

BASIC DESIGN REPORT
ON
THE DEVELOPMENT CENTRE FOR PHARMACEUTICAL TECHNOLOGY
IN
THE SOCIALIST REPUBLIC OF THE UNION OF BURMA

MARCH 1980

JAPAN INTERNATIONAL COOPERATION AGENCY

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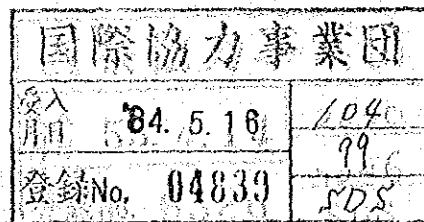
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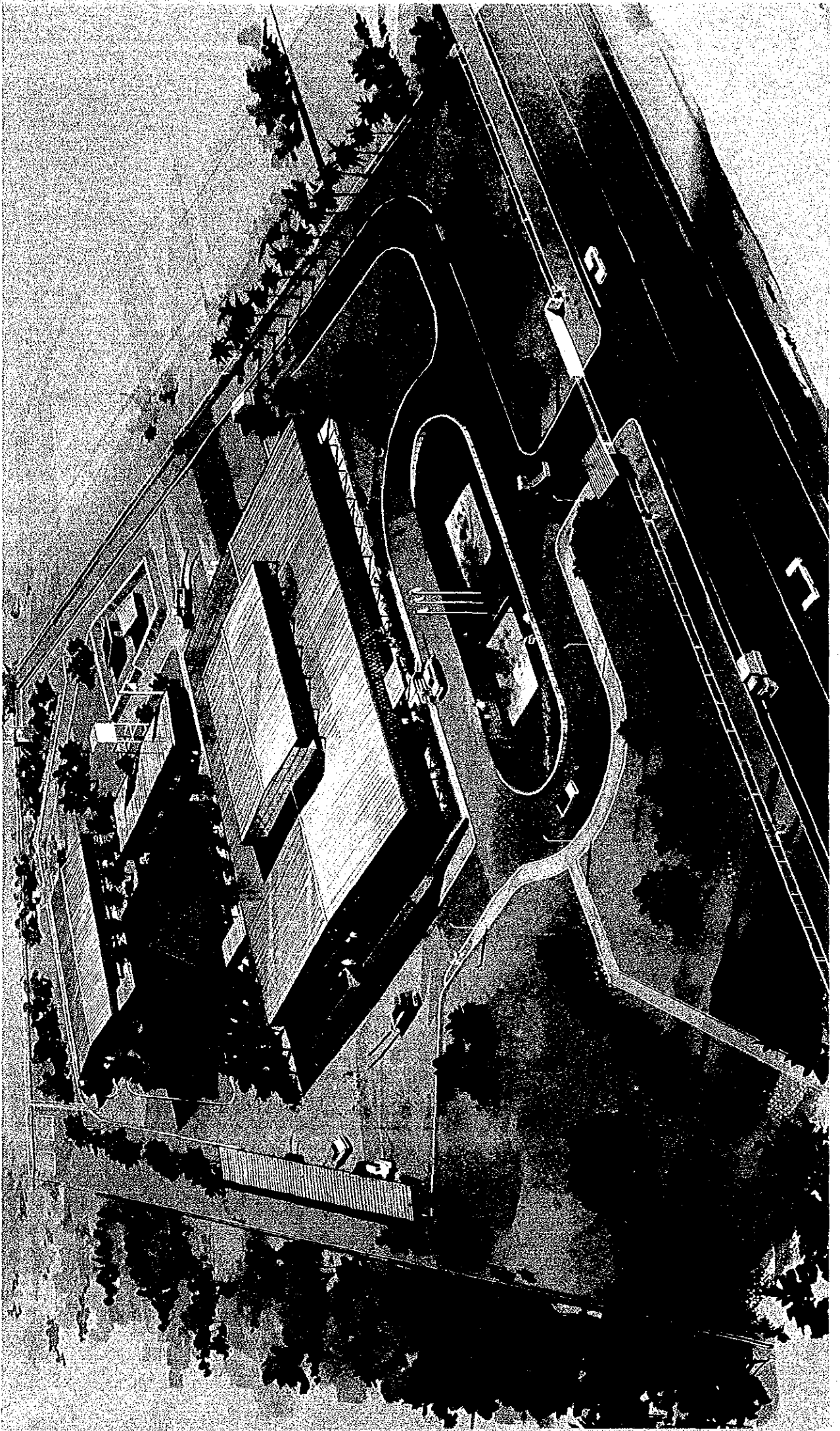
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ABBREVIATIONS

BPI	Burma Pharmaceutical Industry
Centre	The Development Centre for Pharmaceutical Technology
CC	Construction Corporation
GMP	Good Manufacturing Practice
IPD	Industrial Planning Department, Ministry of No. 1 Industry
JICA	Japan International Cooperation Agency
PIC	Pharmaceutical Industries Corporation



BIRD'S EYE VIEW OF COMPOUND



PREFACE


At the request of the Government of the Socialist Republic of the Union of Burma, the Government of Japan has decided to undertake a survey necessary for preparing a basic design for establishing a Development Centre on Pharmaceutical Technology in Burma.

The Japan International Cooperation Agency conducted this survey on behalf of the Government of Japan by dispatching to Burma from December 3 to December 21 of 1979 a survey team headed by Mr. Hisanori Uchiyama of the Ministry of Health and Welfare and composed of six other members.

The team, with close cooperation of the officials of Burma, conducted a survey on the background, requirements and conditions of the proposed Center. This Report is based on the local survey, further studies in Japan and on the consultations with the officials concerned of Burma.

I wish to express my deep appreciation to the concerned officials of the Government of Burma for their full cooperation extended to the survey team. I hope that this Report will prove useful for the development of the Project and that it will contribute to promoting the friendly relationships existing between Burma and Japan.

March, 1980



Keisuke Arita
President

Japan International Cooperation Agency

SUMMARY

The present pharmaceutical supply situation in Burma requires considerable improvement. Drugs of better quality and in more variety, forms, and quantity are urgently needed, and their availability will have a direct bearing in bettering the national health situation.

Though implementation of additional production facilities, as well as improvement of the manufacturing efficiency of existing facilities is imperative, the present level of production technique and quality control must first be improved, and facilities provided to develop drugs which are not in production in spite of their essential necessity.

In view of these circumstances, the Government of the Socialist Republic of the Union of Burma has requested assistance from the Government of Japan in the establishment of the Development Centre for Pharmaceutical Technology.

The Government of Japan, through the Japan International Cooperation Agency, has conducted surveys on this matter, and following discussions with officials of the Government of Burma, the Survey Team has confirmed the necessity for the Centre and has recommended that its establishment is justifiable.

It is recommended that facilities be provided for the development of, and training in, production and quality control techniques for modern pharmaceutical products, as well as for developing fermentation technology as a step towards future production of antibiotics from domestic resources. Lastly, research facilities leading to the development and improvement of pharmaceutical products from indigenous plants should also be provided.

The proposed site offered by the Government of Burma for the Centre faces the Insein Road and is very close to the Burma Pharmaceutical Industry. Subsoil and earth bearing conditions are favourable, and the surrounding environment is also ideal for a facility of this nature.

The Basic Design calls for provision of the following departments:

1. Fermentation Process Department
2. Preparations Research Department
3. Medicinal Plants Department
4. Testing, Quality Control and Pharmacology Department

Development and training facilities for the Preparations Research Department are planned to provide equipment for development of modern pharmaceutical production techniques, especially in the forms of tablets and injections, and at the same time to enable training in these production operations. Laboratory scale fermentation equipment is to be provided in the Fermentation Process

Department for research, development and training in fermentation fundamentals as a step towards future industrial production of antibiotics from domestic resources. The Medicinal Plants Department is to be provided with extraction, purification and analysis evaluation equipment to enable research and development of techniques required for the development of drugs from indigenous plants. The Testing, Quality Control and Pharmacology Department is to be equipped with physicochemical and other necessary equipment, to analyse and evaluate the effectiveness, safety, toxicity and pharmacological aspects of drugs.

The Preparations Research Department, Testing, Quality Control and Pharmacology Department and administrative facilities are to be located in a two-storey Main Building facing the Insein Road with a landscaped area in front. The Fermentation Process and Medicinal Plants Departments are planned in a separate building located in back of the Main Building. A utility building and canteen are located inbetween these two buildings.

Main buildings are designed as steel framed structures in view of the precision required for their functions, and also to shorten construction time as required by the Japanese grant programme. A unique high performance steel roof structure will characterize the main buildings. Indigenous materials and methods are to be employed for brick masonry walls and steel grillworks.

Due to the non-commercial nature of the Centre, its staffing, operation and maintenance will become an additional financial burden. It has however been confirmed that the Government of Burma is prepared in all respects to perform all its portion of responsibilities in the establishment and operation of the Centre.

The establishment of the Centre is justified in that it is destined to play a most crucial role in promoting production efficiency and quality improvement of both present BPI and future pharmaceutical industries, and accordingly will contribute to the uplift of the health standard of the people of Burma, as well as to the elevation of their technical knowledge and know-how. Social benefits of providing additional employment opportunities for the Burmese people will also be obtained.

It is recommended that a technical cooperation programme be implemented to effect exchanges of Japanese and Burmese personnel for training in pharmaceutical technology at the Centre and at similar facilities in Japan.

The Centre, to be located in a prominent location with favourable surroundings, will also become a monument to the joint efforts by the two governments, not only towards improving the welfare of the Burmese people, but also towards deepening friendship between the people of Burma and Japan.

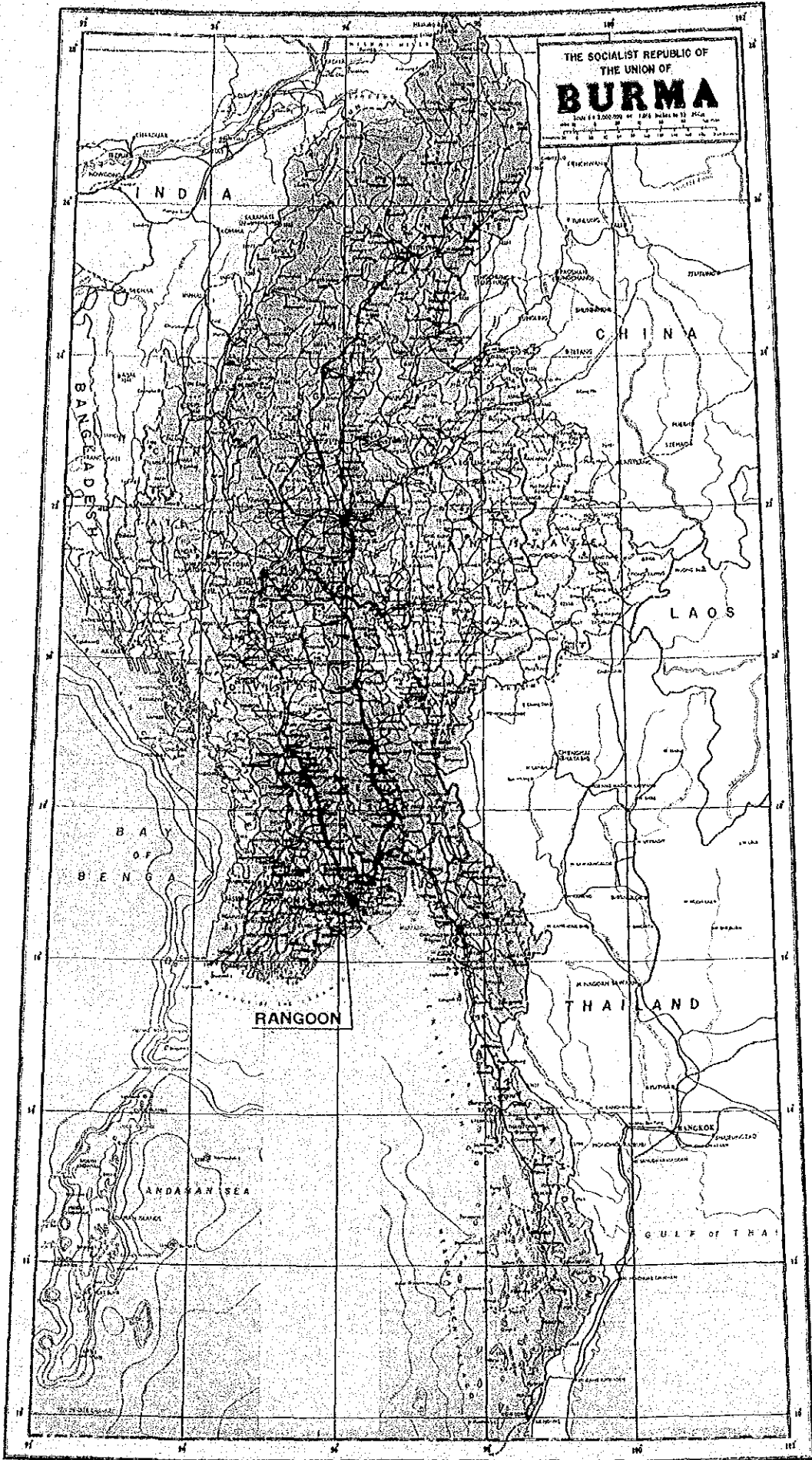


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OUTLINE OF THE PROJECT

CHAPTER 1 OUTLINE OF THE PROJECT

A. INTRODUCTION

A request was made to the Government of Japan by the Government of the Socialist Republic of the Union of Burma in 1978 for assistance in the establishment of the Development Centre for Pharmaceutical Technology. As a result, the Government of Japan dispatched a Preliminary Survey Team in October 1979, and, subsequently a Basic Design Survey Team* in December of the same year.

The findings outlined in this Report were made by the above mentioned missions by virtue of enthusiastic and sincere assistance and cooperation from officials of the Government of Burma.

* The firm of Matsuda, Hirata & Sakamoto, Architects, Planners & Engineers, Inc. participated in the Basic Design Survey Team to prepare the basic designs for the Centre.

B. FIELD SURVEY

1. Preliminary Survey

A team headed by Dr. Goro Funamoto of the Ministry of Health and Welfare was dispatched from 18th to 25th of October 1979 by the Japanese Government through the Japan International Cooperation Agency to carry out preliminary studies for the establishment of the Centre.

Through a series of discussions and exchange of views between the Team and the Burmese Government organizations concerned, the contents of the Burmese request, mentioned later in this chapter, were examined and agreed upon by both sides.

A copy of the Summary of Discussions exchanged between both sides and the list of participants are found in the Appendix of this Report.

2. Basic Design Survey

A team headed by Mr. Hisanori Uchiyama of the Ministry of Health and Welfare was dispatched from 3rd to 21st, December 1979 by the Japanese Government through JICA to conduct a basic design survey for the establishment of the Centre.

Through a series of field surveys, discussions and exchange of views between the Team and the Burmese Government organizations concerned as to the construction and equipping of the Centre, both sides agreed to recommend their respective Governments to take necessary measures towards the establishment of the Centre. As a result of these discussions, Minutes were exchanged.

A copy of the Minutes and the list of participants are found in the Appendix of this Report.



