soaking vat	3
Washing machine for clothes	3
Dryer for clothes	2

Iron	2
Wear locker	L.S.
Maintenance tools	L.S.
Miscellaneous	L.S.

4) Formulation Improving Equipment

All-round formulator for tablet	1
Accessories to the abvoe	L.S.
Ventilation dryer	1
Workbench	L.S.
Storage cabinet	L.S.
Vacuum cleaner	1
Desk	1
Stool	L.S.
Sink	1

5) Quality Control Instruments

a) Instruments for Physico-chemical Experiments

Ultraviolet spectrometer	Spectrophotometer
Refractometer	Melting point tester
pH meter	Balance
Viscometer	Oil Bath
Glassware washer	Glassware dryer
Atomizer	Hardness tester
Disintegrator	Shaker
Flyability tester	Moisture determinator
Vacuum pump	Aspirator
Rotary evaporator	Water pump
Separatory funnel shaker	Shaker-water bath
Heating mantle	Voltage regulator
Bench	Draft chamber
Bath	Sink
Chemicals shelves	Stool
Glassware	

b) Instruments for Biological Experiments

Constant temperature unit	Centrifuge
Milipore filtering apparatus	Steam sterilizer
Microscope	Colony counter
Vacuum pump	Dry sterilizer
Steam bath	Clean bench
Bench	Sink
Chemicals shelves	Stool
Glassware	

c) Instruments for General Analyses

Balance	Refrigerator
Flame photometer	Distilling unit
Dryer for instrument	Vacuum dryer
Muffle furnace	Nitrogen determinator
Ammonium ion distilling apparatus	Karlfischer apparatus
Table top stirrer	Mixer
Electromatic buret	Potentiometric titration apparatus
Cooled centrifuge	Ultrasonic cleaner
Water bath	Compressor
Infrared spectrometer	Liquid chromatograph
Dissolution tester	Ultraviolet projector
Glassware washer	Temperature/humidity recorder
Standard white lamp	Gas chromatograph
Draft chamber	Bench
Sink	Chemicals shelves
Stool	Storage cabinet
Glassware	Miscellaneous

4.2.5 Basic Design Drawings

(1) Outline of Buildings

1) Name of the Project : The Construction Project for Pharmaceutical Formulation Centre of Essential Drugs

2) Location : No. 2 Kandawala Estate, Sir John Kotalawala, Mawatha, Ratmalana, Dehiwala-Mt. Lavinia

3) Site area : About 1.6 ha

4) Building area : 4,306 m^2

5) Total floor area :

The Main Building	4,229.8 m^2
The Utility Building	293.8 m^2
The Guardhouse	15.0 m^2
Total	4,538.6 m^2

6) Structure :

The Main Building	One storey (in part two storeys), reinforced concrete
The Utility Building	One storey, reinforced concrete
The Guardhouse	One storey, reinforced concrete

7) Height :

The Main Building	Top	: GL + 10,000 mm
	Ground Floor	: GL + 750 mm
The Utility Building	Top	: GL + 5,150 mm
	Ground Floor	: GL + 100 mm
The Guardhouse	Top	: GL + 2,800 mm
	Ground Floor	: GL + 100 mm

8) Principal Exterior Finish

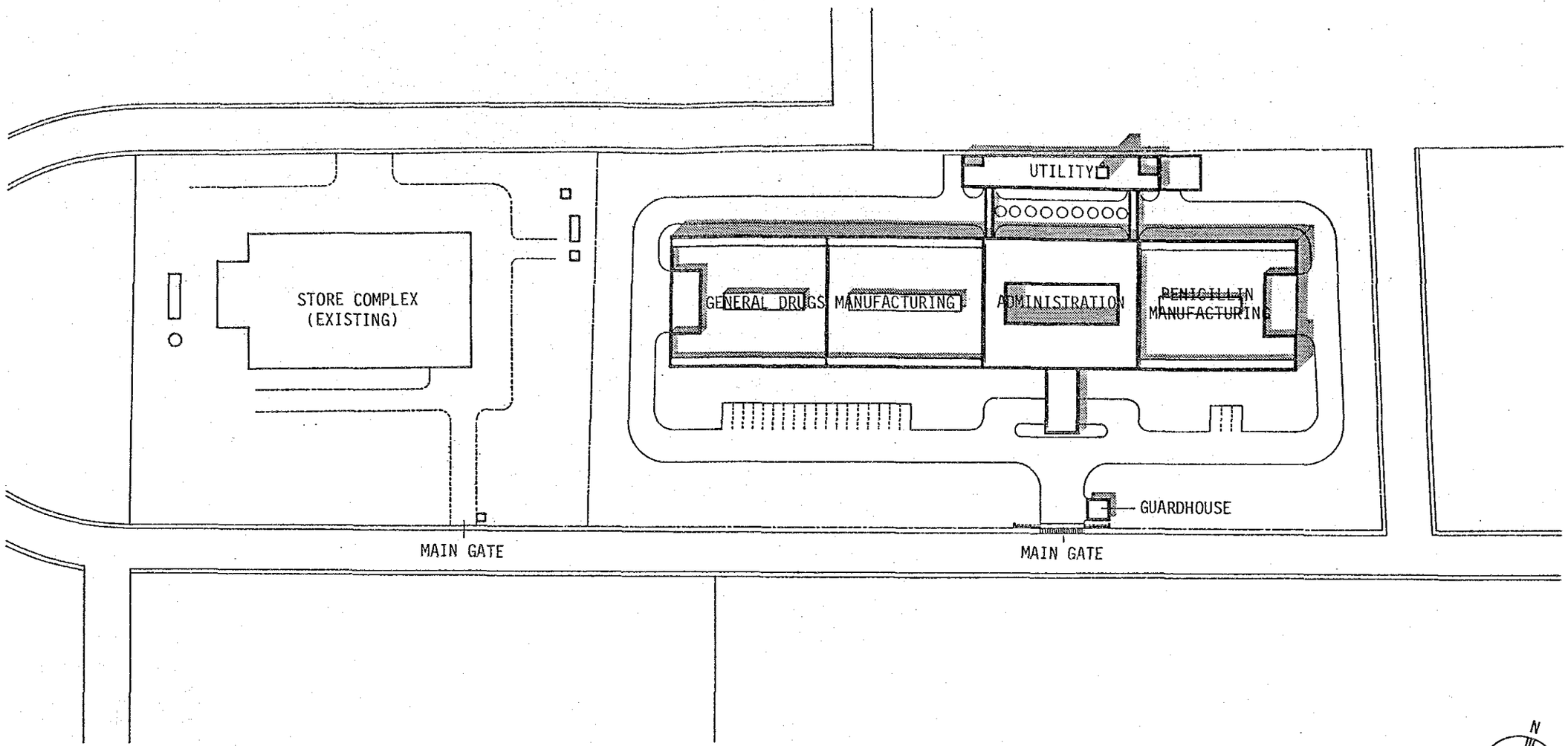
Roof : Corrugated asbestos cement board on urethane resin waterproofing

Wall : Sprayed-on tile-like coating in off-the-form concrete

Doors/Windows : Aluminium, wood, steel or stainless steel frame and sash

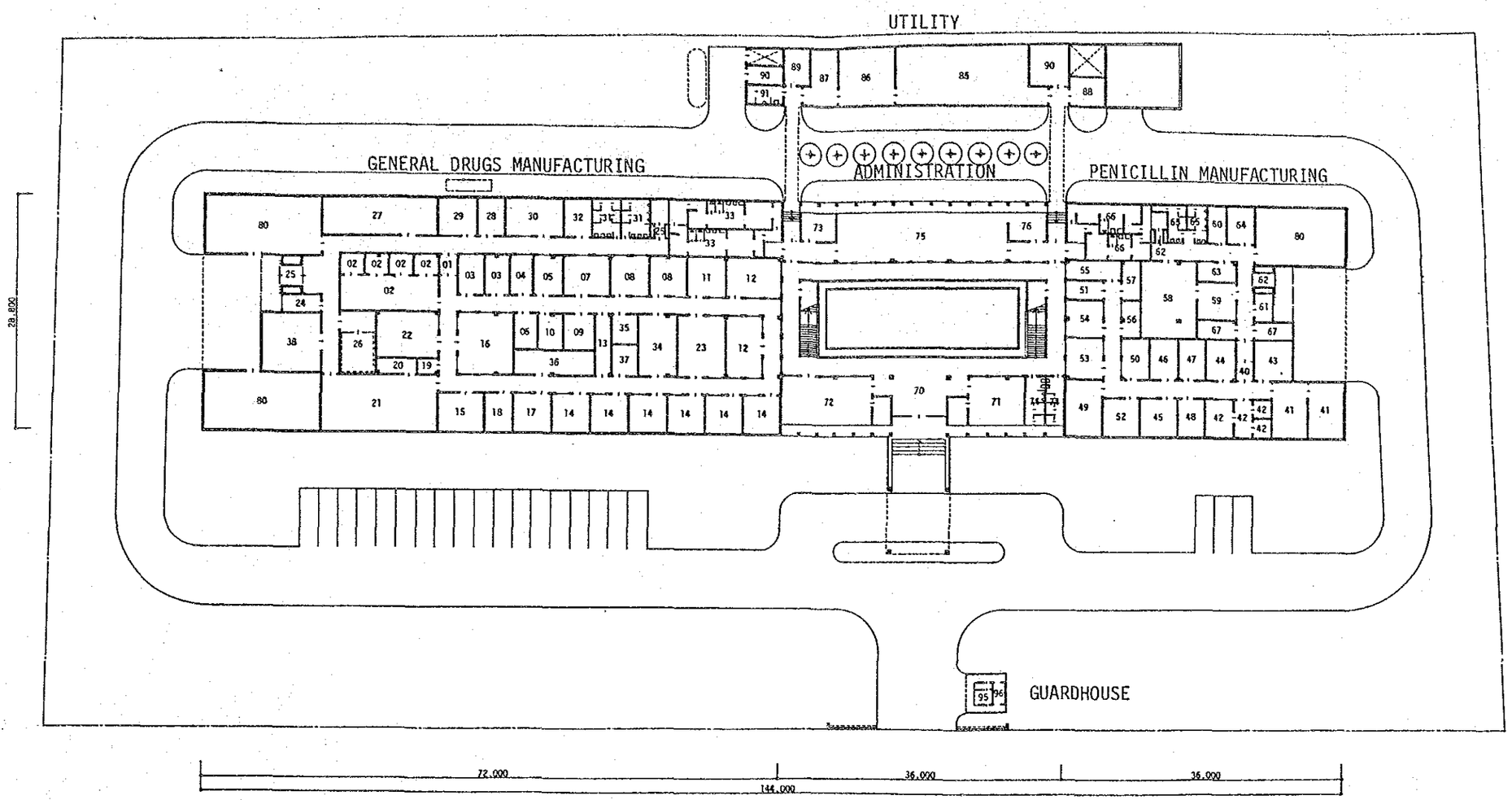
(2) Basic Design Drawings

Site plan (Fig. 4.16)
Ground floor plan (Fig. 4.17)
Plans (Fig. 4.18)
Elevations (Fig. 4.19)
Sections (Fig. 4.20)