C. BACKGROUND OF THE PROJECT

The following needs have been confirmed by the Survey Teams:

1. The pharmaceutical need of the country is being met by local manufacture and some imports. The local manufacture is carried out by the Burma Pharmaceutical Industry (BPI) which was established in 1954 when the population of the country was only about 20 millions. With the increase in population (at present 33 millions) and the introduction of national health schemes such as the Social Security and Country Health Programme, the demand for the pharmaceutical products is on the rise and the existing pharmaceutical industry finds it unable to fulfil the increasing needs of the country. (Quotation from "Proposal for the Establishment of the Development Centre for the Pharmaceutical Technology").
2. Additional development and production is required of Essential Drugs which were selected in accordance with the recommendation of WHO by the "First Conference on the Selection of Essential Drugs," but which are not yet being produced by BPI.
3. The present BPI production is about 100 million Kyats which is about 0.50 US\$ per capita. Per capita consumption as compared with other selected countries is shown below. These figures include imported drugs, and are reasonable estimates based on data from different origins, different census policies and methods, and also on fluctuating monetary exchange rates. Though not entirely accurate, they roughly indicate the comparative conditions in these countries and the urgency for Burma to advance at least up to internationally recognized minimum levels.

Estimated 1980
Per Capita Drug Consumption
in US Dollars

Burma	0.6
World Average	12.9
U.S.A.	46.9
Japan	60.3
West Germany	90.2
France	83.6
Australia	36.7
South Korea	6.0
Malaysia	3.6
Philippines	3.5
Thailand	3.4
Indonesia	1.2
Sri Lanka	1.6
India	0.9

4. Despite considerable efforts by BPI, domestic pharmaceutical production requires considerable improvement especially in light of the international recommendations of the World Health Organization (WHO) under Good Manufacturing Practice (GMP). Present BPI facilities are not sufficient for developing modern pharmaceutical techniques, due to overloaded production demand and generally outdated and limited facilities.
5. In view of these circumstances, it is vital and urgent that domestic pharmaceutical production be greatly increased and improved in quality. Increases in production will require implementation of additional production facilities. This demand can be supplemented, to a limited degree, by improving the efficiency of the present BPI.
6. However, as pharmaceutical technology in Burma has not had the opportunity to reach modern standards, an imperative prerequisite to increased production and improved quality is the development and acquisition of modern pharmaceutical manufacturing and quality control techniques and training.
7. Also of urgent need is the capability to produce antibiotics for which there are acute demands in Burma. It is also most desirable that these be produced from domestic resources.
Acquiring such capacities is a lengthy process which first requires basic research in fermentation techniques and pioneering in the search for domestic resources. Another urgent need is the upgrading of techniques for the development of medicine from indigenous medicinal plants.

D. PURPOSES OF THE PROJECT

In view of the needs outlined hereinbefore, a request for assistance in the establishment of the Development Centre for Pharmaceutical Technology has been made by the Government of Burma to the Government of Japan. The following contents of the proposal have been examined and discussed between officials of the Government of Burma and Japanese Survey Teams, and have been confirmed to be most urgent and appropriate for the needs and conditions in Burma.

1. Assistance has been requested for the establishment of the Development Centre for Pharmaceutical Technology as the most urgently required step towards fulfilling the pharmaceutical needs of Burma.

2. The establishment of the Centre is a prerequisite for the national increase and improvement of pharmaceutical products for the people. The objectives for the Centre itself are to provide facilities and an organization for development, research and training in the promotion of pharmaceutical products in forms suited to typical national needs, in utilization of indigenous resources for pharmaceutical products, in modern pharmaceutical production techniques and procedures, in quality control techniques and systems, and in production administration.
3. In order to attain the objectives of the Centre the following Departments are required.
 - a. Fermentation Process Department
Research and training in fundamental fermentation technology in preparation for utilization and uncovering of natural and indigenous resources for pharmaceutical needs such as for antibiotics.
 - b. Preparations Research Department
Development of pharmaceutical products which are called for in the recommended List of Essential and Complementary Drugs but which are not yet being domestically produced. Development, research and training in modern production techniques and procedures.
 - c. Medicinal Plants Department
Research and training in basic and applied technology for development of plant medicine or indigenous drugs.
 - d. Testing, Quality Control and Pharmacology Department
Development of and training in testing, quality control and pharmacological techniques.

BASIC DESIGN

CHAPTER 2 BASIC DESIGN

A. DESIGN PRINCIPLES

1. The Centre is to be planned to provide development and training facilities for pharmaceutical technology by provision of the following four departments.

Fermentation Process Department
Preparations Research Department
Medicinal Plants Department
Testing, Quality Control and Pharmacology Department

2. The Fermentation Process Department is to be equipped with facilities for training of technicians in development of fermentation technology leading to future studies in industrial fermentation processes.
3. The Preparations Research Department is to be equipped with modern automatic or semi-automatic machines and incidental equipment to train technicians in pharmaceutical production and formulation techniques.
4. The Medicinal Plants Department is to be provided with essential facilities for development of technology applicable to manufacturing practices, exploitation and evaluation of indigenous medicinal plants.
5. The Testing, Quality Control and Pharmacology Department is to be designed as a principal part of the Centre. Other departments will require intensive cooperation and precise evaluations of this department during the course of their operations. Equipment is to include advanced analytical apparatus and control measures such as physicochemical, microbiological and pharmacological procedures for verifying the effectiveness and safety of products as well as the *bioavailability, pharmacokinetics and metabolism* of drugs.
6. Administrative and welfare facilities as well as necessary utility services are to be provided.
7. The basic guidelines for the buildings have been established as follows:
 - a. To provide ample frontage for landscaping between buildings and the Insein Road, and attain an architectural design facing the road which will become a *visual asset to the neighbourhood environment*.
 - b. To emphasize the functions of the Centre by clean and simple architectural designs.

- c. To economize on building costs as much as possible to enable provision of a maximum budget for development and training equipment procurement.
- d. To provide high quality interior environments in keeping with Good Manufacturing Practice for critical areas.
- e. To carefully plan and design administration, management and maintenance aspects of the Centre.
- f. To utilize locally accepted construction methods and material.
- g. To incorporate construction systems which will shorten construction time in order to meet time requirements of the Japanese grant programme.

B. SITE

1. The following candidate sites were offered by the Government of Burma for establishment of the Centre.

Site 1: A plot approximately 30,000 m² in area adjoining the present BPI at its back or west side in Gyogon. Presently rice paddies and requiring an earth fill to an appropriate level.

Site 2-A: A plot approximately 26,000 m² in area facing the Insein Road, approximately 700 meters east of the present BPI.

Site 2-B: A plot approximately 22,000 m² in area which is basically the same as Site 2-A but with a shorter frontage on the Insein Road and with greater depth.

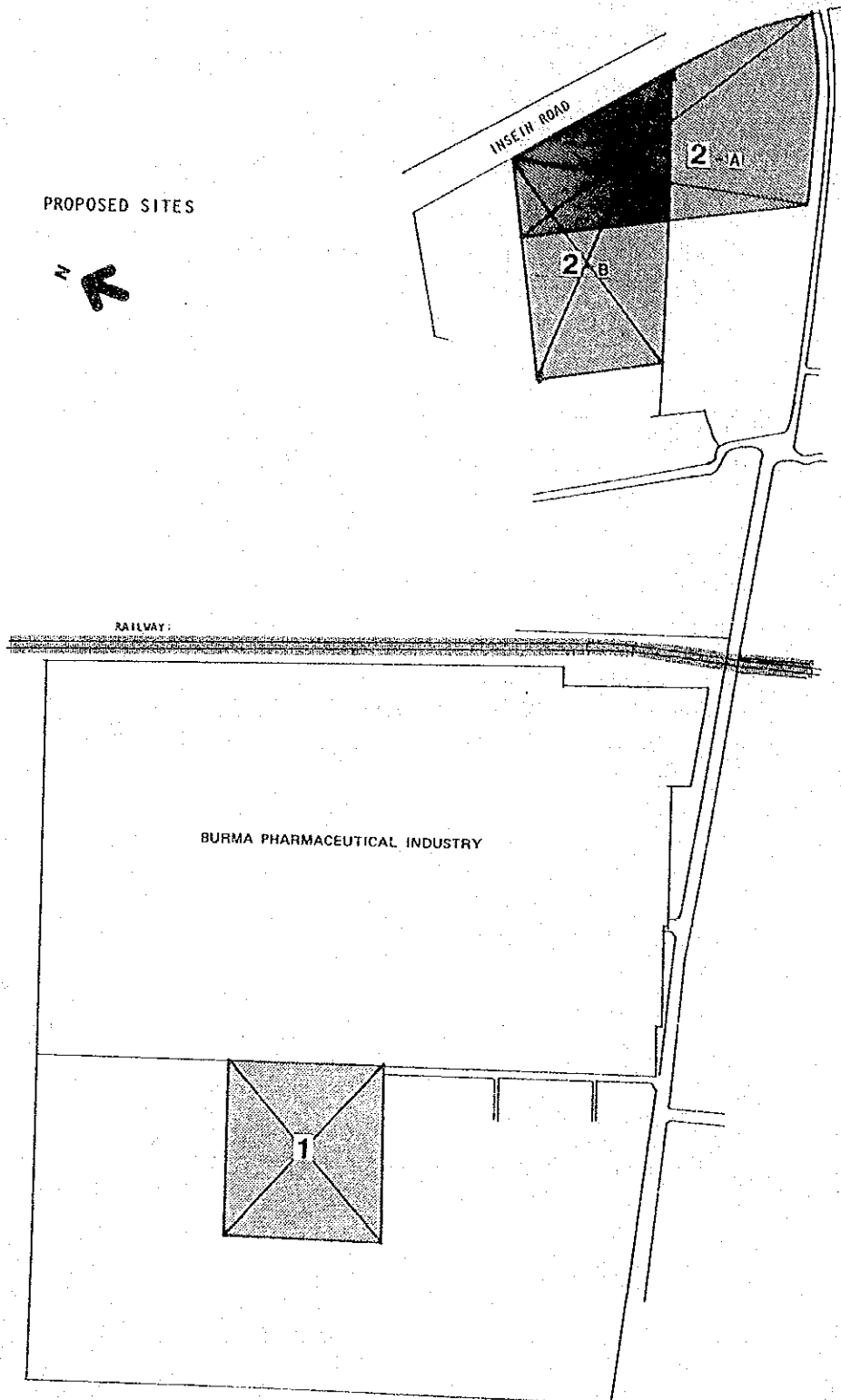
2. Three candidate sites were investigated and compared as follows:

a. Site 1

- (1) Will require an extensive earth-filling operation (depth of approximately 60 cm) prior to construction of facilities. The period required is prohibitive in consideration of the short time allowed for completion of the project.
- (2) The area of the site is sufficient for the Centre.
- (3) Power and utility services can be obtained to a limited degree from existing BPI facilities.

- (4) The access road beyond the gate of BPI will require reconstruction or improvement for earth movement, transportation of construction material and for permanent use after completion.
 - (5) Present administrative and employee welfare facilities of the BPI can be shared.
 - b. Site 2-A and 2-B
 - (1) Both Sites 2-A and 2-B do not require an earth-fill.
 - (2) Both sites have sufficient areas for the Centre.
 - (3) Both sites will require provision of new utilities, such as well water supply, drainage, steam generation, electric power receiving and conversion facilities.
 - (4) No road work will be required as both sites are open to the prominent Insein Road.
 - (5) Independent administrative and employee welfare facilities will be required.
 - (6) The Centre will be very conspicuous from the Insein Road.
 - (7) Site 2-A will require replacement of considerable number of BPI living accommodations. Site 2-B requires removal of one small structure and replacement of a football ground.
 - (8) Site 2-A is covered with numerous trees. Site 2-B has very few trees.
3. Site 1 was eliminated as a candidate for the establishment of the Centre due mainly to the prohibitive earthwork required and the poor access to the lot. Of Site 2-A and 2-B, Site 2-B was judged to be preferable for the following reasons:
 - a. The 60 m depth of Site 2-A is a disadvantage.
 - b. Site 2-B will not require the removal of BPI living accommodations as well as the destruction of the natural tree-covered environment.
 - c. Existence of a spacious open flat area, a well balanced land shape, possibility of providing a relatively deep frontage and absence of shortcomings favour Site 2-B.
4. Subsoil conditions at the selected site were investigated and found basically sound as shown by the boring data included in this Report. Located on

alluvial deposits of the Irrawaddy River delta, relatively stable surface silt with mixtures of sand and clay have been found, and it is judged that relatively light weight industrial or institutional structures can be safely supported on the soil, without going to depths for bearing.



C. DEVELOPMENT AND TRAINING FACILITIES

1. FERMENTATION PROCESS DEPARTMENT

Fermentation research equipment backing up a laboratory scale fermentation tank for basic research on refinement, extraction and other prefermentation processes will be provided with required laboratory equipment.

2. PREPARATIONS RESEARCH DEPARTMENT

Model production machinery lines for production of tablets, injections and other forms of drugs are to be provided in this Department. They are to be of adequate capacity and quality for research and training in modern production techniques with due compliance to GMP requirements.

Though specific details for this equipment will depend on interrelated technical cooperation programmes and future study, the planning and designing intent is to provide equipment which will enable development and production training on essential drugs which are not yet being produced in Burma, as well as for similar development and training on improved quality drugs of types which have already been developed in Burma.

3. MEDICINAL PLANTS DEPARTMENT

Though the basic research activities on harvesting, cultivation and breeding of medicinal plants will have to be performed in the field, the facilities to be provided in this Department are planned to enable the scientific evaluation of such activities, and to provide equipment for development and training in techniques leading to production of drugs from indigenous and new breed medicinal plants.

4. TESTING, QUALITY CONTROL AND PHARMACOLOGY DEPARTMENT

Physical and chemical research equipment for development and training in quality control techniques and methods are to be provided in this department. Equipment for pharmacology study on small animals will also be provided in this Department.