SITE PLAN S. 1:100

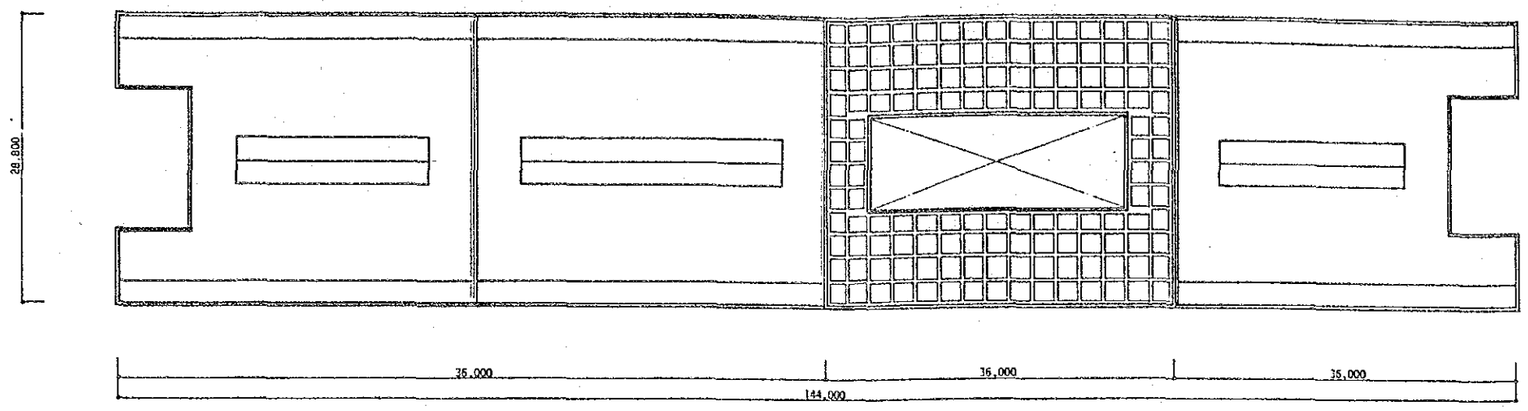
Fig. 4.16 Site Plan



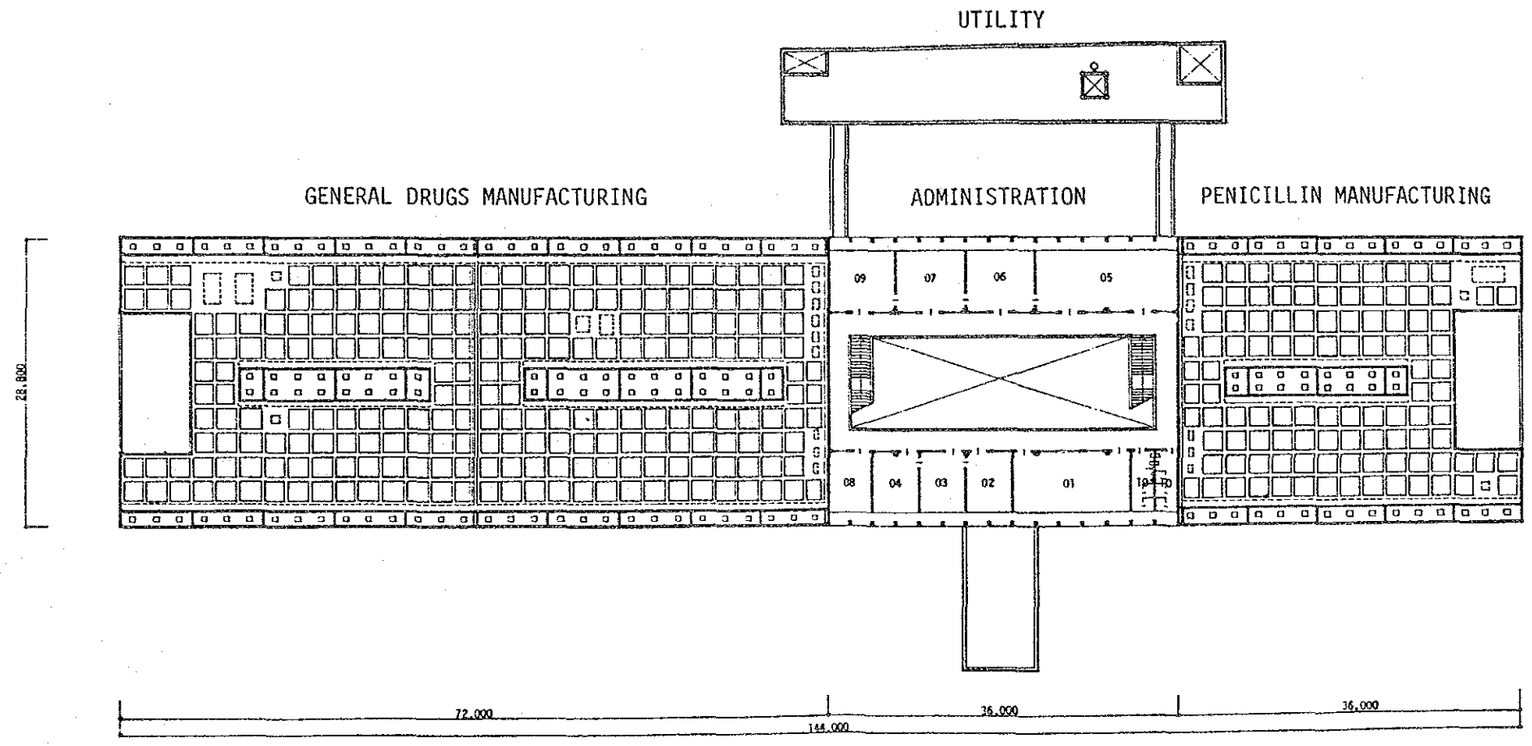
GENERAL DRUGS MANUFACTURING	01	PASS ROOM
	02	PRETREATMENT
	03	WEIGHING
	04	POST-WEIGHING STORAGE
	05	GRANULATING (1)
	06	GRANULATING (2)
	07	OSCILLATING/DRYING (1)
	08	OSCILLATING/DRYING (2)
	09	DRY GRANULATING
	10	SIEVING
	11	OSCILLATING/MIXING (1)
	12	OSCILLATING/MIXING (2)
	13	IN-PROCESS ANALYSIS
	14	TABLETTING
	15	PASTE PREPARATION
	16	FILM COATING
	17	CAPSULE FILLING
	18	TABLET SORTING
	19	CUSTODIAL CLOSET
	20	PACKAGING PREPARATION
	21	PACKAGING
	22	IN-PROCESS GOODS STORAGE
	23	POST-GRANULATING STORAGE
	24	UNLOADING OFFICE
	25	AIR SHOWER
	26	LOW TEMP. STORAGE
	27	RAW MATERIAL STORAGE
	28	OFFICE
	29	MAINTENANCE
	30	RESTING
	31	TOILET
	32	LAUNDRY
	33	CLOTHES CHANGING
	34	EQUIPMENT WASHING
	35	EQUIPMENT DRYING
	36	PARTS STORE
	37	BOTTLE WASHING/DRYING
	38	PRODUCT STORAGE
PENICILLIN MANUFACTURING	40	PASS ROOM
	41	RAW MATERIAL STORAGE
	42	PRETREATMENT
	43	WEIGHING
	44	GRANULATING
	45	DRYING
	46	IN-PROCESS ANALYSIS
	47	EQUIPMENT WASHING
	48	EQUIPMENT DRYING
	49	IN-PROCESS GOODS STORAGE
	50	BOTTLE WASHING
	51	MAINTENANCE
	52	MIXING
	53	TABLETTING
	54	CAPSULE FILLING
	55	TABLET SORTING
	56	BOTTLE FILLING
	57	FILLING ROOM
	58	PACKAGING
	59	PRODUCT STORAGE
	60	LAUNDRY
	61	UNLOADING OFFICE
	62	AIR SHOWER
	63	OFFICE
	64	RESTING
	65	TOILET
	66	CLOTHES CHANGING
	67	PARTS STORE
ADMINISTRATION	70	ENTRANCE HALL
	71	ANTEROOM
	72	OFFICE
	73	MEDICAL
	74	TOILET
	75	CANTEEN
	76	KITCHENETTE
OTHERS	80	MACHINE
UTILITY BUILDING	85	PUMP, COMPRESSOR ROOM
	86	BOILER ROOM
	87	GENERATOR ROOM
	88	BLOWER ROOM
	89	NAPPING
	90	STORAGE
	91	TOILET
GUARDHOUSE	95	GUARD
	96	TIME

GROUND FLOOR PLAN S. 1:600

Fig. 4.17 Ground Floor Plan



ROOF PLAN



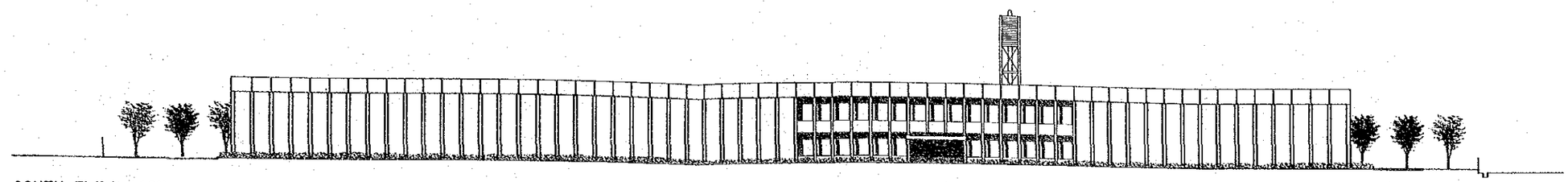
1st FLOOR PLAN

ADMINISTRATION

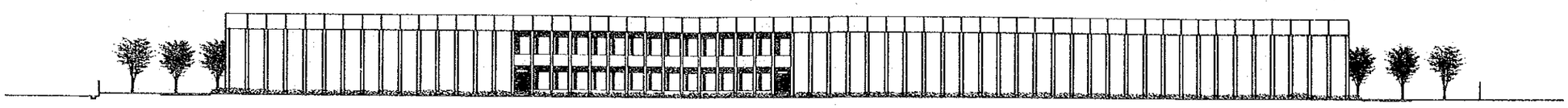
01 CONFERENCE ROOM (1)
02 CONFERENCE ROOM (2)
03 ANTEROOM
04 MANAGER
05 PHYSICO-CHEMICAL LABOLATORY
06 INSTRUMENTATION
07 BIOLOGICAL LABORATORY
08 SAMPLE STORAGE
09 LABORATORY
10 TOILET