D. BUILDINGS

1. Site Layout

Considerations taken in layout planning of facilities on the site are as follows:

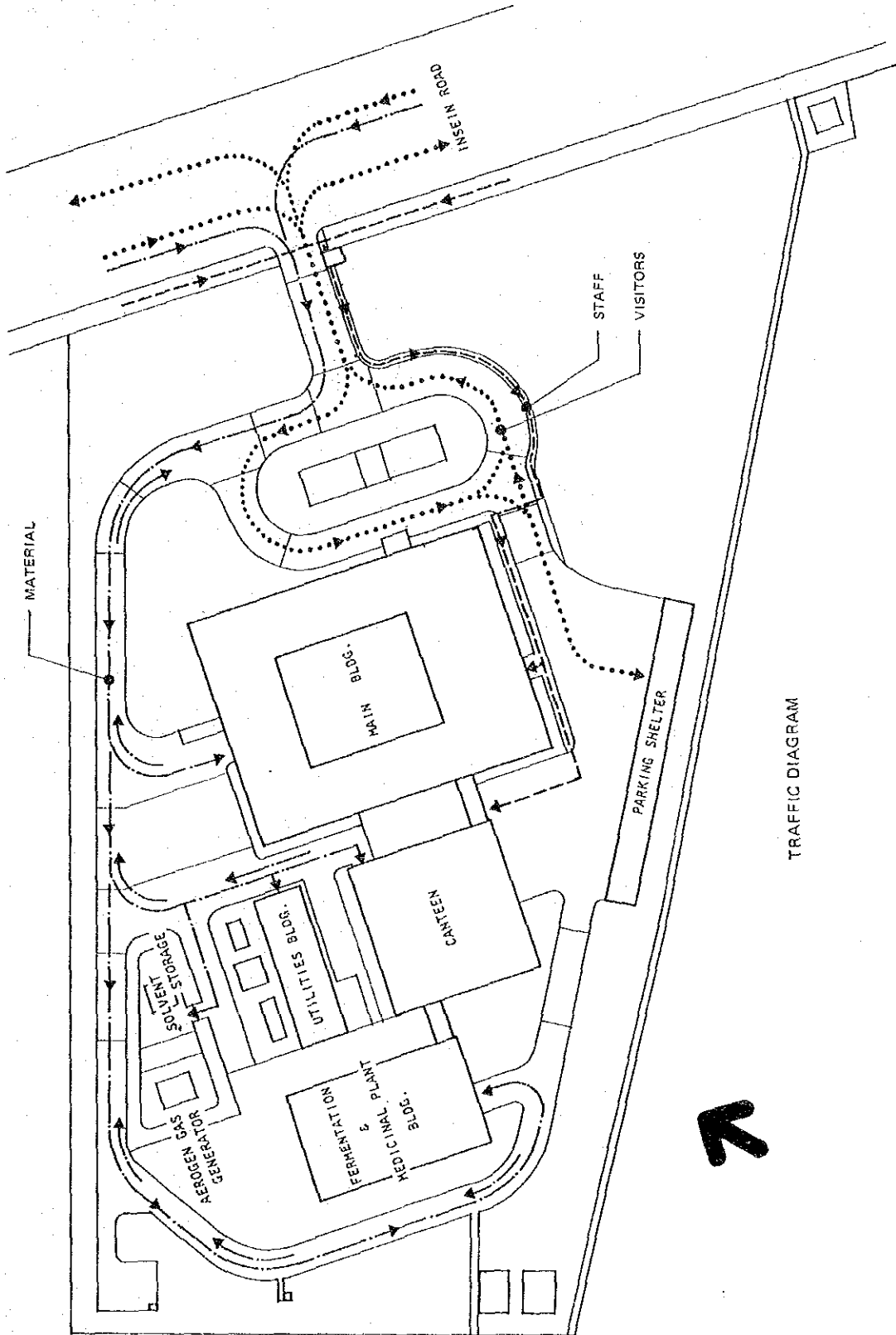
- a. As the portion of the land directly adjoining the Insein Road is relatively inclined towards the back of the site, and as the remaining portion of the site is quite flat, the inclined portion of a distance of about 60 m has been utilized as the approach and landscaped frontage for facilities erected on the flat portion of the site.
- b. The main building which is required to be larger and of relatively higher quality due to its functions is being placed to face the Insein Road as the feature building of the Centre. The Fermentation and Medicinal Plants Building is located in back of the Main Building. Utilities and welfare facilities are placed between these two buildings. Walking distances and utility line lengths between the buildings are minimized, and covered walks are to be provided for protection against the elements.
- c. Sewage and industrial waste treatment facilities are located at the southwest corner, and an incinerator at the northwest corner of the site. A solvent storage is located apart from other facilities at the north side. Covered parking facilities for about 20 cars are to be provided at the south side of the Main Building.
- d. Visitors and main personnel have a central approach to the facilities, while main personnel traffic is planned on the south side. Material transportation and service traffic is routed on the north side.

2. Architectural

a. Floor Planning

(1) Main Building

Administrative functions are placed in this building as direct access can be gained from the front road. Employees must first enter from the south side through controlled locker and clothes changing facilities before coming in to work. Both tablet and ampoule sections of the Preparations Research Department are located on the ground level, but are separated by a central corridor.



TRAFFIC DIAGRAM

The Testing, Quality Control and Pharmacology Department is located on the First Floor. A library is also located on the First Floor as are the vital mechanical facilities which are important for creating sterile environments for the Preparations Research Department. This locationing of mechanical equipment is to shorten duct runs to critical zones.

A spacious covered passage encircles the building to provide shelter from solar radiation and rain, and can be used for visitors who can observe operations without entering the building.

(2) Fermentation and Medicinal Plants Building

The Fermentation Research and Medicinal Plants Departments are separated by a corridor in this building. Perimeter passage is also provided for this building.

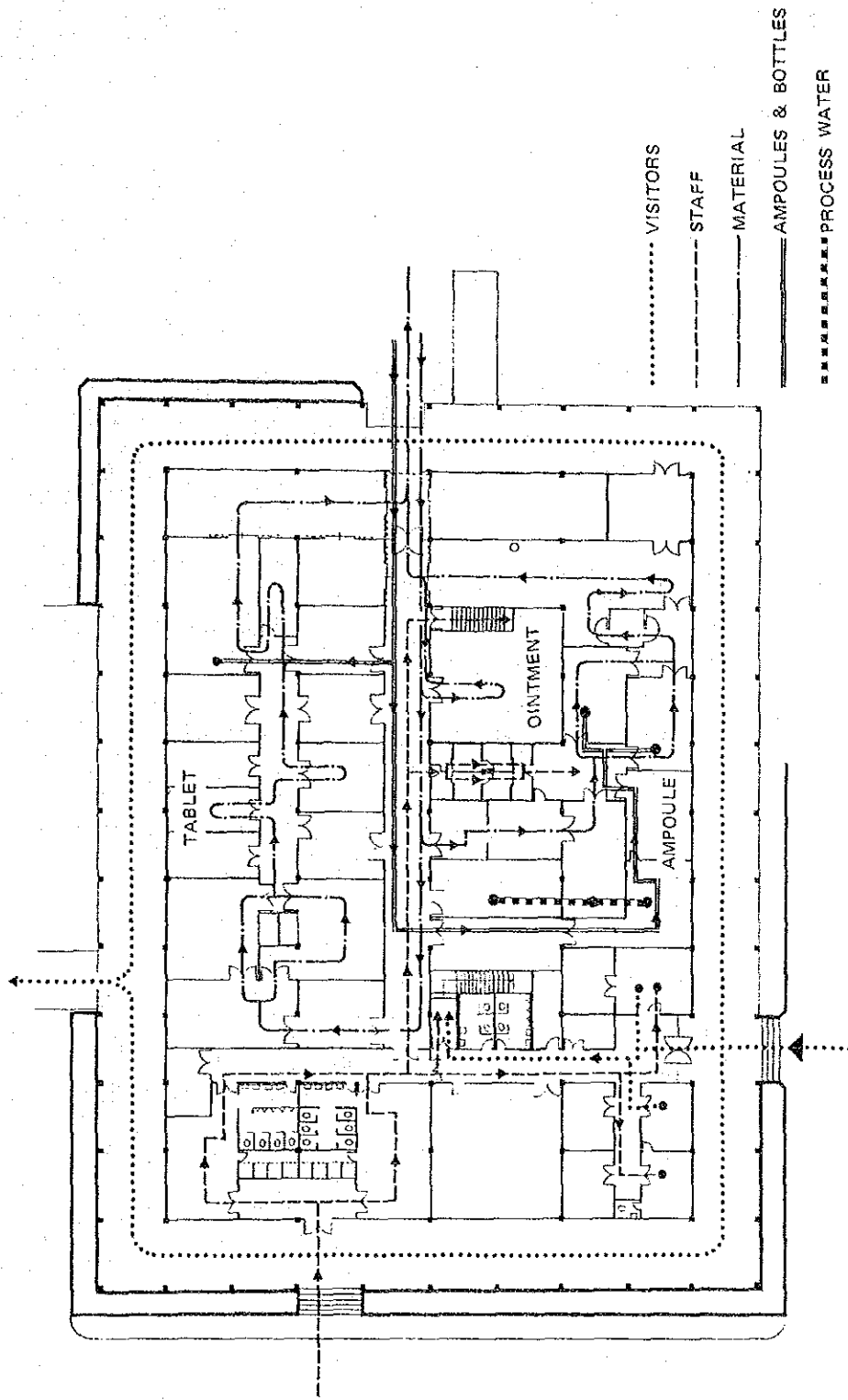
Separate changing and shower facilities are provided in this building for the staff.

(3) Utilities Building

Boiler, compressor, pumps, main electrical source and maintenance shop are placed in this building which is located in a central location to serve the main facilities of the Centre.

(4) Canteen

Canteen, pantry and other staff welfare functions are to be provided in this building. The perimeter passage on the south side can be used for relaxation and for small assemblies.



FLOW DIAGRAM

b. Span Planning

The following spans for the buildings have been selected mainly in consideration of equipment to be accommodated:

Main Building	4,6 x 9.0 m
Fermentation & Medicinal Plants Building	7.0 x 7.0 m
Utilities Building	10.0 x 5.0 m

c. Ceiling and Storey Heights

Ceiling clearances of main rooms and storey heights have been selected as follows mainly in consideration of equipment heights and duct and/or piping requirements:

	Ceiling Height	Storey Height
Main Building		
Ground Floor	4.0 m	4.5 m
1st Floor	3.0 m	3.8 m
Fermentation & Medicinal Plants Building	3.0 m	3.7 m
Utilities Building		5.5 m

d. Building Components

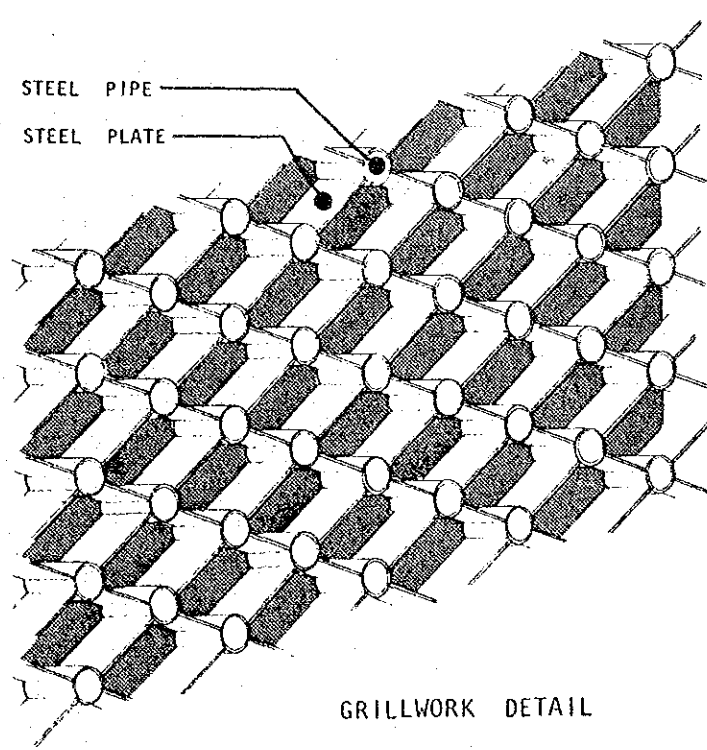
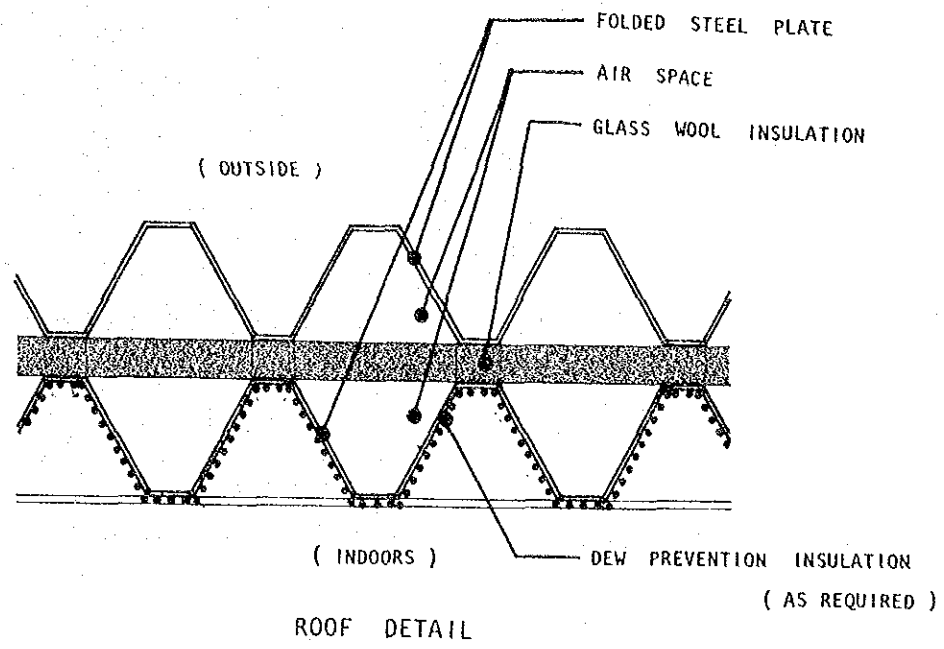
(1) Structure

Steel framed structure has been selected in consideration of precision requirement imposed by the functions and to shorten construction time at the site.

(2) Roofs

A roll-formed endless-type galvanized steel roof structure has been selected to securely protect the facilities from torrential rains and to shorten erection time at the site.

The roof structure, to be roll-formed at the site from steel coils, is to be of double layer construction with air space and insulation inbetween. An aluminum coloured protective coat is to be applied to its top surface to reflect solar heat.



(3) Exterior Walls

Local brick construction is to be used for perimeter walls on ground level. Exterior surfaces of these walls are to be of exposed brick finish and to become a feature of the building design. Interior surfaces are to be plastered and painted. Exterior walls of the upper level of the Main Building are to be of dry construction clad with asbestos cement siding.

(4) Windows and Doors

Aluminum frames and sashes are to be used for windows in general to ensure required airtightness. Exterior light and ventilation openings of the Utilities Building are to be without sash but protected with aluminium louvers.

Exterior doors and important interior doors are to be of steel construction. Other doors are to be of wood construction.

(5) Perimeter Passages

The open passages around development buildings are to be covered by the roof overhang, and are to have steel louver protection against rain and solar radiation.

(6) Partitions

Plastered brick partitioning and dry construction partitioning are to be used inside the buildings. Partitions in the Preparations Research Department are to be of dry construction to permit easier future rearrangements. They are, however, to have double-layer board surfacing with polysulphate caulked joints to maintain the required airtightness.

(7) Ceilings

Hung ceilings covered with acoustic units are to be used throughout in general, except for critical areas. Ceilings for areas requiring special sterility or cleanliness are to be of double layer gypsum board and asbestos cement board construction, painted and with caulked joints. Furring is to be of local timber construction.

(8) Floors

Local terrazzo is to be used for floors of development buildings. Floors for other buildings are to be trowel finished concrete in general.

3. Structural

The proposed buildings are a two-storied structure (Main Building) and two single-storied structures (Fermentation and Medicinal Plants Building and Utilities Building).

The horizontal forces from earthquake and wind pressure in Burma are smaller than those in Japan, but are not to be ignored in design of these structures.

a. Structural Systems

(1) Framing System

The structure of the buildings is planned as a steel frame structure in consideration of the short construction term required and to eliminate the necessity of piles in view of soil conditions at the site.

Rigid and braced frames are to be used as resisting elements against lateral wind pressure and seismic loading.

(2) Roof System

The roof structure is to be designed with double folded steel plates sandwiching insulation, and is to be stiffened by horizontal bracing against plane displacements.

(3) Floor Systems

Steel deck plate system is to be used for the first floor structure of the Main Building. Horizontal bracings are to be used for stiffening against plane displacements.

The ground floor structure is to be a reinforced concrete on-grade slab. However, independent foundations or rigid reinforced concrete slabs will be provided as necessary for equipment of excessive weight, vibration or unique specifications.

(4) Foundation System

Foundations are to be designed to bear directly on the silt and clay stratum, 1.0–1.5 meter under ground level, which has N-value (hammer blows/ft) ranging from 15 to 30.

b. Structural Design

(1) Design References

Though there is no uniform design code and standard in Burma, it is the local practice in structural design, though not compulsory, to refer mainly to the British Standards.

As the structure is to be prefabricated mainly in Japan with Japanese materials, Japanese Building Codes are to be referred to by making necessary revisions to adopt them to local conditions.

(2) Design Loads and External Forces

The following loads and external forces are to be taken in accordance with the recommendations of the Japanese Building Codes and the local conditions.

(a) Live Loads

Concentrated loads of heavy equipment are to be considered in the design in cases when they are larger than those of the following uniformly distributed live loads.

General live loads are to be taken as follows:

	Design Live Load (kg/m ²)		
	Floor	Frame and Foundation	Seismic Load
Office and Research Rooms	300	180	80
Laboratories	500	400	250
Library and Storages	600	500	300
Corridors, Lobbies and Stairs	300	180	80
Toilets	300	180	80

Special live loads shall be determined otherwise.

(b) Earthquake Force

Seismic coefficient K is to be taken as 0.15, and the earthquake force assumed to act on the structure is to be derived by considering the weight of the building.

(c) Wind Forces

The design wind velocity recorded in Rangoon is estimated as 100 miles/hour (44.7 m/sec.) by referring to the Design Considerations for Timber set forth by the Standardization Committee – 1974. This is equivalent to a basic horizontal wind pressure of about 25.58 pounds/sq.ft. (125.6 kg/m²). Therefore, the design wind pressure is to be taken by assuming a basic horizontal wind pressure of 130 kg/m².

(d) Temperature Stress

Temperature variation in elongationally restricted members produces a stress. Such stress can not be ignored for steel structures.

For the analysis of the temperature stress, (1) for outdoors, maximum temperature is to be taken as 97°F (36.2°C), which is the mean maximum temperature in Rangoon and the minimum as 66°F (18.9°C), which is the mean minimum temperature in Rangoon, and, (2) for indoors, 26°C, the air conditioning temperature.

(3) Deflection and Vibration

The building structure and its components are to be designed to have sufficient stiffness and stability.

Beams and girders supporting floors and roofs are to be designed with due regard given to deflection produced by design loads.

Beams and girders supporting general floors and roofs are to be designed so that the maximum live load deflection does not exceed 1/360 of the span.

Beams and girders are to be designed with consideration given to vibration as well as deflection.

(4) Structural Materials

(a) Structural Steel and Steel Members

The buildings are to be designed for structural steel produced in Japan. Steel members are to be prefabricated mainly in Japan. Main structural steel is to be as follows:

Rolled Steel for General Structure (JIS.G.3101)

SS41 (Specified minimum yield stress = 2,400 kg/cm²)

Field joints are to be made by friction-type high strength bolts.

(b) Concrete

Concrete is to be made by normal Portland cement produced in Burma.

The compressive strength of concrete (F_c) is to be 180 kg/cm².

Concrete slump is to be 10–15 cm considering the high temperature in Burma.

Concrete proportioning is to be selected in accordance with Japanese specifications and in conformance to the local conditions.

(c) Reinforcement

Reinforcement produced in Japan under following specifications is to be used.

Steel Bars for Concrete Reinforcement (JIS.G.3112)

SD30 (Specified minimum yield stress = 3,000 kg/cm²)

SR24 (Specified minimum yield stress = 2,400 kg/cm²)

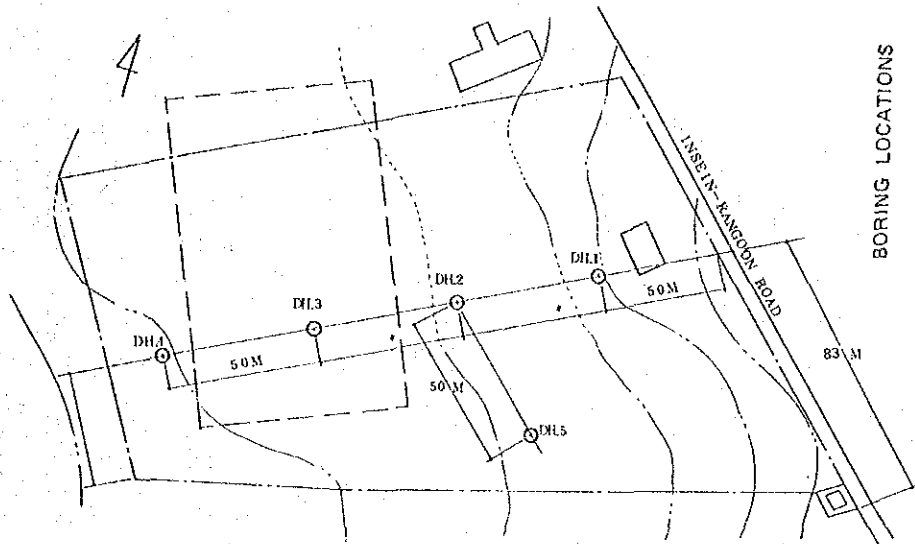
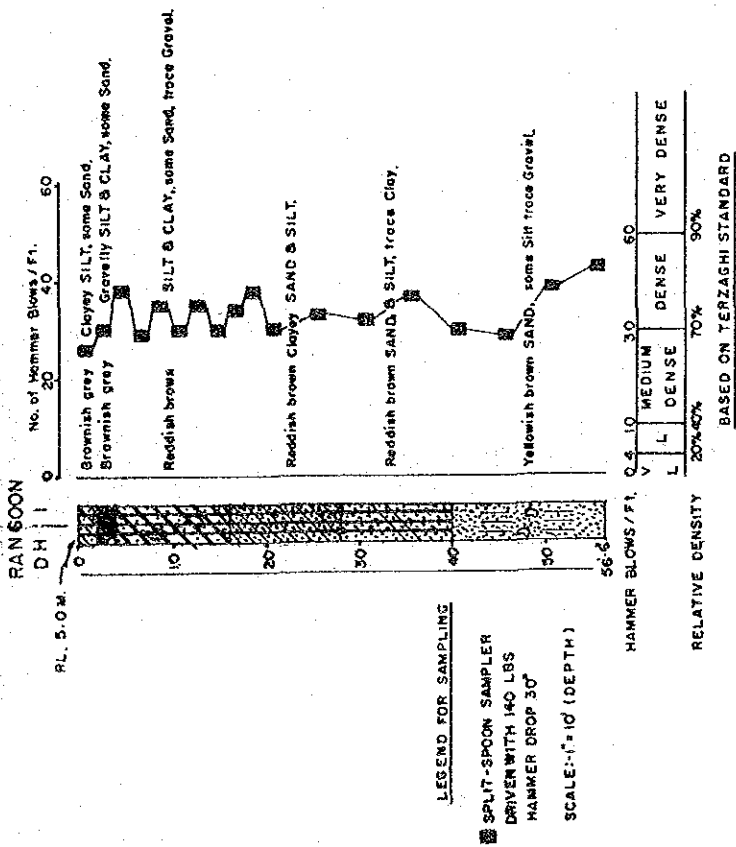
Lap joints of reinforcement bars are to be used in the field.

(5) Soil Bearing Capacity

Upon consideration of soil conditions, soil bearing capacity at the site is assumed as 7.0 t/m², which coincides with the generally adopted figure in Rangoon.

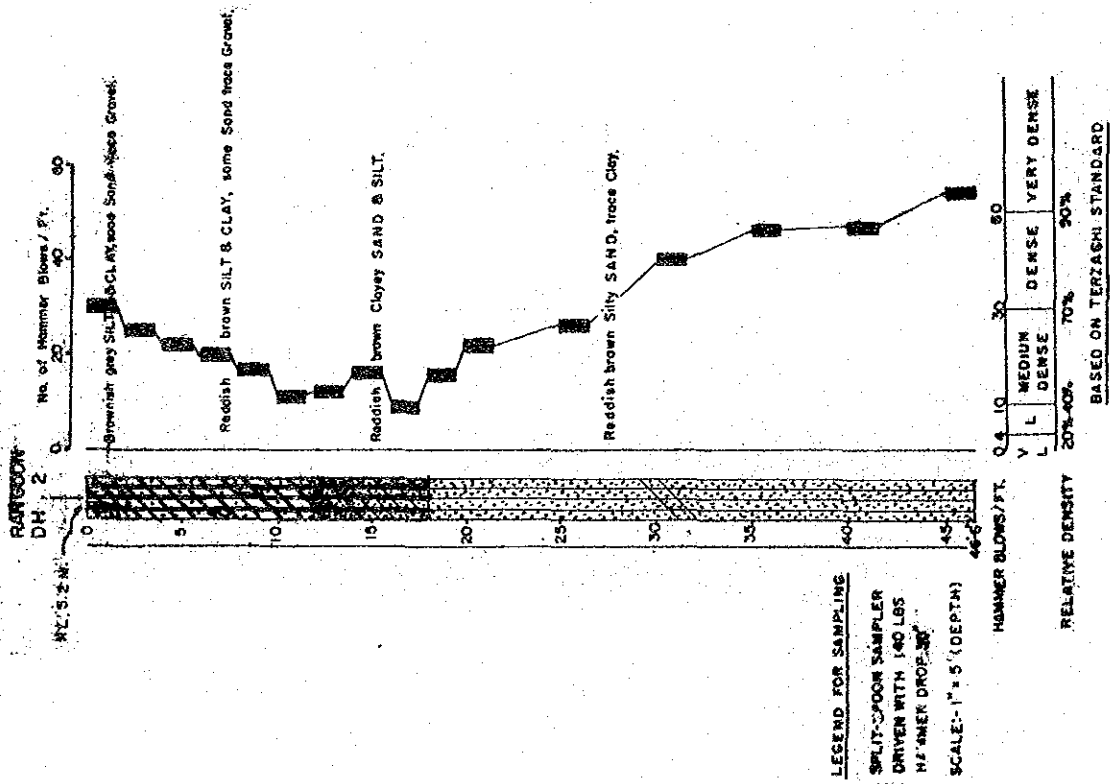
The bearing capacity to be actually adopted is to be determined after verification by loading tests at the site.

**SUBSURFACE SOIL PROFILE
BURMA PHARMACEUTICAL INDUSTRIES**



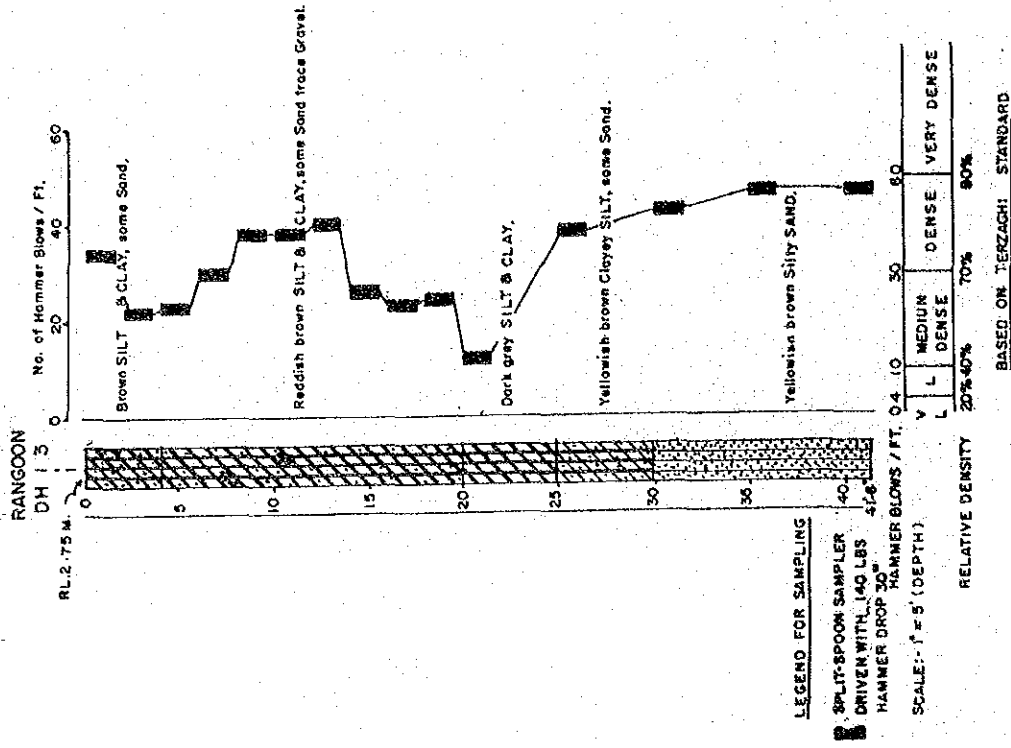
DH 1

SUB SURFACE SOIL PROFILE
BURMA PHARMACEUTICAL INDUSTRIES



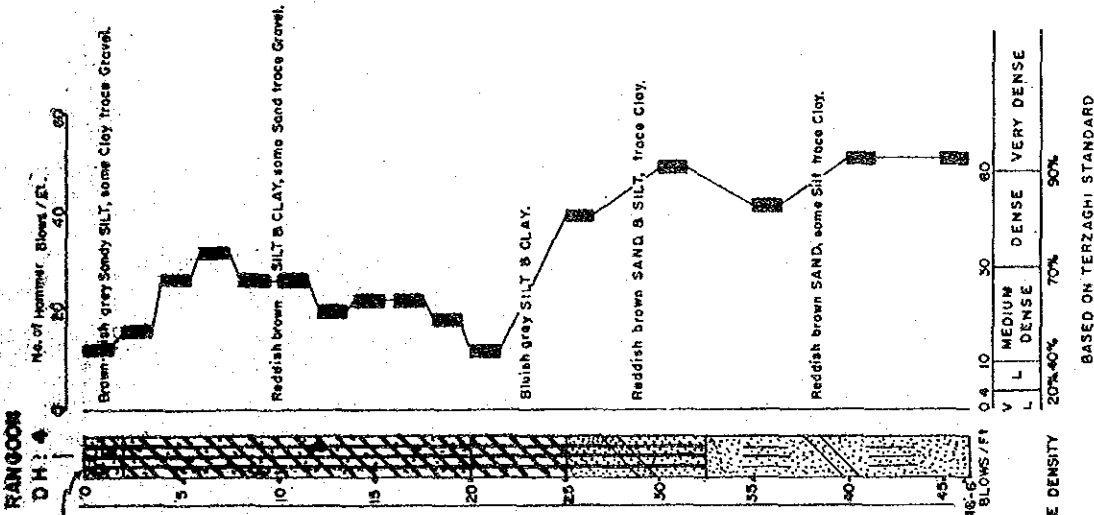
DH. 2

SUB SURFACE SOIL PROFILE
BURMA PHARMACEUTICAL INDUSTRIES



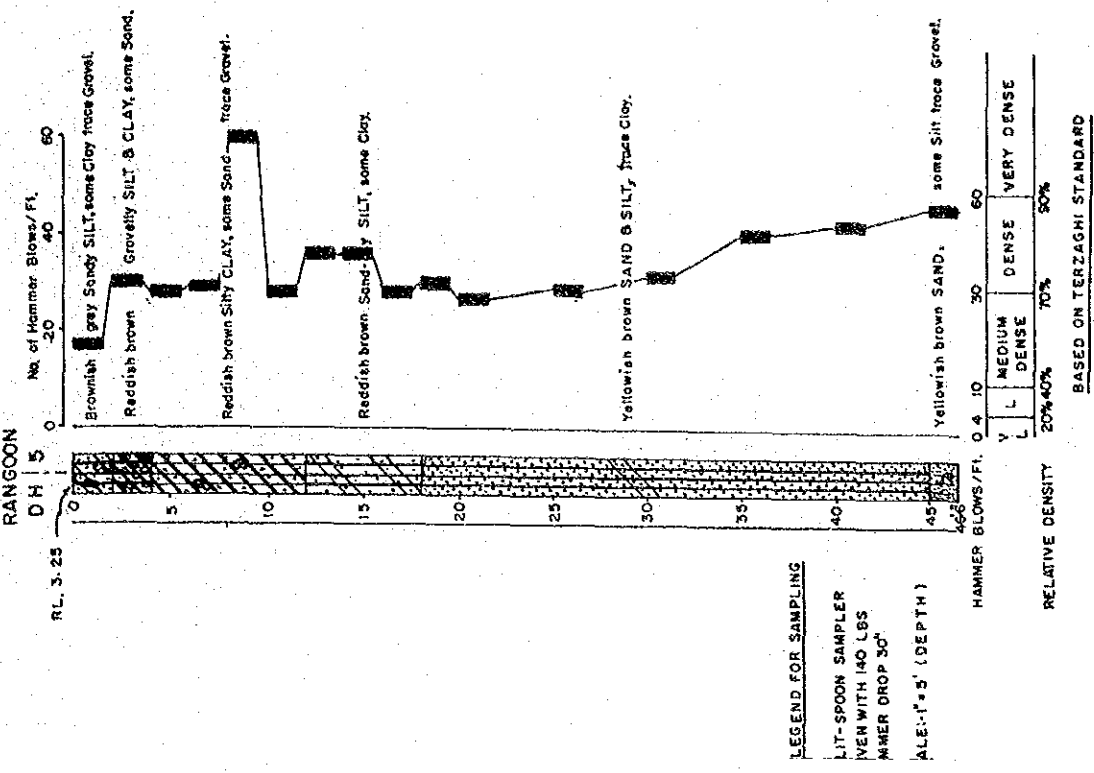
DH. 3

SUBSURFACE SOIL PROFILE
BURMA PHARMACEUTICAL INDUSTRIES
RANGOON



DH. 4

SUBSURFACE SOIL PROFILE
BURMA PHARMACEUTICAL INDUSTRIES
RANGOON



DH. 5

4. UTILITIES

Utility equipment is to be designed in accordance with the basic design policies with emphasis placed on the fact that most equipment cannot be of domestic origin and that they must therefore be of utmost reliability and durability.