PLANS S. 1:600

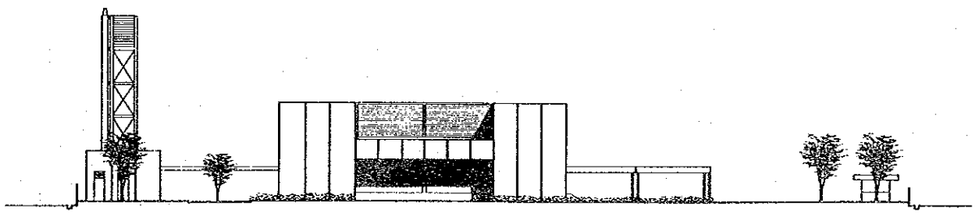
Fig. 4.18 Plans



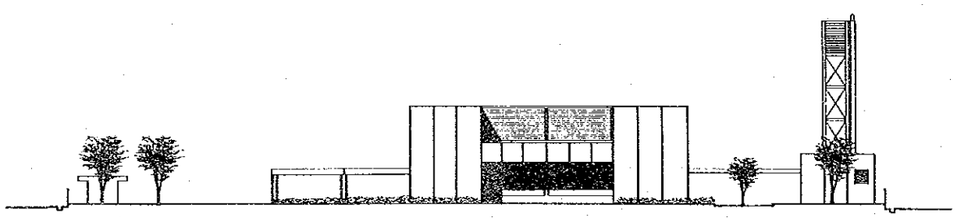
SOUTH ELEVATION



NORTH ELEVATION



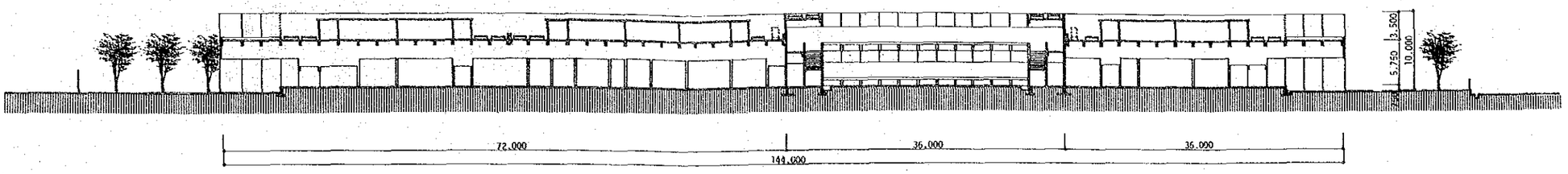
WEST ELEVATION



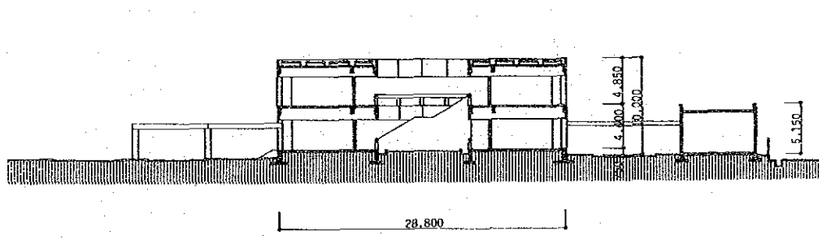
EAST ELEVATION

ELEVATIONS S. 1:600

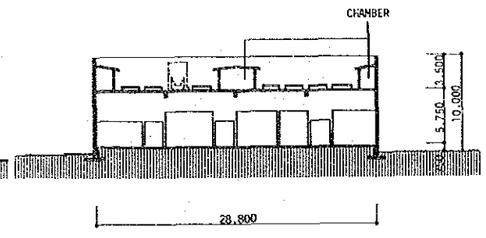
Fig. 4.19 Elevations



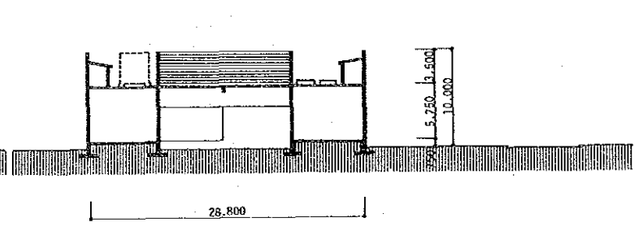
A-A SECTION



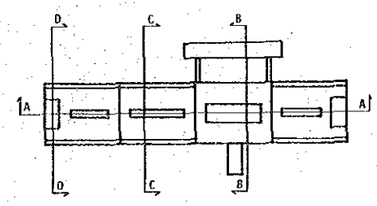
B-B SECTION



C-C SECTION



D-D SECTION



SECTIONS S. 1:600

Fig. 4.20 Sections

4.3 Construction Plan

4.3.1 General Situation of Construction in Sri Lanka and Principles of Construction

Visiting several construction sites in Colombo, the basic design study team had the following observations. In local contractors' construction sites, bamboo is being still used for scaffolding; human power even now plays an important role in construction. On the other hand, in construction sites managed by contractors from Japan, Singapore and other foreign countries is used modern construction equipment, such as steel scaffolds and tower cranes. Thus, it may be concluded that the situation of construction in and near Colombo is characterised by the mixture of obsolete and modern construction technology.

In the field survey, it was also found that the labour productivity was not so high in Sri Lanka as to require about three to four times the standard manpower in Japan. Further, there is a plenty of labour in Sri Lanka, but many skilled workers cannot be expected. It is difficult to collect many constrcution hands experienced in modernised constructional work. To make matters worse, labourers who by chance acquired new techniques in foreign contractors' construction site are liable to flow out to Singapore, the Middle and Near Eastern countries, etc. in pursuit of larger incomes. In order to carry out quality construction effectively in the above situation, it may be a best solution for construction experts from Japan or another country to undertake constructional supervision or extend technical assistance to Sri Lanka.

As for procurement of construction materials, most of them are available in Sri Lanka provided that their quality and quantity are left out of consideration. Actually, however, the greater part of the available materials are imports, and so have many problems with respect to prices, delivery time, available amount, etc. Products made in Sri Lanka are problematic in amount and delivery time because of their low production. On the other hand, use of locally available products has a great advantage in maintenance after completion, etc. With the above situation in view, every effort will be made to use local materials with due consideration for the required locations, amount, etc.

Regulations, application procedures, etc. concerning building construction are as summarised in Table 4.4. According to the field survey, special regulations or procedures by which construction time or process might be greatly influenced were not found. However, since the authorities' examinations may require long time because part of the procedures are now being reviewed, necessary procedures, etc. will have to be carried out as early as possible on the basis of in-depth discussion with the concerned authorities.

Table 4.4 Regulations and Application Procedures concerning Building Construciton

Item	Law/Regulation	Authorities	Remarks
Development	Urban Development Authority Law Act No. 41 of 1978; UDA Planning and Building Regulation 1982	UDA	
Application for Building Permit	do.	UDA; Municipal Council	
Fire Precaution	Fire law or the like is not in force. For tall buildings, Regulation for High Riser Buildings over Four Floors or over 40 Feet is applied.	Fire Brigade	British Standards are applied in practice. After receiving the application for building permit, instructions are issued by writing. A building completed or under construction is inspected from a viewpoint of fire fighting.
Environment	National Environment Act (1980)	Central Environment Authority (CEA)	Basic Guideline for Environment Assessment is applied.

After the exchange of notes on the grant aid between the Government of Japan and the Government of Sri Lanka, SPC and the Consultant will proceed with the project without hitch, discussing further the detail design, the tendering, the construction contracting and the construction on the basis of what is specified in the basic design.

Prior to the commencement of construction, the following work will have to be assuredly completed by all the concerned parties in Sri Lanka.

- Clearing and grubbing in the site
- Filling
- Fencing
- Providing such temporary utilities as power, telephone and water
- Making the roadside gutters better

To draw out the overall construction schedule, the scope and connection of the Japan work and the Sri Lanka work, procurement and delivery of materials, periods of individual work, test run period, etc. will be discussed in detail among SPC, the Consultant and the Contractor.

On the basis of the overall construction schedule thus prepared, detail schedules will be made for each of the building work, the electrical and mechanical work, the processing installation work and the Sri Lanka work, keeping their timing related to each other. In particular, due attention will be paid to delivery and installation of equipment and materials from Japan and stay of technical experts in Sri Lanka so as to enable the work to be smoothly carried out.

Further, local climatological features will be taken into account in establishing the construction programme. That is, every possible measure will be taken in advance for earthwork, foundation work, waterproofing work in rainy seasons (April to June; September to November) and concrete work in hot season (April to June) so that the construction project can be completed in time.

This project as construction of a pharmaceutical manufacturing plant has many technical interfaces among the building work, the utility work and the process equipment work. Therefore, staff members in charge of the work will be essentially required to have close knowledge of similar construction projects.

4.3.2 Division of the Construction Work

This construction project for the Formulation Centre is a project to be realised under the grant aid programme of the Government of Japan. For implementing the project, some items of the constructional work will have

to be undertaken on the part of Sri Lanka at his own cost. Therefore, the success of the project will not be insured without combined execution of the Japan work and the Sri Lanka work. Work assignment to both the parts is briefly proposed as follows subject to further discussion at every stage of the project implementation.

(1) Work to be undertaken under the Grant Aid by the Government of Japan

Building Work (incl. Electrical and Mechanical Work)

The Main Building
The Utility Building
The Guardhouse

Special Utility Work

Steam supply system
Deionized water supply system
Compressed air supply system
Sewage treatment system

External Work

On-premises roads and car park
On-premises drainage
Utility piping rack
Main gate and flag poles

Equipment

Production equipment
QC equipment

(2) Work to be undertaken by the Government of Sri Lanka

Table 4.5 Itemised Work to be undertaken by the Government of Sri Lanka

Work		Remarks
Ground Preparation	Filling and grading	Filling 1.0 m high on average
	Retaining wall for fill	
	Fencing	About 2.0 m high
Temporary Work	Power receiving/transforming	400 V/230 V 50 kVA
	Service piping city water	50 ϕ service pipe (also for permanent use)
	Telephone line receiving	Extending two lines
Relocation of power line existing on the premises		
Repairs and extension of roadside gutters		
Landscaping		
Outdoor lighting and sprinkling		
Power receiving/transforming for permanent use		
Service piping of municipal water for permanent use		That for the temporary work to be used as it is
Telephone line receiving for permanent use		
Furniture, drapery, copier, miscellaneous household equipment and utensils, etc.		
Working clothes and truck		
Other production implements than those to be furnished by Japan		
Application for building permit and document preparation appurtenant thereto		Incl. application charge and all necessary costs
Initial Environmental Examination and preparation of report thereon		Incl. all necessary costs
Payment of taxes on imported materials and equipment		If necessary

4.3.3 Constructional Supervision

After the exchange of notes on the grant aid, the Consultant will place a contract for detail design and constructional supervision of this project with SPC, the implementing agency of the Formulation Centre. In compliance with the same contract, the Consultant will prepare the detail design documents for building facilities and equipment on the basis of the basic design, manage the tendering and contracting for construction and supervise the construction.

The Consultant will, from the commencement to the completion of construction, send a resident supervisor having ability and knowledge necessary to attain the object of the project in conformity with the requirements of the design documents and, as the construction progresses, will despatch technical experts in every work at appropriate times for the purpose of detail discussion or instructions, inspection, attendance to test run, etc.

As described in 4.4.1 "General Confirmation Method for Pharmaceutical Process Plant," the process equipment will be delivered to SPC after confirming the operability by the use of placebo (i.e., a substance having no pharmacological effect).

In view of the above, organisation of the constructional supervision is proposed as follows:

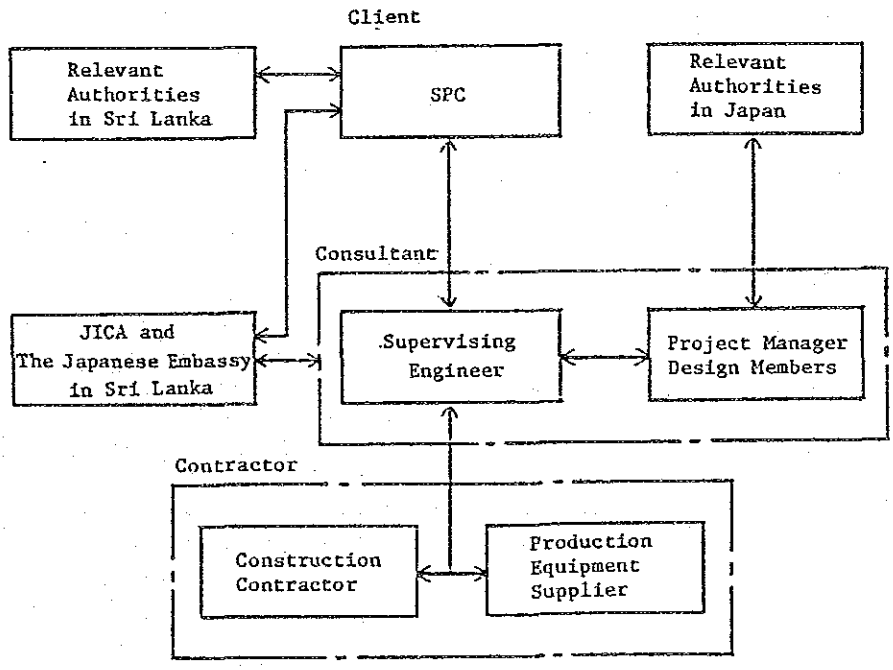


Fig. 4.21 Organisation of the Constructional Supervision

4.3.4 Procurement of Building Materials and Equipment

It will be the fundamental principle in procurement to use products available in Sri Lanka so far as they have no technical and economic problems. To ascertain availability of building materials and equipment, market research of Sri Lanka was made by the Phase II study team in July 1985. As for imported products, it was found that many of them are problematic with respect to price, quality, availability in time and maintenance.

From the above considerations and the requirements (e.g., cleanness, preciseness, durability) for the project, the procurement of building materials and equipment is proposed as shown in Table 4.6. In this connection, the Government of Sri Lanka does not lay down any restriction on importation of the kind of equipment to be installed in the Formulation Centre.