Due to the absence of local codes and regulations, Japanese codes, regulations and specifications are to be followed.

Equipment is to be selected for ease of operation and maintenance, and is to satisfy the requirements of GMP in the Preparations Research Department.

a. Electrical Equipment

(1) Service, Transforming and Feeder Equipment

Primary power is to be received at 6.6 KV from the existing Gyogon Substation located at the south-east corner of the site. This power is to be connected to outdoor type transformers located outside the Utilities Building. The total connected load is estimated at about 1,000 KVA. Primary power is to be converted at transformers to 3 ϕ 400 V for power and 1 ϕ 230 V for lighting and convenience outlets, and distributed to individual building panelboards from a main distribution panel in the Utilities Building. Single phase power at 200 V and 100 V is also to be supplied as required for operating equipment of Japanese source.

(2) Emergency Generation Equipment

A motor generator is to be installed as standby for power failure. Capacity is to be sized to operate critical lighting and power requirements of the Centre.

(3) Power Supply Equipment

Power wiring in conduit piping is to be designed for building equipment such as water supply and hydrant pumps, air conditioning equipment, development and training equipment. Power distribution or control panels are to be provided in each building. Development and training equipment are to be provided with local control panels or with convenience outlets as required.

(4) Lighting Fixtures and Convenience Outlets

Lighting in general is to be by fluorescent fixtures with supplementary lighting by incandescent fixtures. Lighting fixtures are to be controlled by room switches conveniently located at doorways. Convenience outlets (1 ϕ 230 V) are to be distributed as required. Critical lighting is to be supplemented with emergency power.

Lighting intensities for main areas are to be as follows:

Main Building

Preparations Research Department	300–700 Lx
Testing, Quality Control and Pharmacology Department	300–700 Lx
Administrative	300–500 Lx

Fermentation & Medicinal Plants Building

Fermentation Process & Medicinal Plants Departments	300–700 Lx
Offices	300–500 Lx

Utilities Building

Workshop	200 Lx
Electric, Boiler, Water Treatment Rooms	200 Lx
Storages	100 Lx

(5) Telephone Equipment

A central connection panel and switchboard is to be provided on the ground floor of the Main Building. Conduit lines and wiring are to be provided from the central panel to stations via local panels in individual buildings. Handsets are to be provided as required.

(6) Interphone Equipment

An interphone system is to be provided for communication between main rooms of the Centre. Wiring is to be installed in conduit piping lines.

(7) Fire Alarm Equipment

Fire alarm system consisting of alarm bells and buttons are to be provided adjacent to fire hydrant boxes.

b. Water Supply, Drainage, Sanitary and Fire Hydrant Equipment

(1) Water Supply Equipment

Two wells are to be provided as the water source for the Centre.

Well water stored in a reservoir is to be pumped to an elevated tank and distributed by gravity to outlets. Depending on conditions of the well water, filtration equipment will be provided.

(2) Drainage Equipment

Three separate drainage systems are to be provided, i.e., a sewer system for sanitary waste, an industrial waste water system for drainage from laboratory and training facilities, and a storm drainage system to handle rain water.

Separate treatment facilities for the sewer system and the industrial waste water system are to be provided before they are discharged together with the storm drainage to a nearby creek.

(3) Fire Hydrant System

A fire hydrant system is to be provided within buildings for protection against fire. The elevated storage tank is to be shared for this system.

(4) Gas Supply Equipment

An Aerogen gas generator and pipe distribution system is to be provided for gas supply to required locations.

c. Air Conditioning and Ventilation Equipment

(1) Air Conditioning Equipment

(a) Sterile Ampoule Zone

Sterile filling and incidental areas are to be served by a special system incorporating an air-cooled package type air conditioner and a high-efficiency filter system.

(b) General Ampoule Zone

Preparation, ampoule washing and ampoule preparation rooms are to be served by a system incorporating an air-cooled package type cooler and a medium efficiency filter system.

(c) Tablet Zone

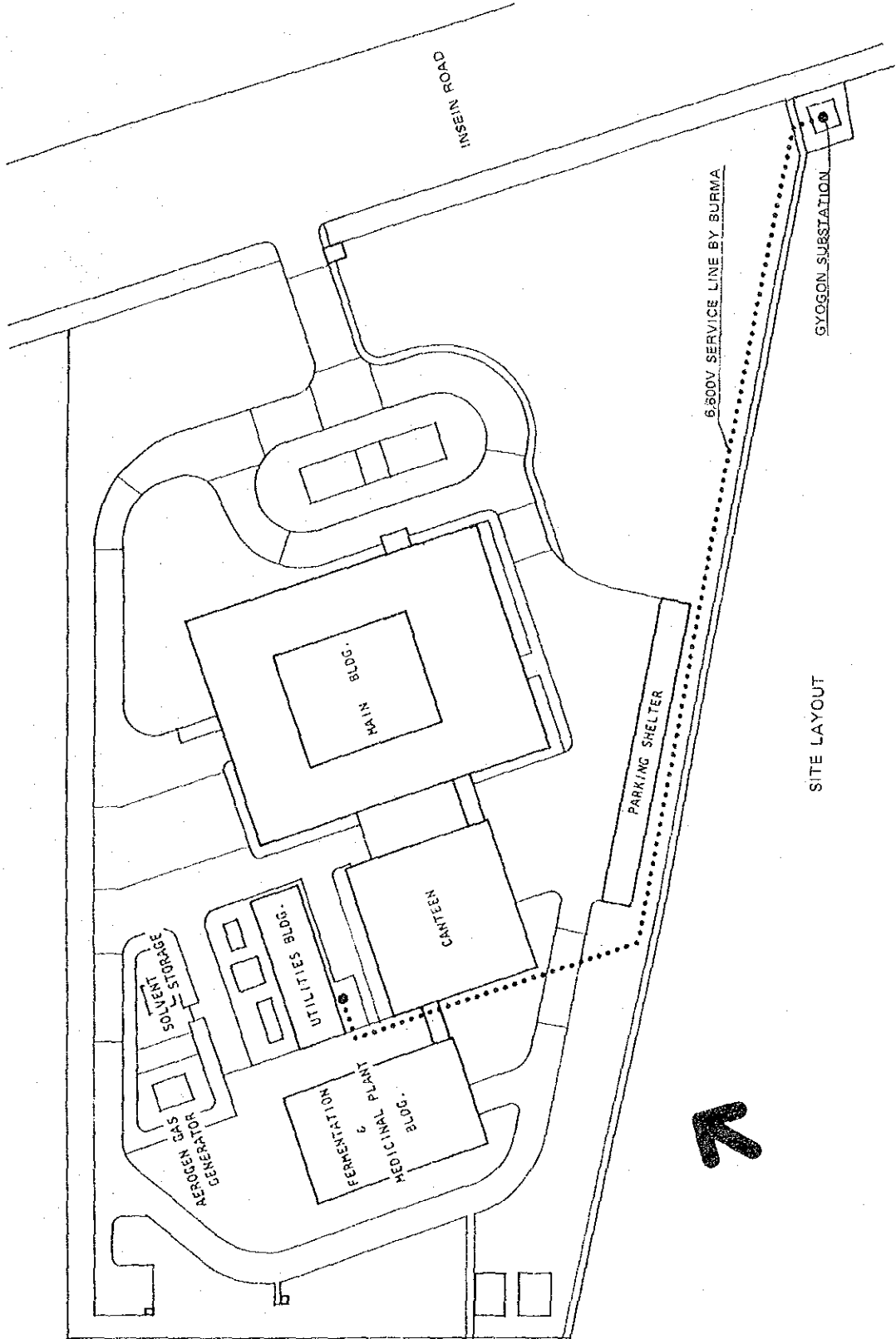
Granulating, tableting and incidental areas are to be served by a system incorporating an air-cooled package type cooler and a medium efficiency filter system.

(d) Other Zones





Office and conference rooms are to be individually cooled by window type, separated type or package type air conditioners.

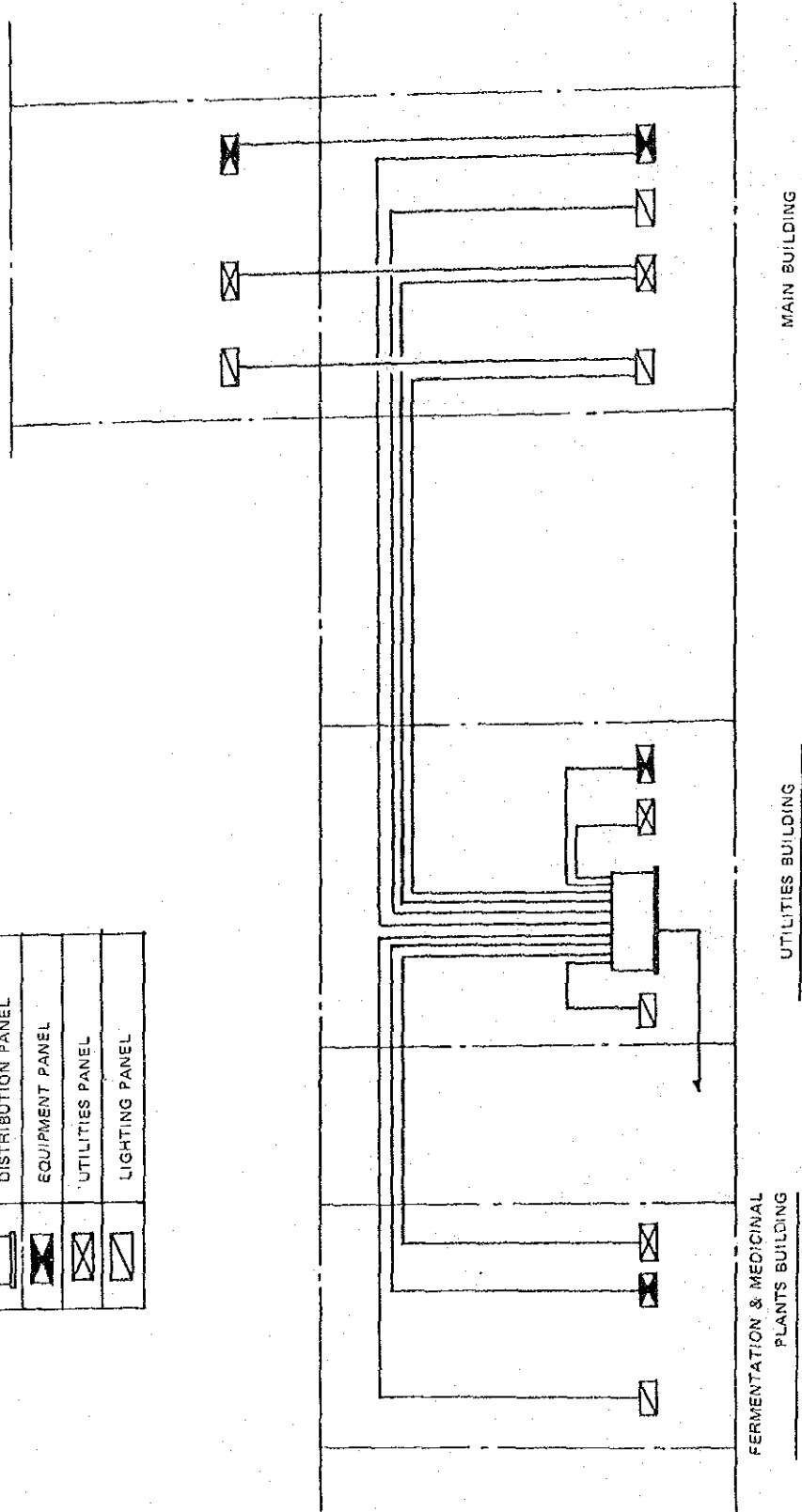
(2) Ventilating Equipment

Foul air and waste heat is to be discharged by mechanical exhausts as necessary.

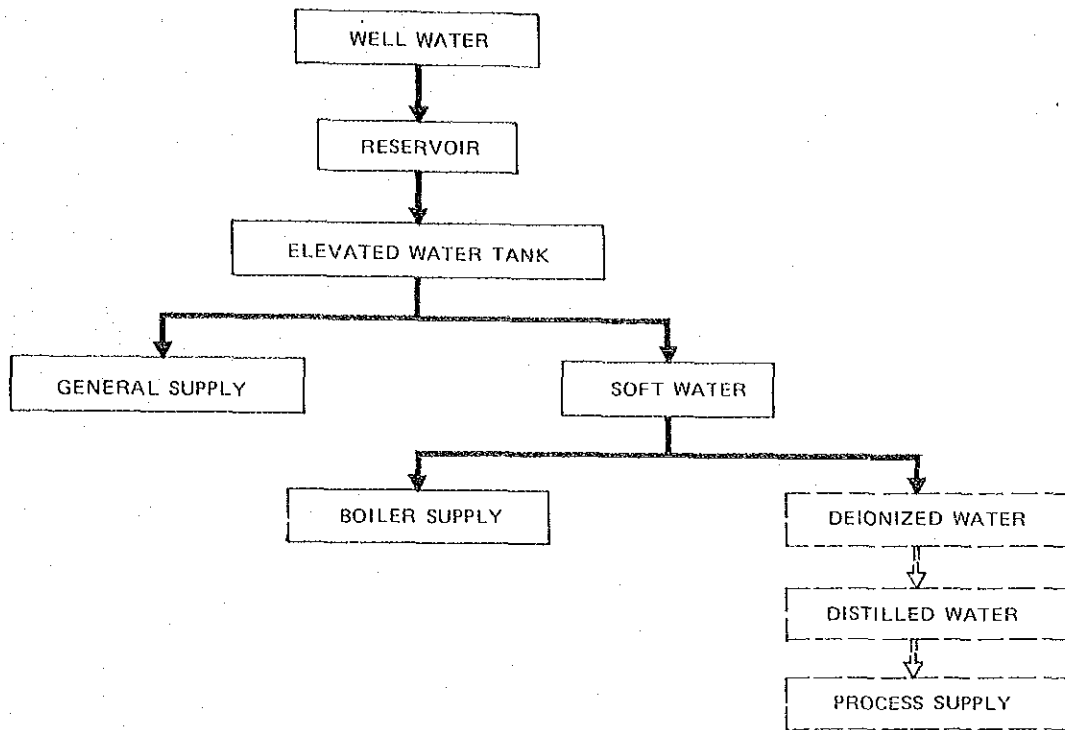


SITE LAYOUT

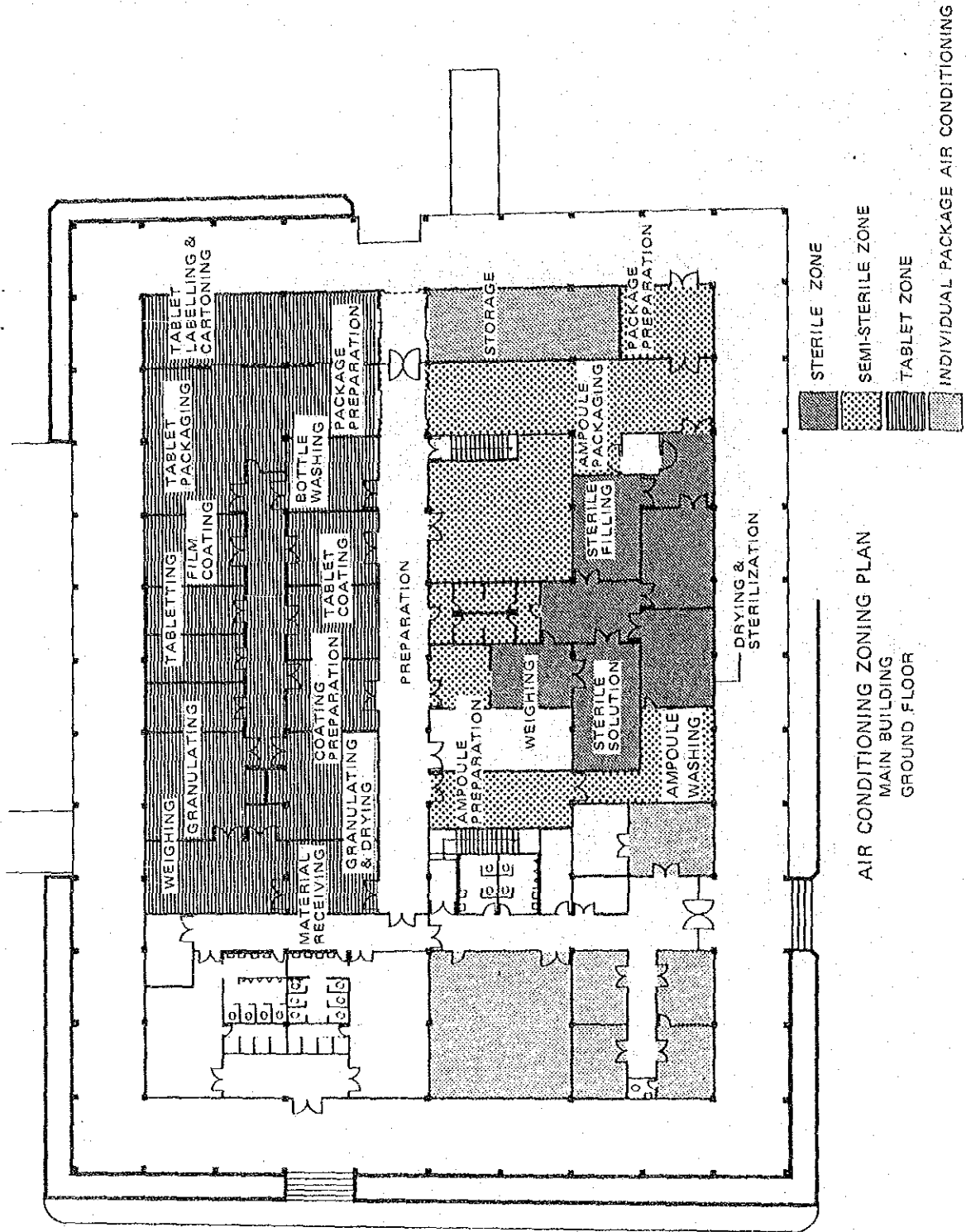
	DISTRIBUTION PANEL
	EQUIPMENT PANEL
	UTILITIES PANEL
	LIGHTING PANEL

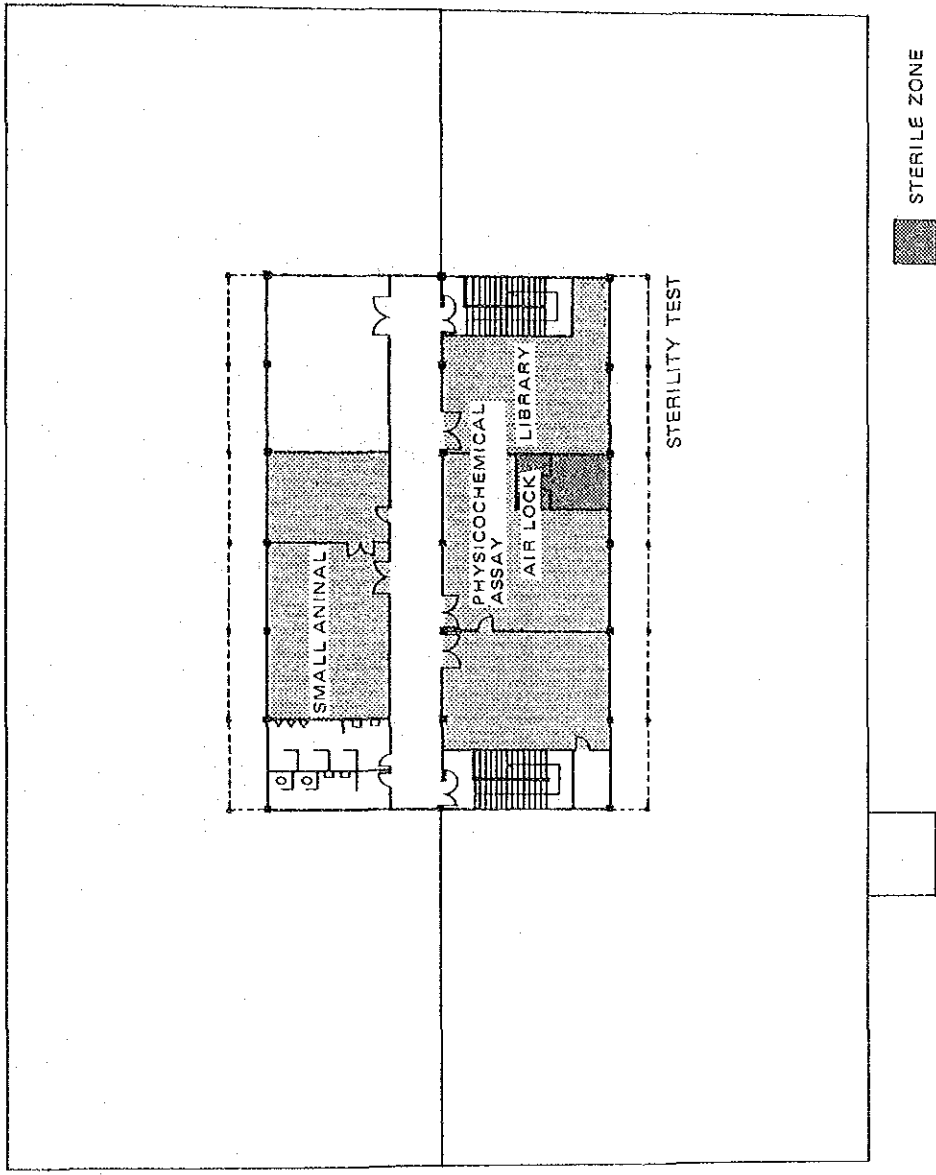


ELECTRIC POWER DIAGRAM





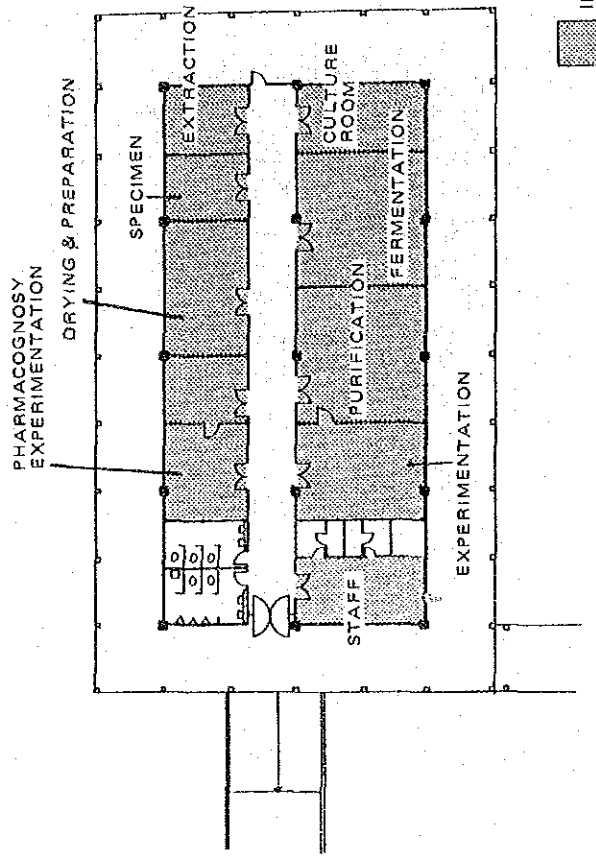
WATER SUPPLY FLOW DIAGRAM





AIR CONDITIONING ZONING PLAN
 MAIN BUILDING FIRST FLOOR

-  STERILE ZONE
-  INDIVIDUAL PACKAGE AIR CONDITIONING



AIR CONDITIONING ZONING PLAN
 FERMENTATION AND MIDICINAL PANTS BUILDING

5. TABULATION OF APPROXIMATE FLOOR AREAS

a.	Main Building	
	Ground Floor	1,821.6 m ²
	First Floor	496.8
	<hr/>	
	Total	2,318.4
b.	Fermentation & Medicinal Plants Building	392
c.	Utilities Building	300
d.	Aerogen Gas Generator	25
e.	Canteen	500
f.	Covered Walk	70
g.	Solvent Storage	25
h.	Parking Shelter	360
i.	Guard House	15

E. EQUIPMENT LIST AND DRAWINGS

1. LIST OF MAIN EQUIPMENT

a. Fermentation Process Department

1) Fermenter, Lab Scale	1 set
2) Vacuum Filter	1
3) Filter Press	1
4) Orbital Shaker	1
5) Extractor	1
6) Evaporator	1
7) Spray Dryer	1
8) Autoclave	1
9) Deionizer	1
10) Precision Distiller	1
11) Laminar Flow Cabinet	1
12) Incubator	1
13) pH Meter	1
14) Microscope	1
15) Miscellaneous Equipment & Apparatus	1

b. Preparations Research Department

b-1 Tablet Formulation & Processing

1) Scales	1 set
2) Atomizer	1
3) Sieving Machine	1
4) Mixer	2
5) Kneader	2
6) Granulator	2
7) Dryer	2
8) Tableting Machine	3
9) Sugar Coating Machine	2
10) Sugar Solution Preparation Tank	1
11) Film Coating Machine	1
12) Tablet Counting Machine	1
13) Capping Machine	1
14) Labeller	1
15) Cartoner	1
16) Bottle Washing Machine	1
17) Lifter & Palleter	1
18) Miscellaneous Equipment & Apparatus	1

b-2 Ampoule Formulation and Processing

1) Scales	1 set
2) Ampoule Washing Machine	1
3) Ampoule Drying & Sterilizing Machine	1
4) Filling & Sealing Machine	2
5) Autoclave	1
6) Purified Water Supply System	1
7) Water Distiller	1
8) Preparation Tank	2
9) Solution Tank	2
10) Membrane Filter	2
11) Ampoule Containers & Trays	1
12) Ampoule Printer	1
13) Ampoule Cartoner	1
14) Lifter & Palleter	1
15) Miscellaneous Equipment & Apparatus	1

b-3 Ointment Formulation and Processing

1) Agitator	1 set
2) Homogenizer	1
3) Kneader	1
4) Mixer	1
5) Ointment Filling Machine	1
6) Miscellaneous Equipment & Apparatus	1

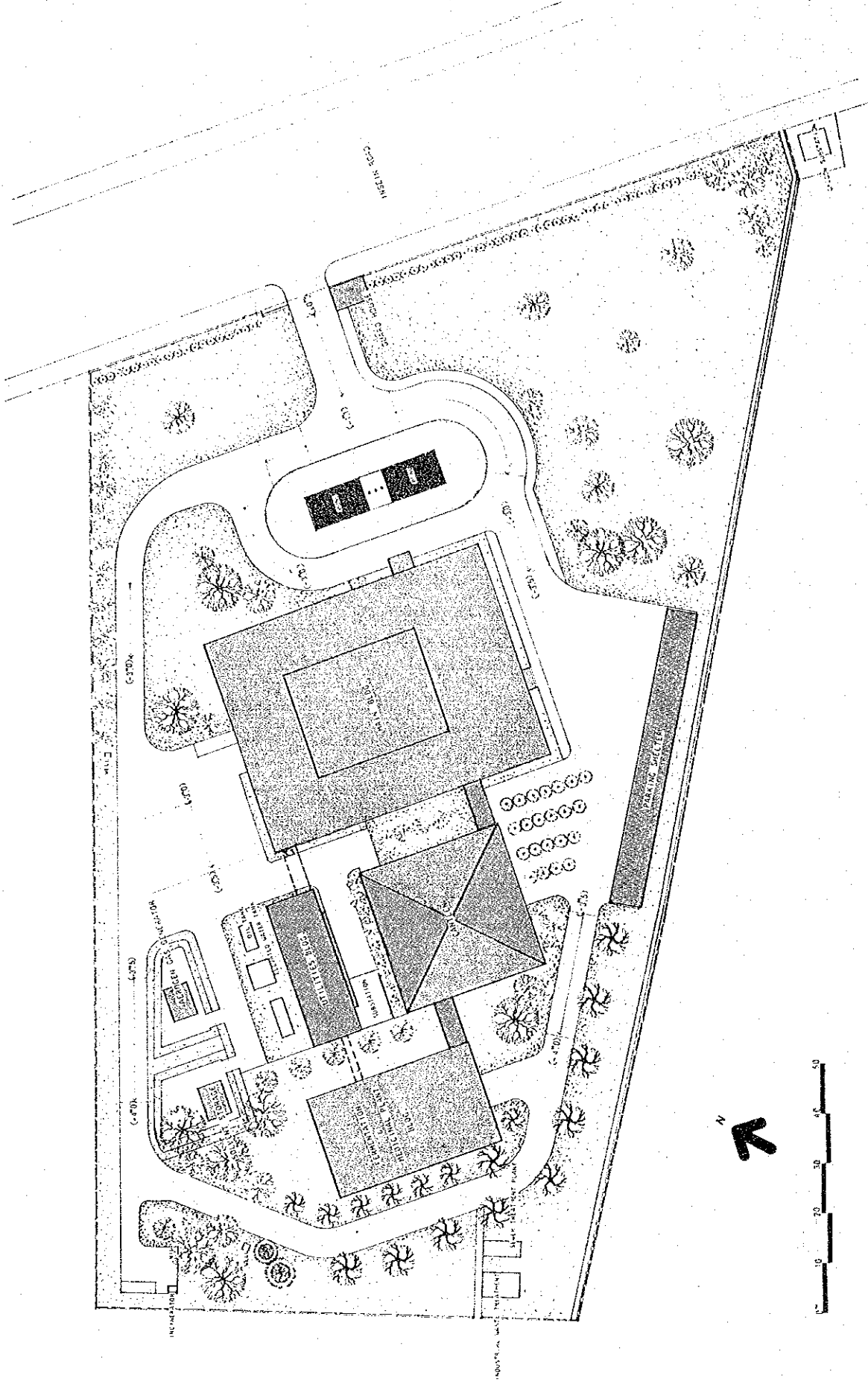
c. Medicinal Plants Department

1) Grinding Mill	1 set
2) Percolators	1
3) Vacuum Distillator	1
4) Climbing Film Evaporator	1
5) Glass Separator	1
6) Steel Extraction Vessels	1
7) Fractional Distillation Unit	1
8) Crystallizing Vessel	1
9) Vacuum Dryer	1
10) Filter Press	1
11) Deep Freezer	1
12) Gas Chromatograph	1
13) T.L.C. Apparatus	1
14) Column Chromatograph	1
15) Miscellaneous Equipment & Apparatus	1