Table 4.6 Plan of Procurement of Building Materials and Equipment

Work	Materials and Equipment	
	In Sri Lanka	From Japan
Building	Cement (in part), Aggregate (crushed stone, sand), Brick, Concrete block, Glass (for general use), Tile, Asphalt for paving, Timber	Cement (in part), Plywood for formwork, Reinforcing bar, Structural steel, Steel doors and windows, Paint, Resilient flooring, Light gauge steel frame, Ceiling frame, Gypsum, Acoustic and other boards, Urethane resin roofing, Glass (in part)
Electrical	Socket outlet, Switch, PVC conduit	Switch board, Power circuit control panel, Wire and cable, Lighting fixture, Communication system
Air-conditioning	PVC pipe	Water chilling unit, Boiler, Cooling tower, Pump, Fan, Air-condi-tioner, Steel pipe, Duct
Plumbing	PVC pipe, Catch basin	Sanitary fixture, Steel pipe, Pump, Synthetic resin water tank

4.4 Confirmation of Performance in Production

4.4.1 General Confirmation Method for Pharmaceutical Process Plant

In general, processing equipment consists of two types: one manufacturing a sole specific product and the other manufacturing many kinds of products by changing materials. Pharmaceutical process is composed of the latter type of equipment. For example, aluminium hydroxide tablets, and aluminium hydroxide and magnesium hydroxide tablets are manufactured by the use of common equipment such as a mixer and a tabletter in most of the process. This role of equipment in pharmaceutical process resembles that of kitchen equipment in cooking in that many kinds of products or dishes can be served by the same equipment.

The pharmaceutical process which is a set of comparatively simple physical process, such as weighing, sieving, mixing, kneading, tabletting, etc. is completely different from the process of a chemical plant characterised by chemical reactions.

On the other hand, the act of pharmaceutical manufacturing is composed of software (protocol, technical know-how, etc.), hardware (process equipment, etc.), materials and utilities. This relation is as illustrated below:

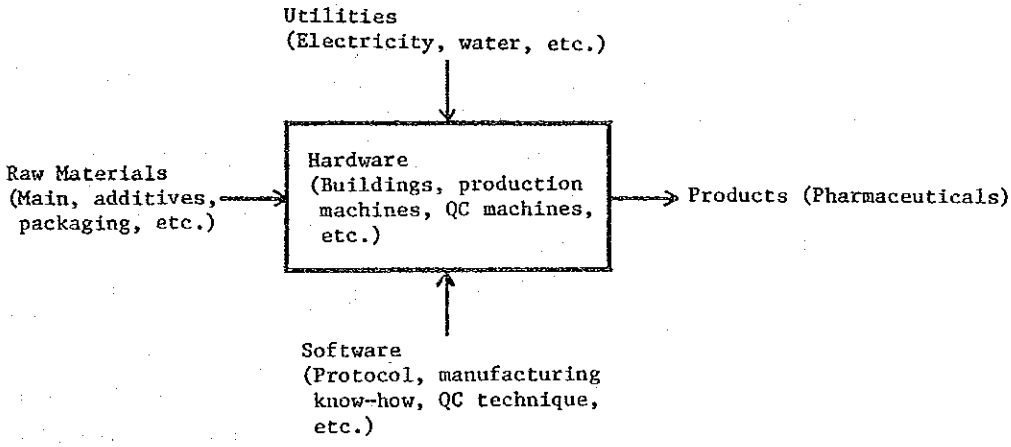


Fig. 4.22 Position of Hardware in Pharmaceutical Manufacturing

Of these elements, the software is not held by the contractors or the equipment suppliers, but by the owner of a pharmaceutical plant. In general, confirmation of performance upon completion of plant facilities is made only for the hardware. Process equipment of which performance is most important in the hardware is delivered to the owner after the contractors and/or the equipment suppliers test the operation by idling and then confirming the operation stability and the amount of hourly or daily production by the use of placebo.

Subsequently, test run of the process using actual materials is conducted by the owner at his own responsibility. The test run is led to permanent production, establishing the protocol and know-how (e.g., mixing order, drying time) of individual kinds of drugs, inspecting qualities in and after process and thus completing the manufacturing technique on a trial-and-error basis.

4.4.2 Confirmation Method for this Project

Functions of this Formulation Centre will be fulfilled by harmonious integration of the following three matters.

- Completion of facilities and installations under the grant aid of the Government of Japan
- Technical cooperation by Japanese experts
- Technical development on the part of Sri Lanka

As described in 3.3.2 "Capacity and Scale of the Project," the quantitative performance required of the Formulation Centre is, for example, 427.5-million pieces/year for general drugs in tablets and the qualitative performance is related to the formulation of 43 items in total.

As pointed out in 4.4.1, the quantitative performance will be confirmed by testing the amount of production using placebo, before the delivery of the facilities and installations to SPC. In this connection, the required 427.5 million pieces/year of general drugs in tablets is equivalent to 232,000 pieces/hour for tabletting and 309,000 pieces/hour for other processes if the actual running days and hours are taken into account.

On the other hand, the qualitative performance will be confirmed by establishing the manufacturing technique of each item on a trial-and-error

basis. It will take two or three months per item to get such technique in conformity with the relevant protocols. Fortunately, however, the 43 items can be divided into some groups because of similarity in the manufacturing techniques. Therefore, it is considered reasonable that a few representative items out of the said groups should be selected as initial production items so that qualitative performance of these representative items can be intensively confirmed during the Japanese technical cooperation. As for the remaining items, their qualitative performance will be able to be confirmed by Sri Lankan staff because the technique acquired in the initial production can be applied to them. If economic advantages and present availability of protocols in SPC are taken into account in addition to the aforesaid similarity of individual processes, it is proposed that qualitative performance of the following five items should be confirmed in the initial production.

(43) Ampicillin capsule
(32) Paracetamole tablet
(44) Cloxacillin capsule
(1) Aluminium hydroxide tablet
(21) Promethazine HCl tablet

( ) : Item No. in Table 3.4

Until the manufacturing technique for all the 43 items is established, the output of these five items which meets the predicted demand is expected to be only 30 to 40 % of the stabilised production ability of equipment.

It will take about one year for SPC to establish the manufacturing techniques of all the five initial production items. In view of the project schedule, it is not considered reasonable to incorporate the said period of technique establishment into this grant aid programme. Therefore, another technical cooperation programme should preferably be arranged for making the SPC staff attain the proper manufacturing technique.

The above-mentioned proposal for performance confirmation of this project is summarized as follows:

Table 4.7 Performance Confirmation of this Project

	Before Delivery	During Initial Operation	In Stationary Operation
Quantitative Performance	100 % operation by placebo	30 to 40 % production	100 % production
Qualitative Performance	-	Five representative items	43 items
Confirmed by	Japanese staff under the grant aid	SPC (preferably under another cooperation programme)	SPC

4.5 Project Schedule

The schedule of the project implementation after the exchange of notes on the grant aid programme is proposed as follows:

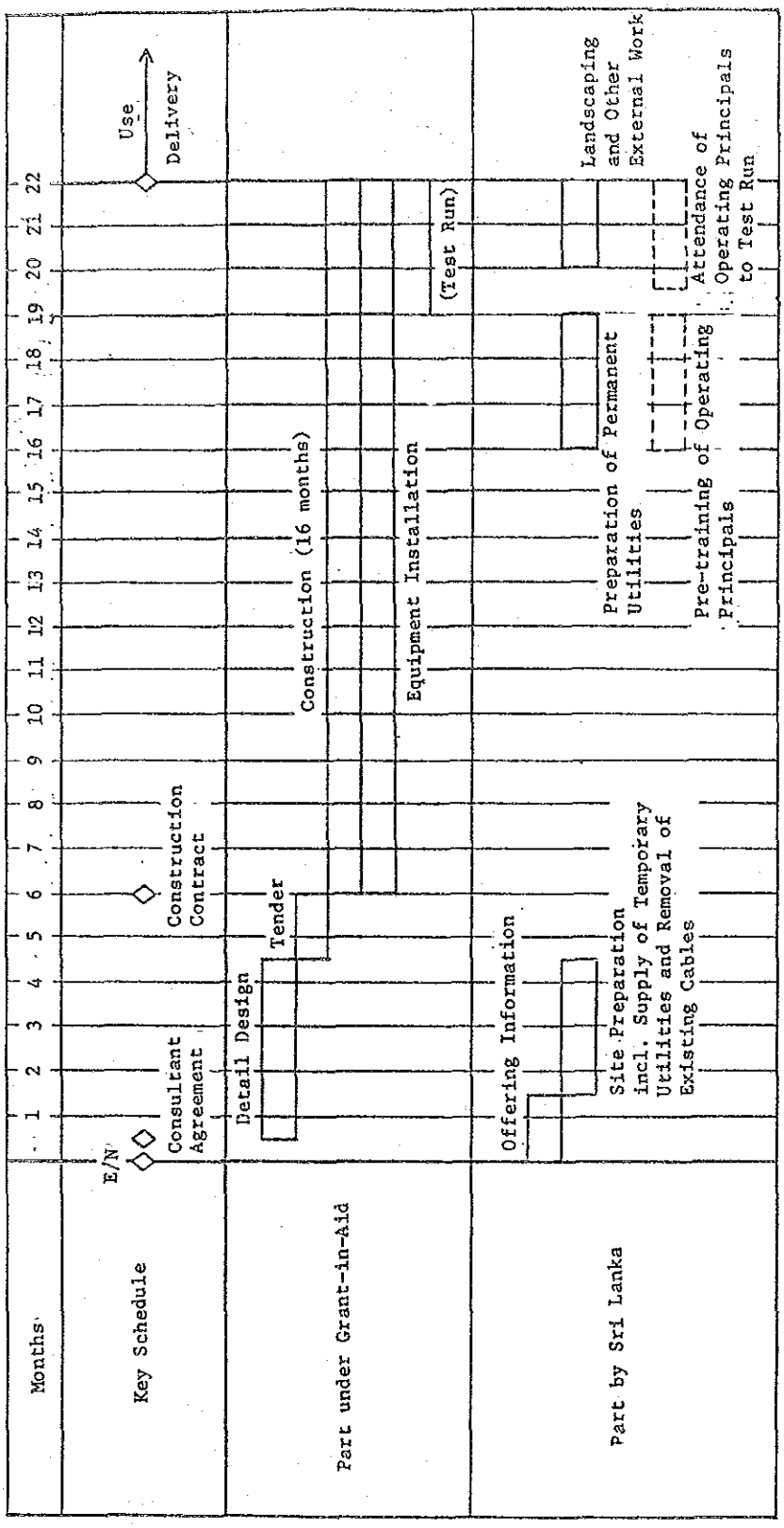


Fig. 4.23 Schedule of the Project Implementation

4.6 Management Plan

4.6.1 Plan of Employment

Generally in Sri Lanka, employees whether public or private often change their job in pursuit of higher social positions or larger incomes. This means that employees of the Formulation Centre can be easily hired from the private sector and conversely that labour sufficiently skilled in the Formulation Centre may be drained into private manufacturers. Of the staff described in Fig. 3.1 "Predicted Organisation (Tentative) of the Formulation Centre," the following six persons will be key personnel necessary for satisfactory operation of the Formulation Centre and will have to be trained in Japan before the inauguration of the centre.

Works Manager	1 person	
Maintenance Engineer	1 person	
Quality Controller	1 person	
Formulation Development	1 person	
Production Engineer	2 persons	(incl. one for sugar coating)

SPC is making preparations for employment of excellent key personnel and has a specific intent to take the following measures for the stable employment of the key personnel.

(1) The employment is made under a deposit contract lawfully witnessed by at least two persons so that he cannot resign before a certain period expires.

(2) Promotion and rise in salary are made before the expiration of the contracted term.

(3) To the key personnel are paid higher salaries than those in similar pharmaceutical manufacturers in Sri Lanka. In addition, a supplementary system is introduced so that part of profits can be shared with the key personnel.

(4) Assistant staff is periodically trained so as to cope with unexpected resignation of anyone of the key personnel.

As for other employees than the key personnel, their employment is considered comparatively easy and stable, viewed from the fact that the unemployment rate in Sri Lanka is at present high.