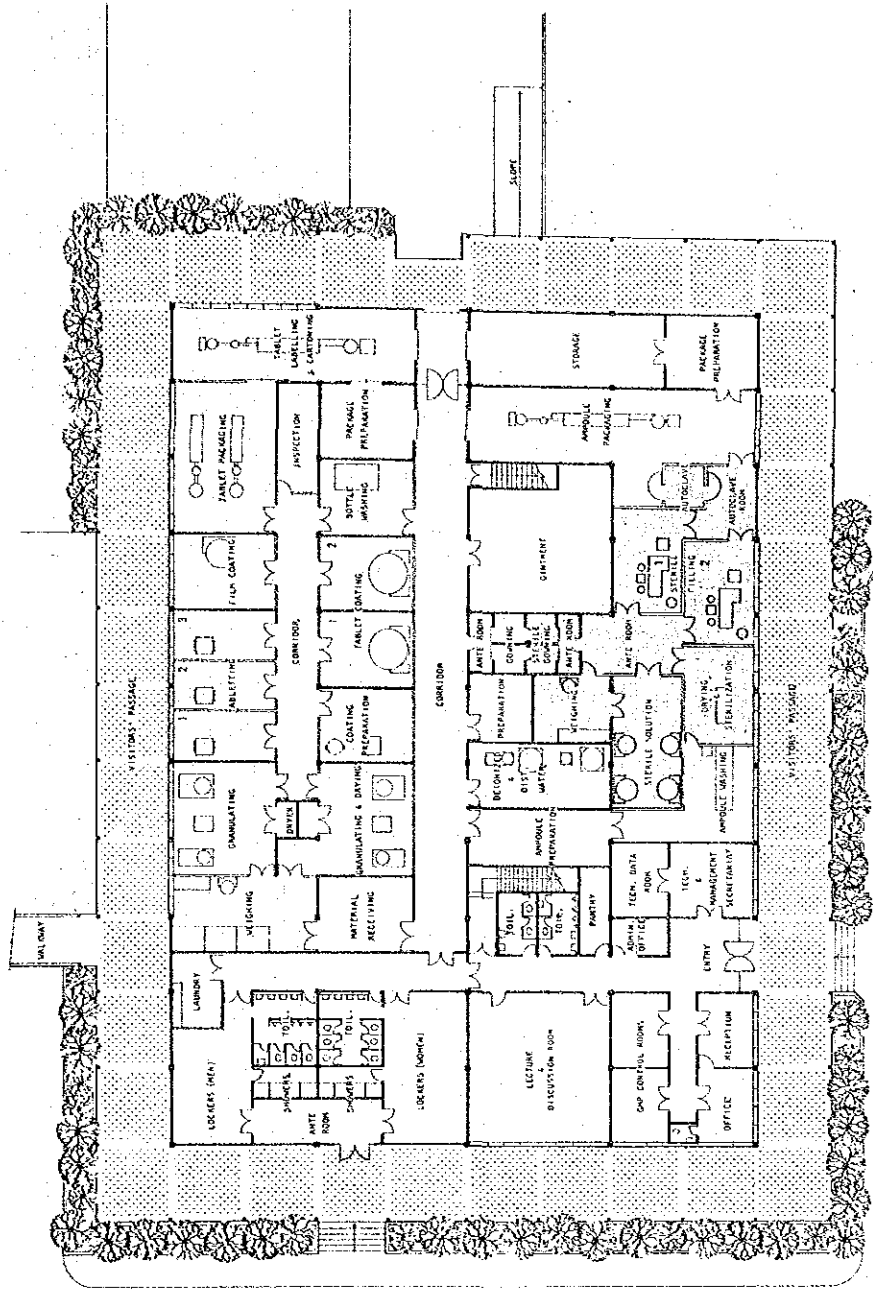
d. Testing, Quality Control and Pharmacology Department

1) Infrared Spectrophotometer	1 set
2) Atomic Absorption Spectrophotometer	1
3) Densitometer	1
4) Dissolution Tester	1
5) Analytical Balance	2
6) Oven	1
7) Highspeed Centrifuge	1
8) Cool Circulator	1
9) pH Meter	1
10) Rotary Viscometer	1
11) Disintegration Tester	1
12) Grinding Mill	1
13) Muffle Furnace	1
14) Chilled Water Circulator	1
15) Liquid Chromatograph	1
16) Spectrophotometer	1
17) Microscope	1
18) Miscellaneous Equipment & Apparatus	1

2. DRAWINGS



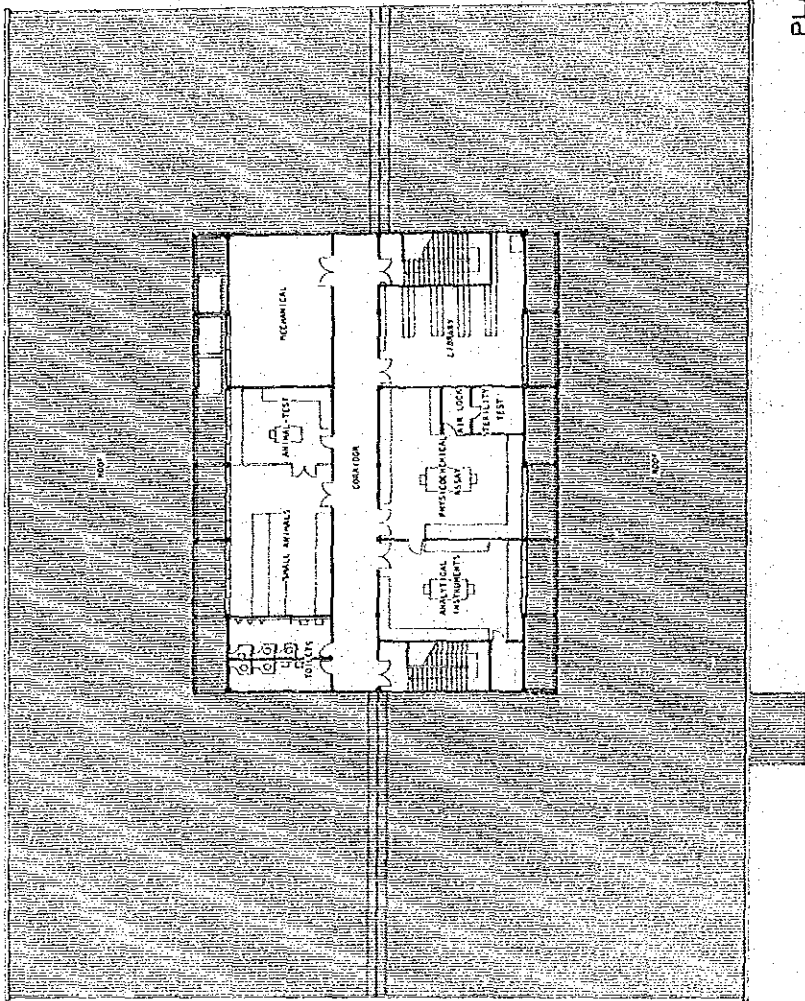
LAYOUT PLAN



PLAN

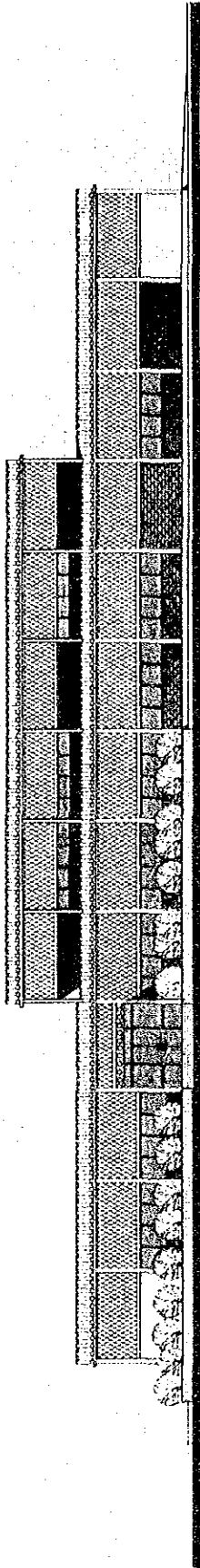


MAIN BUILDING

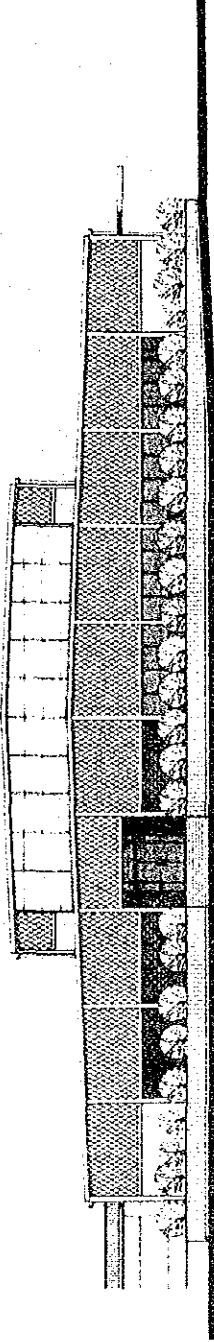


PLAN

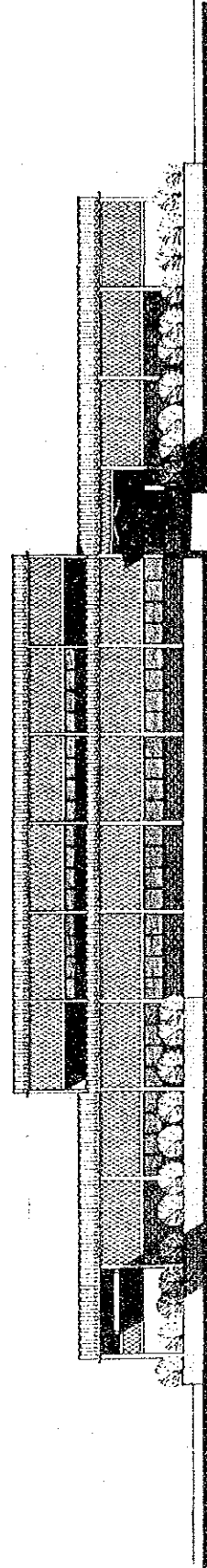
MAIN BUILDING



EAST ELEVATION

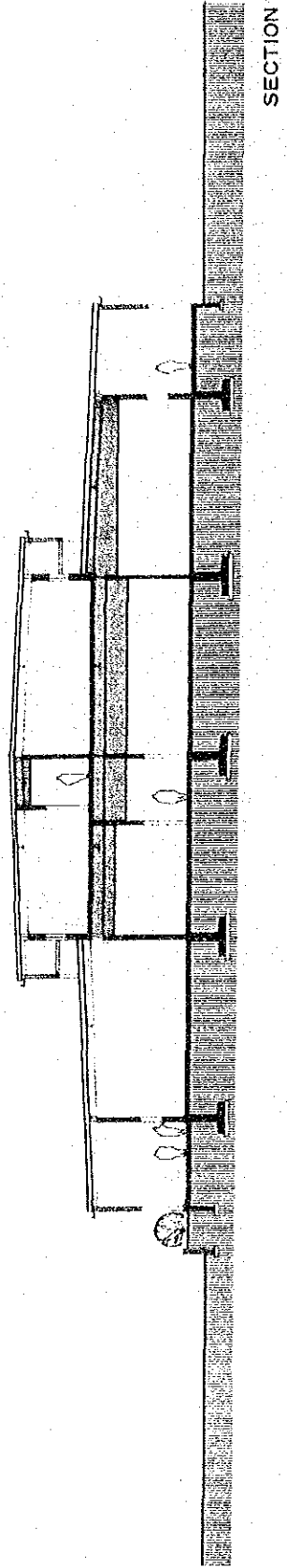
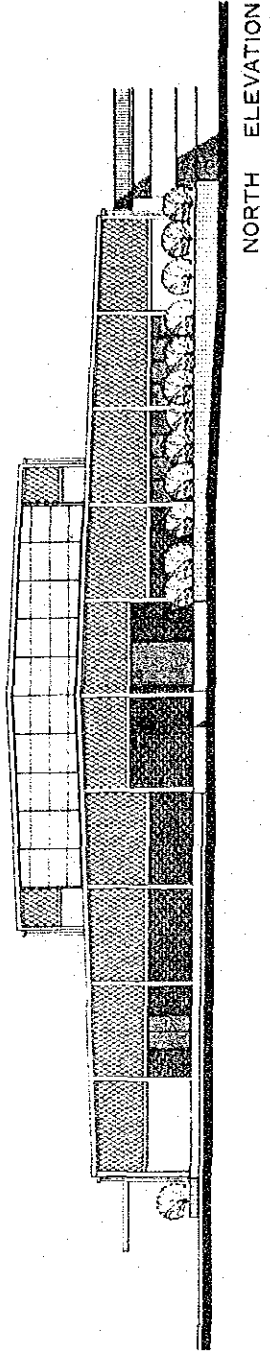


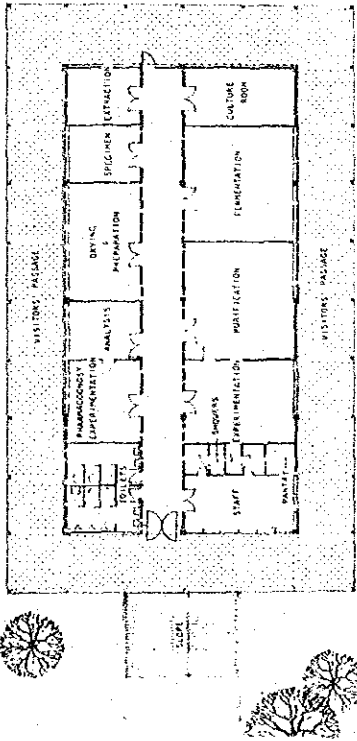
SOUTH ELEVATION



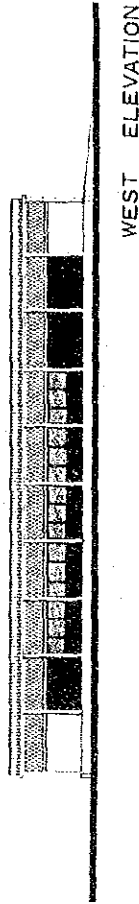
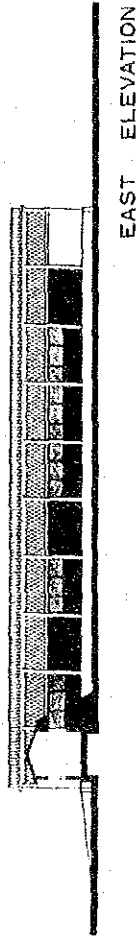
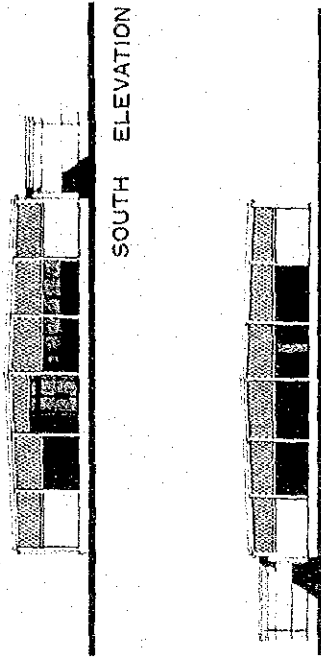
WEST ELEVATION

MAIN BUILDING

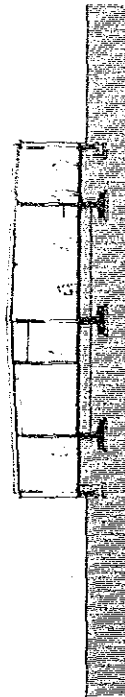




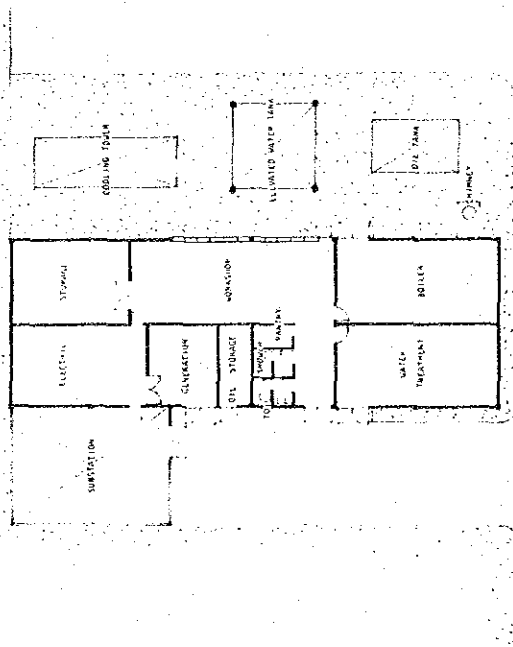
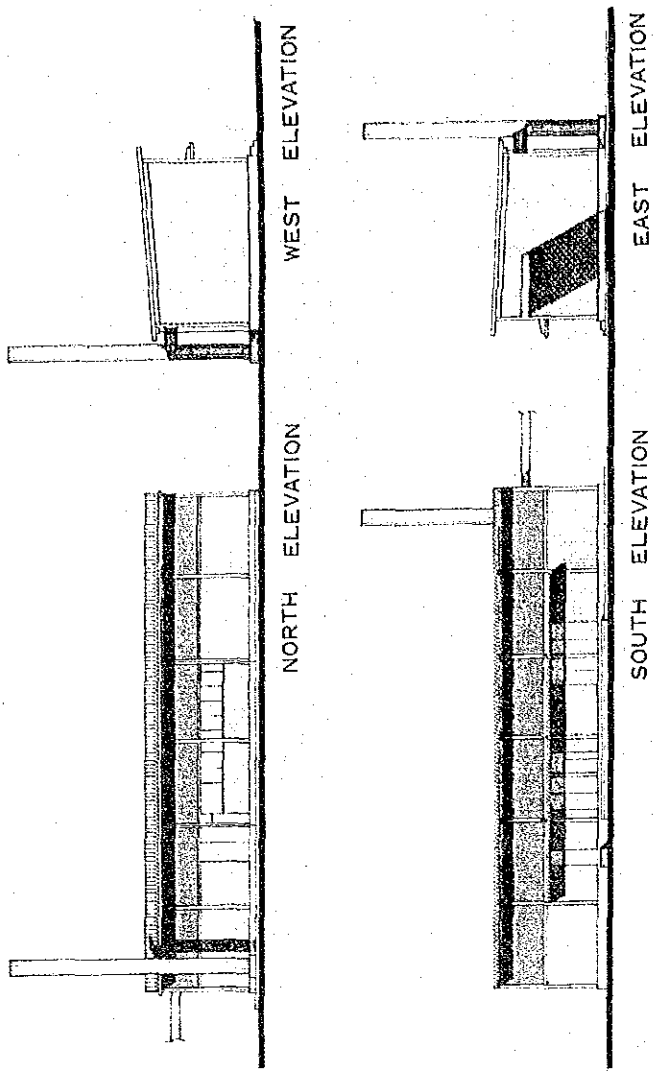
PLAN



SECTION



FERMENTATION & MEDICINAL PLANTS BUILDING



PLAN



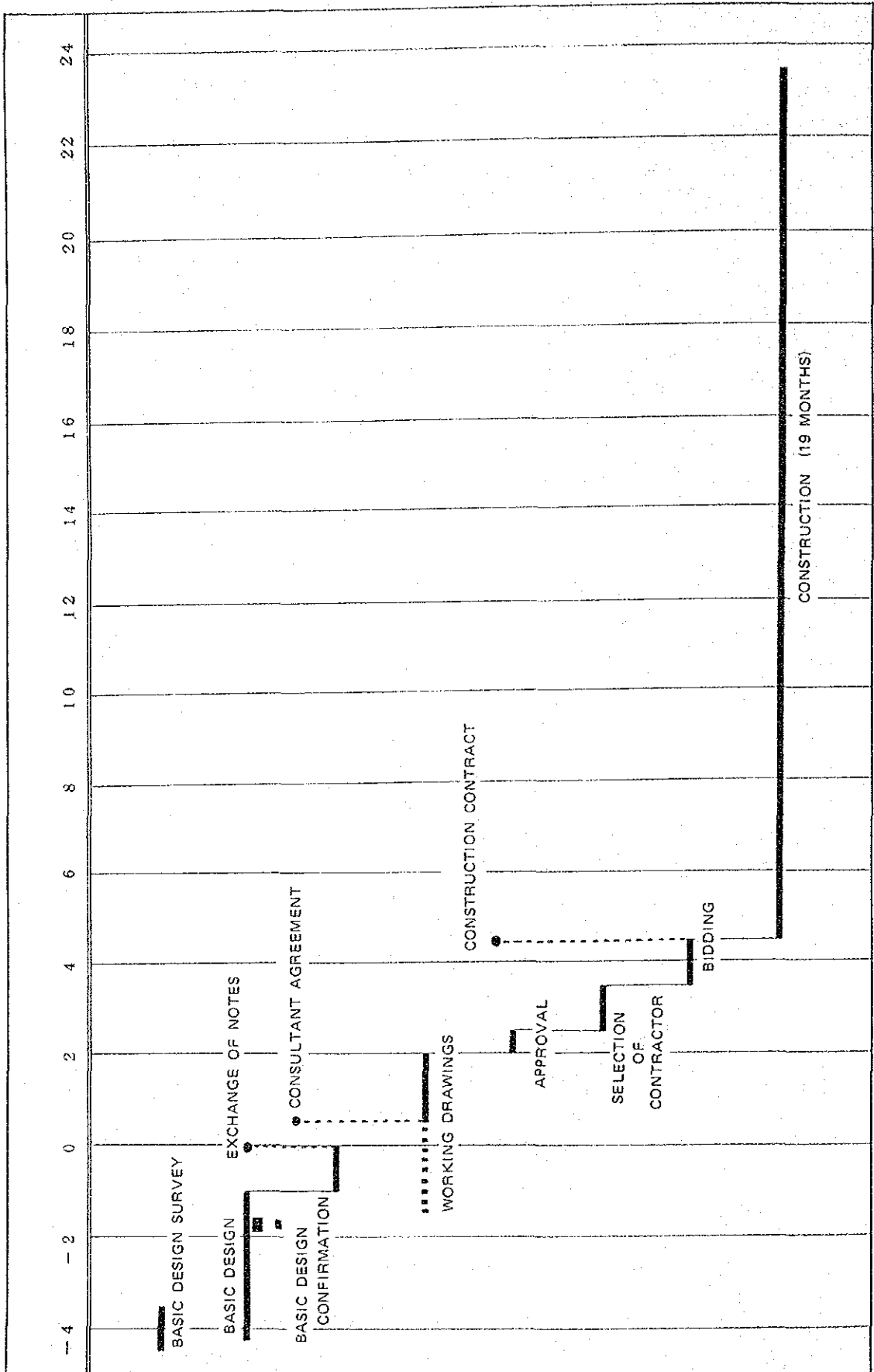
SECTION

F. IMPLEMENTATION

1. SCOPE OF WORK

- a. Development, training, laboratory and accessory equipment for the Fermentation Process, Preparations Research, Medicinal Plants and Testing, Quality Control and Pharmacology Departments
- b. Structure, architectural finishes and utilities for the Main Building, Fermentation and Medicinal Plants Building and Utilities Building
- c. Utility connections from the Utilities Building to the Main Building and the Fermentation and Medicinal Plants Building
- d. Well pumps and water supply therefrom to the Utilities Building
- e. Industrial waste treatment facilities
- f. Incinerator
- g. Basic plans and designs for the Canteen Building, exterior facilities and landscaping
- h. Aerogen gas generation facilities and gas piping supply system
- i. Canteen Building
- j. Solvent storage facilities
- k. Sewer treatment facilities
- l. Exterior utility and drainage facilities
- m. Exterior facilities, landscaping, fencing, gate and guard facilities
- n. Preparation of the site for construction, including removal of existing buildings and objects of hindrance
- o. Parking shelter
- p. Furniture, furnishings, curtains and carpets
- q. Drilling of wells
- r. Furnishment of electric power and water for construction
- s. Other items to be designated so by Exchange of Notes between the two Governments

2. WORK SCHEDULE



CONCLUSIONS AND RECOMMENDATIONS

CHAPTER 3 CONCLUSIONS AND RECOMMENDATIONS

A. JUSTIFICATION OF THE PROJECT

1. The establishment of the Development Centre for Pharmaceutical Technology is in compliance with the high priority request of the Government of Burma and is in line with the policy of increasing and improving production of pharmaceutical products, not only based on normally imported raw materials, but also based on indigenous raw materials and medicinal plants.
2. Fundamental techniques will be developed which will lead to future manufacturing of antibiotics and vitamins using locally available resources. Opportunity will be provided for conductance of studies on basic pharmaceutical technology leading to higher technical knowledge and elevating the technological level of the Burmese people.
3. The Centre will no doubt play a promotional role for advancing manufacturing efficiency and quality control techniques of the present Burma Pharmaceutical Industry, as well as pharmaceutical industries which are to be implemented in the future, and thus accelerate the development of the country's Health Programme.
4. By assuming developmental and training aspects of pharmaceutical technology, the Centre will enable the existing Burma Pharmaceutical Industry as well as forthcoming pharmaceutical industries to concentrate more on production efficiency and increased output.
5. Development of new types of drugs which are deemed essential to Burma, but which are not yet being produced by the BPI, will be an important function of the Centre.
6. The Centre is aimed at imparting technical know-how, and it is not envisaged to undertake commercial production or activities. On the contrary, staffing of the Centre as well as its operation and maintenance will become an additional financial burden. It has however been confirmed that the Government of Burma is prepared in all respects to perform all its portion of responsibilities in the establishment of the Centre and to staff, operate and maintain the Centre in accordance with its objectives.

7. During the course of constructing and equipping the Centre, full cooperation and understanding will be required between Japanese and Burmese counterparts in harmonizing procedures and activities due to differences in established policies, rules and customary practices. Special attention and due measures will be required of both sides in order to complete the project within the established time limit in spite of the long rainy season.

B. TECHNICAL COOPERATION

It is recommended that a technical cooperation programme be implemented in parallel with the physical establishment of the Centre. The training of Burmese personnel on the various aspects of the functions of the Centre can be most effectively performed by a technical cooperation programme involving exchange of personnel between Burma and Japan.

APPENDIX

A. SUMMARY OF DISCUSSIONS ON THE ESTABLISHMENT OF
THE DEVELOPMENT CENTRE FOR THE PHARMACEUTICAL
TECHNOLOGY

SUMMARY OF DISCUSSIONS
ON
THE ESTABLISHMENT OF THE DEVELOPMENT CENTRE
FOR THE PHARMACEUTICAL TECHNOLOGY

DATED OCTOBER 24, 1979.

SUMMARY OF DISCUSSIONS
ON
THE ESTABLISHMENT OF THE DEVELOPMENT CENTRE
FOR THE PHARMACEUTICAL TECHNOLOGY

In response to a request of the Government of the Socialist Republic of the Union of Burma, the Government of Japan dispatched the Survey Team (the Team) from 18th to 25th of October 1979, through the Japan International Cooperation Agency (JICA) to carry out the preliminary study on the establishment of the Development Centre for the Pharmaceutical Technology (DCPT) in Burma.

During the stay in Burma, the Team had a series of discussions and exchanged views with representatives of various Burmese Corporations and Departments concerned particularly the Pharmaceutical Industries Corporation (PHIC) and Burma Pharmaceutical Industry (BPI) (the Burmese Side) as to the contents and direction of the above-mentioned study. As a result of the discussions the Team and the Burmese Side agreed as follows:

1. The Team confirmed that the Burmese Side understood the systems of Japan's technical cooperation and grant aid programme to be extended by the Government of Japan

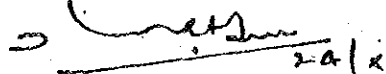
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2. The Team confirmed that the Burmese Side explained the objectives of DCPT are as follows:
 - (1) The proposed DCPT aims at promoting the following field of pharmaceutical technology as fermentation process, preparation for tablet and injection, development of medicinal plants and pharmacology and quality control through its research and experimentation and it is not envisaged to have direct commercial profit.
 - (2) In order to achieve this, the DCPT has four departments namely; Fermentation Process Department, Tablet and Injection Department, Medicinal Plants Department and Testing, Quality Control and Pharmacology Department.
3. The Team confirmed that the Burmese Side submitted the purposes and equipment list of each department as attached. (Annexure A)

Rangoon

Dated October 24, 1979.


For the Burmese Side


2-a/x

(U THEIN TUN)

Managing Director,
Pharmaceutical
Industries
Corporation.

For the Japan Survey Team


(DR. GORO FUNAMOTO)
Deputy Director,
Evaluation & Registration
Division,
Ministry of Health and
Welfare.





1. Fermentation Process Department as experimental laboratory for antibiotics, vitamins - 300 litre capacity x 2
2. Machineries and equipment for producing tablets and injections with automatic machines to conform to Good Manufacturing Practice (G.M.P.) Standard.

<u>Tablets</u>	Plain tablets	470 millions
	Film coated	100 "
	Sugar coated	100 "

Injectable solution

	1 to 5 ml ampoules	17 millions
	Transfusion 500 ml size	2 "

3. Machineries and equipment for physico-chemical analysis, stability testing, sterility test, pharmacological laboratories.
4. Equipment for development of medicines from domestic indigenous medicinal plants.
5. And other auxillary services such as air conditioning, electrical materials, steam pipes, nitrogen gas generators and any other construction materials that are not available locally.
6. To provide the required Japanese Technicians as needed for DCPT and training of Burmese personnel in the appropriate number in Japan for DCPT.
7. Intended activities of the Quality Control, DCPT.
 - 7.1 Testing and development of local packaging components.
 - 7.2 Testing of local raw materials of plant origin and of medicinal value and potential production.
 - 7.3 Testing of all raw materials, intermediates and finished products produced by the centre.

8. The section on pharmacology will be concerned with research work in the following areas:

8.1 Testing of purified products from plant sources.

8.2 Testing of pharmaceutical preparations as to their bioavailability, pharmacokinetics, metabolism with collaboration of Hospitals.

8.3 Equipment and machineries for biological testing.