4.6.2 Estimation of Income and Expenditure

This construction project is purposed to make stable supply of uniformly high quality essential drugs as part of the national programme to achieve acceptable level of health for all citizens of Sri Lanka by the year 2000. Actually, however, the Formulation Centre is a kind of economic activities ruled by income and expenditure in the form of pharmaceutical manufacturing. On the other hand, SPC managing the Formulation Centre is under the direction and control of MOH, but is financially an autonomous body. In consideration of these facts, it is a key to the success of the project to ascertain whether the Formulation Centre will have suitable profitability.

The profitability of the Formulation Centre was studied under the following conditions.

(1) Annual income and expenditure of the Formulation Centre under the stabilised operation and management are used as the basic index.

(2) The study is made only for the income and expenditure relating to pharmaceutical manufacturing in the Formulation Centre. Financial accounts of other SPC's activities (e.g., import and supply of drugs not manufactured in the Formulation Centre) are disregarded. Thus, the study is made on the basis of manufacturing cost in the Formulation Centre.

(3) For income accounts, since assumed selling unit prices (i.e., the unit prices of imports presently adopted for costing by SPC) are different between supply to the public sector and that to the private sector, the income is assumed by summing up the assumed respective selling unit prices multiplied by demands of both the sectors.

(4) In Sri Lanka, sales turnover tax equivalent to 5 % of the amount of sales is imposed on the manufacturing industry. Therefore, the real income is obtained by deducting the sales turnover tax from gross income.

(5) The expenditure is calculated by accumulating individual items necessary for operation and management of the Formulation Centre.

(6) Considering that the Formulation Centre is constructed under the grant aid, depriciation account for building facilities, process equipment and installations is not included in the expenditure.

Annual balance of the Formulation Centre is estimated on trial as follows from the above conditions.

Table 4.8 Trial Annual Balance of the Formulation Centre

		In million rupees
Gross Sales	Gross sales	116.819
	Sales turnover tax	5.841
	Real sales income	110.978
Variable Expenses	Pharmaceutical materials cost	79.634
	Packing materials cost	6.801
	Utilities : Power	1.000
	Fuel	0.075
	Water	0.055
	Spareparts	0.500
	Total of variable expeses	88.065
Fixed Expenses	Personal expense	2.000
	Maintenance expense	3.000
	Insurance expense	0.250
	Welfare expense	0.100
	Transportation expense	0.250
	Overhead	0.150
	Ground rent	0.052
	Total of fixed expenses	5.802
Total of Expenditure		93.867
Recurring Profit		17.111
Profit ratio (for real sales income)		15.42 %
Profit ratio (for gross sales income)		14.65 %

As shown in Table 4.8, the Formulation Centre will bring a profit of Rs. 17.111-million every year. Financially, therefore, it is reasonable to conclude that the pharmaceutical manufacturing in the Formulation Centre will have profitability. This also means that there is less possibility of reduction in production size and return to dependence on imports in future. If the said profit is decreased, manufactured drugs will be able to be supplied to the public sector at lower prices, the national reorientation programme of the primary health care thereby being advanced more rapidly.

The trial balance given in Table 4.8 is based on the assumption that all the 43 units are manufactured in the stabilised production. It should be noted that the said profitability cannot be expected for a transition period from the commencement to the stabilised production because the yield rate is low due to improvement of formulation and acquisition or development of manufacturing techniques. As for the transitional period, it is expected that the Formulation Centre will be financially supported by MOH and other authorities of Sri Lanka irrespective of the self-supporting account system of SPC.

4.7 Approximate Project Cost on the Part of Sri Lanka

The approximate cost for this project is estimated as follows for the work to be undertaken on the part of Sri Lanka.

Table 4.9 Approximate Cost Estimate of the Work by Sri Lanka

Work	Approximate Cost (Rs.)	Remarks
Site preparation	4,830,000	Incl. retaining walls and fences
Temporary utilities	120,000	Power, water and telephone
Relocation of power line on the premises	100,000	
Charge for application for building permit	4,000	
Landscaping	908,000	Incl. sprinkling
Deep wells	200,000	Four wells in total
Outdoor lighting	670,000	
Power receiving/transforming for permanent use	900,000	
Telephone line receiving for permanent use	100,000	
Furniture and miscellaneous household equipment and utensils	1,150,000	Incl. drapery, copier, etc.
Production implements	1,150,000	Working clothes, truck, vacuum cleaners, etc.
Total	10,132,000	= ca. ¥88,000,000

CHAPTER 5 PROJECT EVALUATION

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The principal objective of this construction project is for SPC to locally manufacture the most important essential drugs for the primary health care in Sri Lanka in lieu of some of the drugs being presently imported by SPC. As a result of such import substitution by this project, the following benefits are expected to solve the pharmaceutical problems in Sri Lanka.

(1) If drugs are imported, it takes about 10 months to check samples, confirm pharmacopoeia, make a tender, etc. Such long lead time will be reduced.

(2) Drugs having the same efficacy will become uniform in their shape, size and colour. Since drugs different in efficacy can be easily distinguished, the anxiety presently caused by supply of drugs from various sources will be taken out from users.

(3) Since products are carefully packed, the amount of faulty drugs before use will be reduced.

(4) Tablets for the public sector will be marked "DHS" in the process of tabletting. This will become an effective solution to prevent these free-of-charge durgs from being illegally sold to the private sector.

(5) For imported drugs, it cannot be examined for every process stage whether they have been manufactured in conformity with GMP. Local manufacturing will make it possible to supply uniformly high quality drugs meeting the GMP requirements.

(6) Even if drugs are manufactured by the same protocol, their bioavailability varies with manufacturers. This problem will be improved by local manufacturing of uniformly high quality drugs.

(7) Import of drugs is liable to be governed by market fluctuations. If raw materials only are imported for local manufacturing, drugs will be supplied at a more stable price.

(8) SPC is compelled to purchase a considerable amount of drugs at a time instead of placing small orders from time to time. Raw materials can be imported in small lots. Therefore, it will be made possible to shorten the storage time, supply freshly manufactured stocks and therefore reduce interest on SPC's procurement fund.

(9) Most of essential drugs being imported by SPC are manufactured by small enterprises. Therefore, delay in supply often occurs; in particular no reliable supply can be expected for emergency use. In the case of local manufacturing, raw materials are considered to be steadily and punctually supplied from large foreign companies.

(10) Judging from the trial annual balance of the Formulation Centre estimated using the costing method presently adopted for imported drugs by SPC, pharmaceutical manufacture within Sri Lanka will have more financial benefits than the present heavy dependence on import. Also, there is a possibility of supply of essential drugs at lower prices.

On the other hand, the local manufacturing of drugs is expected to bring about the following indirect effects on the state of Sri Lanka.

(1) Import of raw materials instead of products will results in foreign exchange saving.

(2) Technological know-how of pharmaceutical manufacture will be increased.

(3) The Formulation Centre will serve as facilities for education and training in industrial pharmacy.

(4) The Formulation Centre will create opportunity of direct and indirect employment.

(5) The Formulation Centre will stimulate supporting industries and services such as packaging, printing, etc.

CHAPTER 6 CONCLUSION AND RECOMMENDATIONS

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In order to realise the steady supply of uniformly high quality drugs forming part of the national reorientation programme of the primary health care, local production instead of the present reliance on imports is indispensable as described in 3.2.2 "Justification for Construction of the Formulation Centre." Also, the local production is expected to have great effect on the social and economic fields as well as on the pharmaceutical administration of Sri Lanka as pointed out in Chapter 5 Project Evaluation.

The Government of Sri Lanka is putting large expectation on this construction project and carrying out the preparatory works for implementation of the project, such as land acquisition, financial preparation for the Sri Lanka work, possession of protoclos of the planned items of drugs, etc. And, as stated in 4.6.1 "Plan of Employment," SPC is giving due consideration to steady operation of the Formulation Centre by skilled key personnel.

For the financial feasibility of the Formulation Centre which is the most critical factor in the project, its profitability is ascertained as estimated in 4.6.2 "Estimation of Income and Expenditure."

In view of all the above, this project is judged to have sufficient adequacy to implement it under the grant aid of the Government of Japan.

In this connection, as referred to in 4.4.2 "Confirmation Method for this Project," hardware such as building facilities, process equipment and installations will be completed in the scope of this construction project while software such as formulation improvement and techniques of manufacturing, quality control and equipment maintenance will be left untouched in the same project. In order to complete the software in the Formulation Centre, the following measures should be taken.

(1) Training the key personnel in Japan
(2) Sending experts from Japan

For the foreign training of (1), it is considered appropriate to train the six key personnel proposed in 4.6.1 "Plan of Employment" for about three months just before the commencement of test run.

For the local training of (2), it is proposed to send a few experts continuously or intermittently for about one year after the inauguration of the Formulation Centre for the purpose of establishment of the technique manufacturing the initial five items.

To secure the success of this project, the Government of Japan is expected to provide technical cooperation for fulfillment of the software separately from the present grant aid programme.

Finally, the following matters are requested of the Government of the Democratic Socialist Republic of Sri Lanka to successfully proceed with this construction project.

(1) MOH should give SPC appropriate directions in conformity with the objectives of the project and, in addition, encourage it to insure production and supply of quality essential drugs at lower prices giving no weight to such pursuance of profitability as presently found in private pharmaceutical manufacturers.

(2) The profitability of the Formulation Centre is ascertained for the stabilised production stage. The yield rate for the transition period before the stabilised production will be low, and so it will be difficult for SPC to manage the Formulation Centre for that period under its own self-supporting account system. Therefore, MOH and other state organisations of Sri Lanka are expected to support SPC in financial and other aspects.

(3) Even if foreign and local training of staff is put into practice, it is purposed to make the staff acquire the basic tecniques. It should be noted that all the 43 items cannot be manufactured without conscious efforts of the Sri Lankan staff.

(4) To stabilise the quality of products, every effort should be made to import materials having uniform quality. For example, it should be strictly avoided to import the same kind material of different makes.

(5) The present supply and distribution systems should be properly rearranged so that uniformly high quality products manufactured by the Formulation Centre can be stably distributed to consumers maintaining their quality.

(6) Workers, in particular key personnel, to be employed for the Formulation Centre should be chosen with due consideration for their experiences and

ability. If the training for the key personnel is conducted before the inauguration of the Formulation Centre, the said choice should be made in time for it.

APPENDICES

APPENDIX 1 INFORMATION ON THE FIELD SURVEY AT PHASES I AND II AND CONFIRMATION PHASE OF THE BASIC DESIGN STUDY

1.1 Members of the Study Teams

(1) Phase I of the Basic Design Study

Masatoshi HARADA, Dr. (Leader)	Head of Pharmacognosy and Phytochemistry Div., National Institute of Hygienic Sciences, Ministry of Health and Welfare
Masahiko SHIBAKAWA	Deputy Director of Pharmaceuticals and Chemicals Safety Div., Pharmaceutical Affairs Bureau Ministry of Health and Welfare
Toshio NAMAI	Basic Design Division Grant Aid Department Japan International Cooperation Agency
Kazuhiro OHMORI	Director of Production Group Fujisawa Pharmaceutical Co., Ltd.
Yasushi KITANO	Manager of Quality Control, Production Planning and Control, Production Group, Fujisawa Pharmaceutical Co., Ltd.

(2) Phase II of the Basic Design Study

Masatoshi HARADA, Dr. (Leader)	Head of Pharmacognosy and Phytochemistry Div., National Institute of Hygienic Sciences, Ministry of Health and Welfare
Toshio NAMAI	First Basic Design Study Division Grant Aid Planning & Survey Department Japan International Cooperation Agency
Nobuya UEDA	General Manager Architectural Dept. Nikken Sekkei Ltd
Toshiaki SUEKI	Architect Architectural Dept. Nikken Sekkei Ltd
Takeshi FUJIMOTO	General Manager Mechanical and Electrical Dept. Nikken Sekkei Ltd
Kazuhiro OHMORI	Director of Production Group Fujisawa Pharmaceutical Co., Ltd.
Kazuyuki TSUJI	Section Chief of Engineering Division Fujisawa Pharmaceutical Co., Ltd.

(3) Confirmation Phase of the Basic Design Study

Toshio NAMAI (Leader)	First Basic Design Study Division Grant Aid Planning & Survey Department Japan International Cooperation Agency
Nobuya UEDA	General Manager Architectural Dept. Nikken Sekkei Ltd
Kazuhiro OHMORI	Director of Production Group Fujisawa Pharmaceutical Co., Ltd.

1.2 Diary of the Study Teams

(1) Phase I of the Basic Design Study

Date	Day	Description
March 5, 1985	Tues.	- Flight from Tokyo to Bangkok by CX501/CX703
March 6	Wed.	- Flight from Bangkok to Colombo by TG307
March 7	Thur.	- Courtesy calls and briefing at the JICA Office and the Japanese Embassy
		- Courtesy call and briefing at SPC (with Dr. S.D.M. Fernando, Director General, MOH)
		- Courtesy call and briefing at Dept. of External Resources, Ministry of Finance and Planning
March 8	Fri.	- First meeting with SPC
		- Visited Glaxo Ceylon Ltd.
		- Surveyed the project site in Ratmalana
March 9	Sat.	- From Colombo to Peradeniya
		- Visited Peradeniya General Hospital
March 10	Sun.	- Compiled data and information; Team meeting
March 11	Mon.	- Second meeting with SPC
March 12	Tues.	- Third meeting with SPC
March 13	Wed.	- Discussed draft of the minutes
		- Visited the warehouse of MSD
		- Visited the Drug Quality Control Laboratory, Colombo General Hospital
		- Visited the Osu Sala Colombo 7
March 14	Thur.	- The minutes signed at SPC
		- Courtesy call at the Director of Colombo General Hospital; Visit to the dispensary thereof

		- Visited the Sri Jayewardanapura General Hospital
		- Visited the Thalangama Peripheral Unit
		- Team meeting; Compiled data and information
March 15	Fri.	- Courtesy calls at the JICA Office and the Japanese Embassy
March 16	Sat.	- Flight from Colombo to Singapore by UT568
March 17	Sun.	- Flight from Singapore to Tokyo by JL714

(2) Phase II of the Basic Design Study

Date	Day	Description
July 8, 1985	Mon.	- Flight from Tokyo to Colombo by UL453
July 9	Tues.	- Courtesy calls and briefing at the JICA Office and the Japanese Embassy
		- Courtesy call at Dept. of External Resources, Ministry of Finance and Planning
		- Courtesy call and briefing at MOH
		- Courtesy call and briefing at SPC
July 10	Wed.	- Meeting with SPC • The study schedule • Request of data collection • Organisation, personnel plan, etc. • Introduction of and discussion with members of the State Engineering Corporation (SEC)
July 11	Thur.	- Meeting with SPC • Demand and production • Land use
July 12	Fri.	- Meeting with SPC • Received the organisation chart • Signed the minutes
		- Visited Warner-Lambert Ltd.
July 13	Sat.	- Visited the Colombo General Hospital

		- Visited the Drug Quality Control Laboratory
		- Visited the Osu Sala Colombo 7
		- Team meeting
July 14	Sun.	- Reconnaissance into building construction
July 15	Mon.	- Meeting with SPC • Initial run • Organisation, etc.
		- Meeting with SEC • Request for filling in the unit cost sheets • Local situation of construction
		- Surveyed the project site and the Store Complex
July 16	Tues.	- Meeting with SEC
		- Meeting with UDA • Building permit
		- Meeting with CEA • Environment protection law
		- Meeting with SPC • Problems of present imports • Financial sheme
July 17	Wed.	- Meeting with SPC • Reply to the questions from the part of Japan
		- Meeting with SEC
		- Meeting with the Fire Brigade • Fire law
		- Meeting with the Dehiwala-Mt. Lavinia Municipality Council • Building permit
July 18	Thur.	- Meeting with Colombo Gas & Water Co., Ltd.

		- Meeting with the National Water Supply and Drainage Board
		- Meeting with Ceylon Petroleum Corporation
		- Meeting with Ceylon Electricity Board
		- Meeting with SEC
		- Visited the Colombo Municipality
		- Visited Dept. of Meteorology
		- Obtained data from Dept. of Survey General
		- Obtained data from Public Bureau
		- Visited Dept. of Geology
		- Visited the State Trading Corporation
July 19	Fri.	- Visited Ceylon Electricity Board, West Division
		- Visited Building Material Corporation
		- Meeting with SEC • Qualifications of engineers in Sri Lanka • Constructor in Sri Lanka • Labour productivity by the trade, etc.
		- Visited MacWoods - Winthrop Ltd.
July 20	Sat.	- Visited Sri Jayewardanapura General Hospital
		- Visited the construction site of Colombo Hilton Hotel
July 21	Sun.	- Compiled data and information
		- Visited Peradeniya Teaching Hospital
July 22	Mon.	- Meeting with SEC • History of SEC • Building materials in Sri Lanka • Social insurance system in Sri Lanka • Sewage treatment system
		- Surveyed pharmacies in general

		- Meeting with SPC • Role of SEC in the project • Financing scheme • Stable employment
July 23	Tues.	- Meeting with SPC
		- Meeting with UDA • Discharge of effluent
		- Meeting with SEC • Received unit cost and labour productivity sheets (for building work) • Construction materials
		- Visited the Ceylon Ceramic Corporation
		- Visited Lanka Walltiles Ltd.
		- Visited Ceylon Plywoods Corporation
		- Meeting with SPC • Protocols received from SPC, etc.
July 24	Wed.	- Meeting with SPC • Technical cooperation for operation • Initial run and test run • Clarification of the minute prepared by SPC
		- Meeting with SEC • Inquiry into the unit cost sheets
July 25	Thur.	- Meeting with SPC • The Record of Technical Meeting
		- Visited the project site • Adjustment of understanding
		- Inquiry into local situation of mechanical and electrical work
July 26	Fri.	- Courtesy calls at the JICA Office and the Japanese Embassy
		- Flight from Colombo to Bangkok by TG308
July 27	Sat.	- Flight from Bangkok to Japan by TG620

(3) Confirmation Phase of the Basic Design Study

Date	Day	Description
Sep. 23, 1985	Mon.	- Flight from Tokyo to Colombo by UL 453
Sep. 24	Tues.	- Meeting with the JICA office
		- Courtesy call at the Japanese Embassy
		- Meeting with SPC
		- Surveyed the project site
		- Meeting with SEC
Sep. 25	Wed.	- Meeting with SPC • Explanation and confirmation of the draft report on the basic design study
Sep. 26	Thur.	- Meeting with SPC • Explanation and confirmation of the draft report on the basic design study
Sep. 27	Fri.	- The minutes signed at SPC
		- Surveyed the project site
Sep. 28	Sat.	- Visited MRI
Sep. 29	Sun.	- Flight from Colombo to Singapore by SR 188
		- Flight from Singapore by JL 710
Sep. 30	Mon.	- Arrived at Tokyo

1.3 Minutes of Discussion

MINUTES OF DISCUSSIONS ON THE ESTABLISHMENT PROJECT OF PHARMACEUTICAL FORMULATION CENTRE OF ESSENTIAL DRUGS IN THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

In response to the request of the Government of the Democratic Socialist Republic of Sri Lanka, the Government of Japan has sent through the Japan International Co-operation Agency (JICA), a study team, headed by Dr.Masatoshi Harada, Head of Pharmacognosy and Phytochemistry Division, National Institute of Hygienic Science, Ministry of Health and Welfare, to conduct a Basic Design Study (Phase I) on the Establishment Project of Pharmaceutical Formulation Centre of Essential Drugs in the Democratic Socialist Republic of Sri Lanka (hereinafter referred to as "the project") for 13 days from March 5 to March 17, 1985.

The team had a series of discussions and exchanged views with the official concerned of the Government of Sri Lanka, observed the related facilities, and conducted the proposed site survey.
As the result of the discussions and the study, both sides confirmed the items which are described in the attached sheets.

Masatoshi Harada
. . . . . .
Dr.Masatoshi Harada
Leader
Japanese Basic Design
Study Team (Phase I)

Dr Jayewardene
. . . . . .
Dr(Mrs)L.G.Jayewardene
Chairman
State Pharmaceuticals Corporation
- of Sri Lanka

March 14th, 1985
COLOMBO, SRI LANKA

ATTACHMENT

1. The objective of the Project is to establish "Pharmaceutical Formulation Centre" for domestic production of essential drugs which are provided to people mainly through Primary Health Care Services.

2. To achieve the above mentioned objective, the Government of Sri Lanka has requested grant-in-aid co-operation to the Government of Japan for the following:

   - to construct a building of Pharmaceutical Formulation Centre of Essential Drugs

   - to provide necessary equipment and materials for the centre.

3. The scope of cooperation to be extended by the Government of Japan will be studied and clarified by a Basic Design Study Team (Phase II) which will be despatched by JICA when the Project has been recognized as feasible by the Government of Japan upon recommendations made by the Team.

4. Both sides expressed and gave their opinions on the Project as follows:

   a) The team confirmed the State Pharmaceuticals Corporation of Sri Lanka (SPC) will be the executing agency for the Project.

   b) The Team confirmed the contents of the Project Proposal made by SPC in May 1982 is still available in principle with minor modifications made by Sri Lanka side.

   c) Sri Lanka side understood the system of Grant Aid Programme to be extended by the Government of Japan.

M. H.

U.L.

d) Though the team conducted the field survey of the proposed site, the determination of the project site should be studied and examined from all points of view by following Basic Design Study Team (Phase II).

e) All the data requested by the Basic Design Study Team (Phase I) was handed over by the SPC.

contd/4

M. H.

MINUTES OF DISCUSSION
BASIC DESIGN STUDY (PHASE II) ON THE ESTABLISHMENT PROJECT OF PHARMACEUTICAL FORMULATION CENTRE OF ESSENTIAL DRUGS IN THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

In response to the request made by the Government of the Democratic Socialist Republic of Sri Lanka for the Establishment Project of Pharmaceutical Formulation Centre of Essential Drugs (hereinafter referred to as 'the Project'), the Government of Japan has sent through the Japan International Cooperation Agency (JICA), a team headed by Dr. Masatoshi HARADA, head of Pharmacognosy and Phytochemistry Division, National Institute of Hygienic Sciences, Ministry of Health and Welfare, to carry out a basic design study (Phase II) for the Project from July 8 to July 27, 1985. The team carried out field survey, had a series of discussions and exchanged views about the Project with the Authorities concerned of the Government of the Democratic Socialist Republic of Sri Lanka.

As a result of the survey and discussions, both parties have agreed to recommend to their respective Governments to examine the result of the survey attached herewith.

Colombo
July 12, 1985.

Masatoshi Harada
. . . . . .

DR. MASATOSHI HARADA
Team Leader
The Japanese Basic Design Study(PHASE II) Team, The Japan International Cooperation Agency

. . . . . .

DR.(MRS.)L.G. JAYEWARDENE
Chairman
State Pharmaceuticals Corporation of Sri Lanka

Main Result of the Basic Design Study (PHASE II) Team

1) Name of Project

Establishment Project of Pharmaceutical Formulation Centre of Essential Drugs

2) The Objective of the Project

The objective of the Project under the Grant Aid is to establish a Pharmaceutical Formulation Centre for domestic production of essential drugs which will be provided to people mainly through Primary Health Care Services.

3) The Items and their outputs to be formulated

The Sri Lanka side has requested the items and their outputs which will be formulated in the Centre as listed in Annex I.

The Japanese Team expressed that the Team will analyse and study the items and their outputs to be formulated in the Centre, based upon the priority given in the said list, immediately after the Team's return to Japan.

4) The Project Site

Project site is located within the property of State Pharmaceuticals Corporation of Sri Lanka at Airport Road, Ratmalana as shown in Annex II. The site occupying approximately 4 acres will exclusively be used for the Project.

5) The Executing Agency for the Project

State Pharmaceuticals Corporation of Sri Lanka is responsible for the administration and execution of the project.

6) The Japanese Team will convey to the Government of Japan the desire of the Government of the Democratic Socialist Republic of Sri Lanka that the former takes necessary measures to cooperate in implementing the Project and bear the cost of the facilities and equipment listed in Annex III within the scope of Japanese Economic Cooperation Programme in Grant Aid Form.

M. H. U.

7) The Japanese Team explained the systems of the Japanese Grant Aid abd the Sri Lanka side understood it.

The Government of the Democratic Socialist Republic of Sri Lanka will take necessary measures listed in Annex IV on condition that the Grant Aid Assistance would be extended.

ANNEX 1

ACTUAL UTILIZATION OF ESSENTIAL DRUGS (TO BE MANUFACTURED IN THE PHARMACEUTICALS FORMULATION) FOR 1984 AND THE PROJECTED DEMAND FOR 1985, 1986 AND 1990

		1984 Actuals (In Millions)	1985 *(1) (In Millions)	1986 *(1) (In Millions)	1990 *(2) Projected (In Millions)
1. Aluminium Hyd. Tablets 500mg	SPC	2.63	3.6	3.6)	25.75
	Govt. Hospit.	13.0	7.0	27.0)	
2. Aluminium + Mag Hydroxide Tabs	SPC	1.38	3.0	3.0)	3.75
	Govt. Hospit.	-	-	-)	
3. Ascorbic Acid Tablets 100mg	SPC	6.14	5.0	6.00)	38.75
	Govt. Hospit.	25.00	15.00	25.00)	
4. - do - 500mg	SPC	0.88	0.90	1.0)	3.5
	Govt. Hospit.	1.00	2.00	2.0)	
5. Aspirin Tablets 300mg	SPC	78.26	60.0	60.0)	293.75
	Govt. Hospit.	130.0	120.0	175.0)	
6. Cotrimoxazole Tablets (A)	SPC	5.04	6.00	6.0)	11.25
	Govt. Hospit.	2.00	2.50	3.0)	
7. Cotrimoxazole Tablets (P)	SPC	0.57	0.72	0.72)	1.65
	Govt. Hospit.	0.50	0.50	0.60)	
8. Diethyl Carbamazine Cit. Tabs 50mg	SPC	10.71	10.8	10.80)	28.5
	Govt. Hospit.	-	16.00	12.00)	
9. Frusemide Tabs 40mg	SPC	1.20	2.10	2.70)	13.38
	Govt. Hospit.	5.00	5.50	8.00)	
10. Griseofulvin Tabs 125mg	SPC	0.35	0.60	0.60)	2.63
	Govt. Hospit.	2.00	1.30	1.50)	
11. Hydrochlorthiazide Tabs 50mg	SPC	2.59	3.60	3.00)	15.00
	Govt. Hospit.	9.00	7.00	9.00)	

		1984 Actuals (In Millions)	1985 *(1) (In. Millions)	1986 *(1) (In Millions)	1990 *(2) Projected (In Millions)
12. Iso Sorbide Dinitrate Tabs 10mg	SPC	2.83	3.60	3.60)	12.0
	Govt. Hospit.	2.00	8.00	6.00)	
13. Magnesium Hydroxide Tablets 300mg	SPC	0.70	0.6	0.80)	1.0
	Govt. Hospit.	-	-	-	
14. Metronidazole Tablets 200mg	SPC	5.17	6.0	6.50)	18.13
	Govt. Hospit.	8.00	8.00	8.00)	
15. Multivitamin + Tablets	SPC	1.47	1.80	10.00)	93.75
	Govt. Hospit.	66.00	50.00	65.00)	
16. Phenoxymethyl Peni. Tabs 125mg	SPC	4.61	6.00	6.0)	61.25
	Govt. Hospit.	32.00	27.00	43.0)	
17. - do - 250mg	SPC	3.51	3.60	3.60)	4.5
	Govt. Hospit.	-	-	-	
18. Ibuprofen Tablets 200mg	SPC	0.61	0.50	0.6)	5.0 *(3)
	Govt. Hospit.	-	-	-	
19. - do - 400mg	SPC	-	-	-	1.0 *(3)
	Govt. Hospit.	-	-	-	-
20. Prednisolone Tablets 5mg	SPC	18.00	18.00	18.00)	43.75
	Govt. Hospit.	12.00	3.00	17.00)	
21. Promethazine Tabs 25mg	SPC	4.04	2.10	2.10)	20.13
	Govt. Hospit.	12.00	9.00	14.00)	
22. Propranolol Tablets 10mg	SPC	0.97	0.98	1.0)	1.25
	Govt. Hospit.	-	-	-	
23. - do - 40mg	SPC	3.98	4.2	4.20)	12.75
	Govt. Hospit.	14.00	6.00	6.00)	
24. Trifluoperazine Tabs 5mg	SPC	1.73	1.68	2.10)	25.13
	Govt. Hospit.	32.00	4.00	18.00)	

		1984 Actuals (In Millions)	1985 *(1) (In Millions)	1986 *(1) (In Millions)	1990 *(2) Projected (In Millions)
25. Vitamin 'B' Com: Tablets	SPC	8.56	10.80	10.00)	200.0
	Govt. Hospit.	140.00	120.00	150.00)	
26. Spironolactone Tabs 25mg	SPC	0.41	0.45	0.42)	1.73
	Govt. Hospit.	0.90	0.10	1.00)	
27. Furazolidone Tablets 100mg	SPC	3.78	5.4	3.60)	17.0
	Govt. Hospit.	10.00	1.00	10.00)	
28. Mebendazole Tabs 100mg	SPC	0.48	1.0	1.00)	1.33
	Govt. Hospit.	0.05	0.20	0.10)	
29. Primaquine Phosphate Tabs	SPC	2.26	2.4	2.40)	15.5
	Govt. Hospit.	10.00	10.00	10.00)	
30. Ethambutol Tablets 400mg	SPC	0.34	0.48	0.50)	11.25
	Govt. Hospit.	7.00	3.00	8.50)	
31. Diloxanide Furoate Tabs 500mg	SPC	0.07	0.1	0.10)	0.14
	Govt. Hospit.	-	0.005	0.015)	
32. Paracetamol Tablets 500mg	SPC	20.82	21.0	24.00)	117.5
	Govt. Hospit.	41.00	40.00	70.00)	
33. Salbutemol Tabs 2mg	SPC	2.7	3.0	3.2)	4.0
	Govt. Hospit.	-	-	-	
34. - do - 4mg	SPC	-	-	-	
	Govt. Hospit.	1.5	1.8	2.0)	2.5
35. Choline Theophyllinate Tabs 100mg	SPC	0.98	1.0	1.00)	1.25
	Govt. Hospit.	-	-	-	
36. - do -	SPC	0.35	0.4	0.5)	0.6
	Govt. Hospit.	0.2	0.5	1.0)	1.25

		1984 Actual (In Millions)	1985 *(1) (In Millions)	1986 *(1) (In Millions)	1990 *(2) Projected (In Millions)
37. Phenobarbitone Tablets 60mg	SPC	2.68	3.0	3.3)	19.13
	Govt. Hospit.	8.00	6.00	12.0)	
38. Ampicillin Tabs 125mg (P)	SPC	1.66	1.75	1.8)	2.25
	Govt. Hospit.	-	-	-	
39. Chloramphenicol Caps 250mg	SPC	5.70	5.4	5.4)	14.25
	Govt. Hospit.	4.5	6.50	6.0)	
40. Indomethacin Caps 25mg	SPC	6.10	6.0	6.0)	25.0 *(3)
	Govt. Hospit.	8.00	6.00	5.0)	
41. Rifampicin Caps 150mg	SPC	0.11	0.18	0.16)	2.7
	Govt. Hospit.	1.00	2.00	2.00)	
42. - do - 300mg	SPC	0.09	0.09	0.1)	1.0
	Govt. Hospit.	0.40	-	0.7)	
43. Ampicillin Caps 250mg	SPC	6.55	9.60	12.0)	52.50
	Govt. Hospit.	12.00	17.50	30.0)	
44. Cloxacillin Caps 250mg	SPC	1.31	2.68	2.4)	11.75
	Govt. Hospit.	3.00	5.00	7.0)	
45. Ampicillin Syrup 125mg/5ml	SPC	2 308L	3 600L	3 600L)	9 500L
	Govt. Hospit.	1 000L	1 000L	4 000L)	
46. Cloxacillin Syrup	SPC	270L	204L	600L)	1 750L
	Govt. Hospit.	400L	200L	800L)	
47. Oral Rehydration Salts	Already manufacturing by SPC				

*(1) Actual requested by SMS for 1986 and Projected SPC requirements for 1986

*(2) Projection for 1990 is calculated, taking in to consideration a 6% increase of volume consumption annually. (25% added to 1986 requirement to calculate 1990 demand)

*(3) Quantity increased due to the withdrawal of Phenulbutazone and Oxyphenbutazone

MINUTES OF DISCUSSIONS

THE DRAFT FINAL REPORT OF THE BASIC DESIGN STUDY
ON
CONSTRUCTION PROJECT
FOR
PHARMACEUTICAL FORMULATION CENTRE OF ESSENTIAL DRUGS
IN
THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

The Government of Japan has sent, through Japan International Cooperation Agency(JICA) a Basic Design Study Team to the Democratic Socialist Republic of Sri Lanka from 23 to 30 September 1985 for the purpose of presenting and explaining the Draft Final Report of the Basic Design Study on Construction Project for Pharmaceutical Formulation Centre of Essential Drugs.

After a series of discussions between the Team and the Sri Lanka side, both parties confirmed the following results attached herewith(ATTACHMENT).

COLOMBO
SEPTEMBER 27, 1985

MR. TOSHIO NAMAI
Leader
Japanese Study Team
JICA

DR.(Mrs)L.G. JAYEWARDENE
Chairman
State Pharmaceuticals Corporation
of Sri Lanka

ATTACHMENT

1. Both parties agreed to reconfirm the Minutes of Discussion which was mutually signed on July 12, 1985.

2. The Sri Lanka side has agreed in principle to the basic design proposed in the Draft Final Report and appropriate alterations agreed upon during the discussions will be incorporated in the Final Report.

3. The Sri Lanka side understood Japan's grant aid system and the arrangement to be taken by the Sri Lanka side for realization of the Project.

4. The Final Report(10 copies in English) will be submitted to the Sri Lanka side by the end of November 1985.

1.4 Persons Concerned in Sri Lanka

(1) Ministry of Health

Mr. Panambalana	- Secretary & Director General
Dr. S.D.M. Fernando	- Secretary
Dr. J. Fernando	- Deputy Director General

(2) Department of External Resources

Mr. M.A. Mohamed	- Director
Mr. S. Weerapana	- Assistant Director

(3) State Pharmaceuticals Corporation (SPC)

Dr. (Mrs.) L.G. Jayewardene	- Chairman
Dr. W.M.T. Weerasinghe	- Director, Professor of Pharmacology
Mr. C. Jayaratne	- Director
Mr. S. Jayawickrama	- General Manager
Mr. A.C.D. de S. Abeysuriya	- Chief Financial Controller
Mr. T. Atapattu	- Manager Inventory Control
Mr. H.S.K. Sirisena	- Assistant Manager, Import Division
Mr. K.L.N.H. Dias	- Technical Assistant
Miss N. Soysa	- Management Accountant
Mr. S. Thrunavucarasu	- Assistant Technical Manager
Mr. D.S. Wijeysiri	- Manager, Personnel Administration Dept.
Mr. M. Viyani	- Assistant Manager, Administration Dept.
Mr. M.T. Fernando	- Store Manager
Mr. M.A. Gunadasa	- Sales & Distribution Manager
Mr. S.L.R. Fernando	- ORS Production Supervisor
Mr. U.L.L. de Silva	- Assistant Technical Manager (Q/C)
Mr. E.F.M. Samuel	- Manager of Osu Sala, Colombo 7

(4) State Engineering Corporation

Mr. G.T.A. Wickramasinghe	- Manager, Consultancy Unit
Mr. H.D. Chandrasena	- Chief Quantity Surveyer
Mr. S. Dantanarayana	- Design Engineer
Mr. R. Perera	- Architect

Mr. S. Perera	- Architect
Mr. R. Samarasingha	- Architect
Mr. P.S.B. Nanayakkara	- Engineer
Mr. L.N. Abeyesekere	- Deputy General Manager, Construction Unit
Mr. G. Silva	- Manager, Mechanical & Electrical Group
Mr. A.T. de S. Gunesekera	- Senior Electrical Engineer
Mr. K.T.D. de S. Jayasekara	- Assistant Chief Engineer

(5) Warner-Lambert Lanka (Pvt) Ltd.

Mr. P.G. de Silva	- General Manager

(6) Colmbo General Hospital

Mr. D.W. Abeysundra	- Director of General Hospital

(7) Urban Development Authority

Mr. G.S. de Silva	- Director, Development Regulation
Mr. N.D. Dickson	- Director of Development Planning

(8) Central Environment Authority

Mr. R.A. Wijewansa	- Director, Environment Management

(9) Fire Brigade

Mr. K.D.B. Udugama	- Deputy Fire Chief, Fire Services Dept.

(10) Dehiwala-Mt. Lavinia Municipal Council

Mr. E.H.R.T. Francisco	- Civil Engineer, Planning Dept.

(11) Colombo Gas & Water Co., Ltd.

Mr. C. R. Perera	- Marketing Manager

(12) National Water Supply and Drainage Board

Mr. C.G. Jayanetti	- Project Manager

(13) Ceylon Petroleum Corporation

Mr. W.R. Weerakody	- Deputy Marketing Manager

(14) Ceylon Electricity Board

Mr. E.N. Wijemanne	- Commercial Manager

(15) Department of Meteorology

Mr. D.P.W. Karunatilaka	- Deputy Director

(16) Department of Geology

Mr. D. Jayewardena	- Acting Director
Mr. H.D.N.C. Pathirana	- Deputy Director, Geological Survey Dept.

(17) State Trading Corporation

Mr. P.N. Jayatilake	- Assistant General Manager, Service Supplies

(18) Telecommunication Mt.Lavinia

Mr. S.L.R. Fernando	- Regional Telecommunication Engineer

(19) Building Material Corporation

Mr. G.W. Chandrasena	- Import Manager
Mrs. L. Perera	- Manager, Local Material Dept.

(20) MacWoods-Winthrop Limited

Mr. M.F. Dias	- Plant Manager

(21) Union Chemist Ltd.

Mr. H.P.S. Rodorigo	- Chairman
Mr. A.M. Bunnows	- Pharmacist

(22) City Dispensary

Mr. H.T. Kanalewatte - Manager

(23) Weeransinghe Bro's

Mr. R. Weeransinghe - Manager

(24) Building Department, Dehiwala-Mt. Lavinia

Mr. D.G.S. Jayakody

(25) JICA Colombo Office

Mr. Jiro Hashiguchi - Manager

(26) The Japanese Embassy in Sri Lanka

Mr. Hiroshi Otaka - Ambassador
Mr. Mitsunori Itami - Secretary
Dr. Yutaka Amino - Secretary

APPENDIX 2 BRIEF DESCRIPTIONS OF PRIVATE PHARMACEUTICAL MANUFACTURERS IN SRI LANKA

Name of Company	M.S.J. Industries (Ceylon) Ltd.	Pfizer Ltd.	Glaxo Ceylon Ltd.	Mackwoods Winthrop Ltd.	Reckitt & Colman of (Ceylon) Ltd.	Unical Ceylon Ltd.	Warner Lambert (Lanka) Ltd.
Address	126 Aluthmawatte Rd. P.O.Box 430, Mutwal, Colombo 15	688 Galle Road, Ratmalana	22 2/1-2/8 Sir Baron Jayatilaka Mawatha, 2nd Floor, Hongkong & Shanghai Bank Bldg., Colombo 1	35 Madampitiya Road, Colombo 15	P.O.Box 16, Mount Lavinia	Lady Catherine Estate, Ratmalana	P.O.Box 1230, 21 Staples Street, Colombo 2
Phone No.	01-31441/3	071-6741/4	01-28915, 28733 and 26597	01-33381/2 & 34080	01-547258	071-5971	01-31771
Name of Foreign Equity Participant	None	Pfizer Corporation Panama	British Glaxo	Sterling Drug Inc. (incorporated in USA)	British (2 Directors)	Calmic Ltd. England	Tabor Corporation U.S.A.
Ratio of Foreign to Local Equity Capital	—	75% by foreign Total equity: Rs. 5,000,200	Not known	45% by foreign Total equity: Rs. 500,000	Not known	49% by foreign Total equity: Rs. 4,704,000	70% by foreign Total equity: Rs. 4,500,720
Total Capital Employed	Rs. 11,232,566 As of 31 March 1984	Rs. 7,264,893 As of July 1984	Rs. 25,561,900 As of June 1984	Not known	Rs. 18,402,452 As of 31 Jan. 1981	Not known	Not known
Annual Turnover for Last Available Year	1983 Rs. 25,884,014 1984 Rs. 27,838,234	1979 Rs. 24,718,730 1980 Rs. 32,125,221	Not known	Not known	Not known	Not known	Not known
Items Manufactured	Syrup 5 Tablet 40 Drop – Capsule 2 Paint – Elixir 2 Liquid 2 Powder 1 Cream – Ointment – Others 2 Total 54	Syrup 6 Tablet 9 Drop 3 Capsule 5 Paint – Elixir 1 Liquid 1 Powder – Cream – Ointment 3 Others 1 Total 29	Syrup 7 Tablet 19 Drop 1 Capsule – Paint 1 Elixir 1 Liquid 3 Powder 1 Cream – Ointment – Others 2 Total 35	Syrup 3 Tablet 6 Drop 1 Capsule – Paint – Elixir 1 Liquid 2 Powder 1 Cream – Ointment – Others – Total 14	Syrup – Tablet 3 Drop – Capsule 2 Paint – Elixir – Liquid 1 Powder – Cream – Ointment – Others – Total 6	Syrup 1 Tablet 2 Drop – Capsule – Paint – Elixir 1 Liquid – Powder 1 Cream 1 Ointment – Others 1 Total 7	Syrup 4 Tablet – Drop – Capsule 2 Paint 2 Elixir 2 Liquid 2 Powder – Cream 1 Ointment 3 Others 2 Total 18

Climatological Table of Observatories in Sri Lanka

Station: RATMALANA Lat.: 6°49'N Long.: 79°53'E Barometer: 17ft. Anemometer: 20ft.
I = 0830 S.L.S.T. II = 1730 S.L.S.T.

Mean Month		Dry bulb temp. °C	Relative humidity %	Mean daily max. temp. °C	Mean daily min. temp. °C	Highest max. temp. recorded °C	Lowest min. temp. recorded °C	Mean wind speed at hour kmph.	Mean daily wind speed kmph.	Prevailing wind direction	Monthly rainfall mm.	Number of rainy days	No. of days of thunder
January	I	24.2	80	30.7	21.8	33.8	14.4	9.2	8.7	NE	78.7	8	6
	II	27.7	68			1965,29	1950,4	13.8		NW			
February	I	24.7	81	30.8	22.2	35.7	16.1	6.1	7.2	NE	94.7	8	8
	II	28.2	68			1950,13	1949,15	13.2	-	NW			
March	I	26.2	81	31.4	23.2	35.7	18.1	4.0	6.4	Var.	142.2	11	16
	II	28.9	68			1958,7	1961,1	10.8	-	W			
April	I	27.2	80	31.6	24.1	33.4	20.1	4.3	6.0	Var.	281.9	18	24
	II	29.0	71			1967,9	1974,18	8.7	-	W			
May	I	27.8	80	30.9	25.9	33.3	20.9	8.7	7.8	W	388.4	22	15
	II	28.7	74			1973,2	1971,20	10.8	-	SW			
June	I	27.6	79	30.2	25.6	32.3	21.6	11.6	8.7	WSW	207.9	21	6
	II	28.1	75			1972,5	1975,16	12.1	-	WSW			
July	I	26.9	80	29.8	24.9	31.3	21.4	10.3	8.4	W	187.5	16	4
	II	27.7	75			1963,28	1975,26	12.2		W			
August	I	26.8	78	29.8	25.1	31.7	21.4	11.8	8.7	SW	107.4	14	3
	II	27.7	74			1964,25	1965,11 1974,16	12.6		SW			
September	I	26.9	79	29.9	24.6	31.8	21.1	10.6	8.0	SW	224.8	19	5
	II	27.6	75			1951,23	1952,30	11.9		SW			
October	I	26.5	81	29.8	23.9	32.3	20.6	7.9	7.2	Var.	375.2	22	12
	II	27.3	75			1947,31	1974,23	10.0	-	SW			
November	I	25.8	81	30.2	22.9	33.2	18.3	6.1	7.0	NE	316.0	18	14
	II	27.2	74			1972,30	1972,21	9.8		NW			
December	I	24.9	80	30.4	22.3	33.6	17.3	9.3	8.3	NE	196.1	13	10
	II	27.1	72			1972,14	1975,3	10.6		NW			
Annual	I	26.3	80	30.5	23.9	35.7	14.4	8.3	7.7	-	2600.8	190	123
	II	27.9	72					11.4		-			
Period of data (yrs.)		25	25	25	25	25	25	25	25	25	25	25	10

APPENDIX 4 CENTRAL ENVIRONMENT AUTHORITY - TOLERANCE LIMITS FOR INDUSTRIAL WASTE WATER DISCHARGED INTO INLAND SURFACE WATERS

Ref. Indian Standard 2490: 1974 with modifications

Parameters	Values (Not to exceed)
BOD in 5 days, at 20°C	30
pH	between 6 and 8.5
Suspended solids, mg/l	50
Temperature °C	40
Oil and grease, mg/l	10
Phenolic compounds, mg/l	1.0
Cyanides, mg/l	0.2
Sulphides, mg/l	2.0
Fluorides, mg/l	2.0
Total residual chlorine, mg/l	1.0
Arsenic, mg/l	0.2
Cadmium, mg/l	0.1
Chromium, mg/l	0.1
Copper, mg/l	3.0
Lead, mg/l	0.1
Mercury, mg/l	0.0005
Nickel, mg/l	3.0
Selenium, mg/l	0.05
Zinc, mg/l	5.0
Ammoniacal Nitrogen, mg/l	50
Pesticides	Absent
Radioactive materials	
Alpha emitters, µc/ml	10^{-7}
Beta emitters, µc/ml	10^{-6}
Chemical Oxygen Demand, mg/l	250

mg/l : Milligrams per litre
µc/ml : Microcuries per millilitre
BOD : Biochemical Oxygen Demand

BUILDING SITE, RATMALANA.
JOB No. G/128

DRILLING RIG...RIICOM 151
DRILLING FLUID.....
BARREL TYPE.....
LOGGED BY.....J.M.T. Ananda.....

CLIENT STATE PHARMACEUTICALS CORPORATION

HOLE		CORE		CASING	
ϕMM	TO	ϕMM	TO	ϕMM	TO
200	7.05			200	7.02

BH No 1

DATE START 30.11.90 FINISH 30.11.90
CO-ORDINATES E..... N.....
GROUND LEVEL.....
INCLINATION .....
BEARING .....

RQD (%)	TCR (%)	SCR (%)	FPM	CASING LEVEL	WATER LEVEL	IN-SITU TEST TYPES AND SAMPLES	DISCONTINUITY DESCRIPTION: TYPE	DIP ON CORE	CHARACTERISTICS	LITHOLOGICAL DESCRIPTION	DEPTH – RL (THICKNESS)	LEGEND
						0.5 D				Soft black silty sandy CLAY with roots and plants	0	
			am	11/40	D	1.0-1.45 SPT, N=1					1	
						1.5 D						
						2.0 D				Medium dense grey silty SAND	2	
						2.0-2.45 SPT, N=21						
						2.5 D					3	
						3.0-3.45 U 100 No Recovery						
						3.5 D				Soft black silty organic CLAY with decomposed timber, sand at some levels.	4	
						4.0-4.45 U 100						
						5.0-5.45 U 100					5	
						6.0-6.45 SPT, N=10				Medium dense grey silty SAND with decomposed rock fragments	6	
						6.75 D						
	80-11- 9			11/9		7.0-7.03					7	
	80-11-10			11/10		SPT, N=200+						
											8	
											9	
											10