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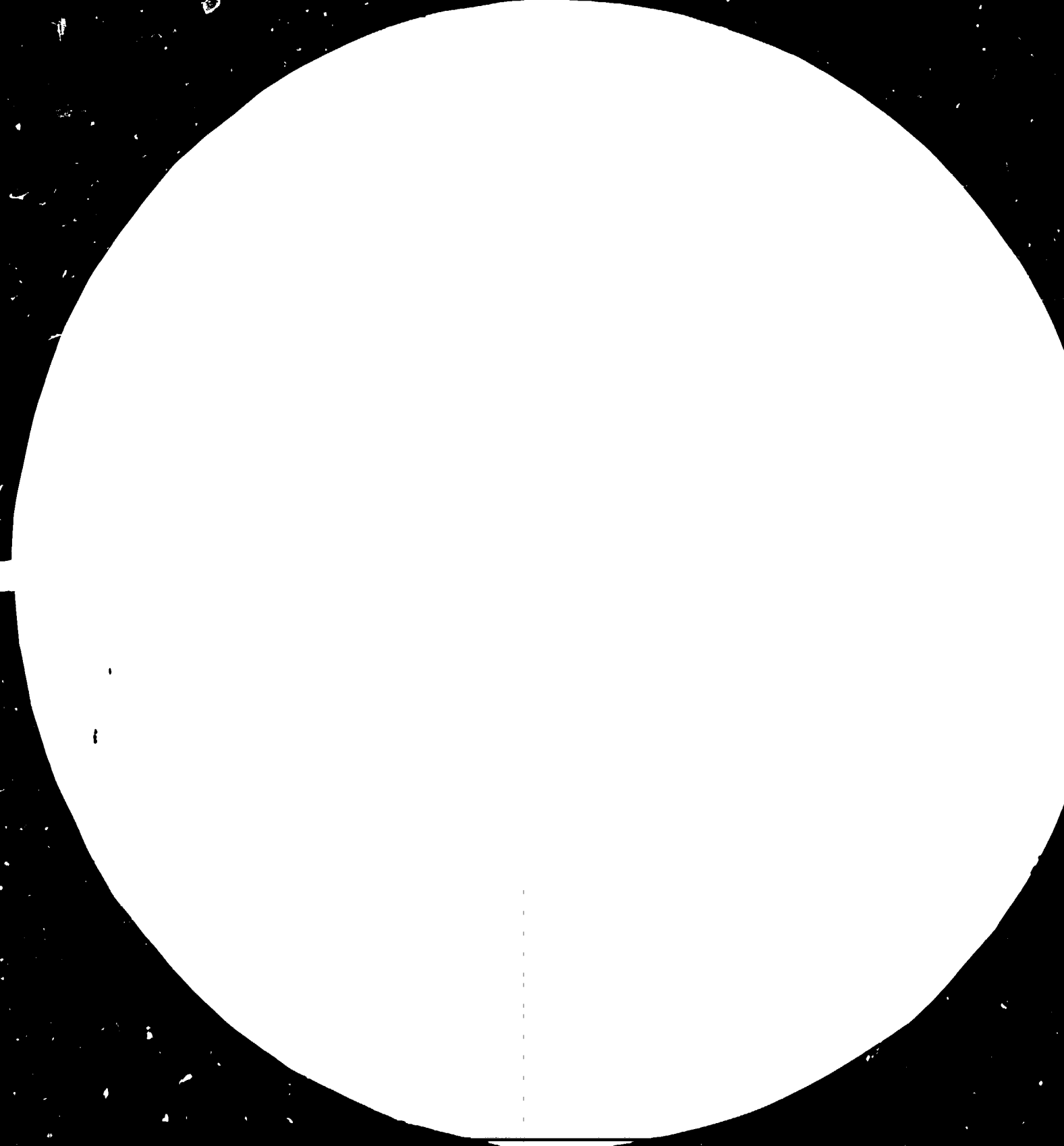
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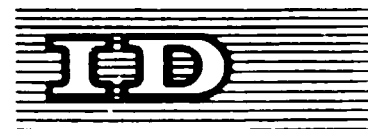


MICROCOPY RESOLUTION TEST CHART

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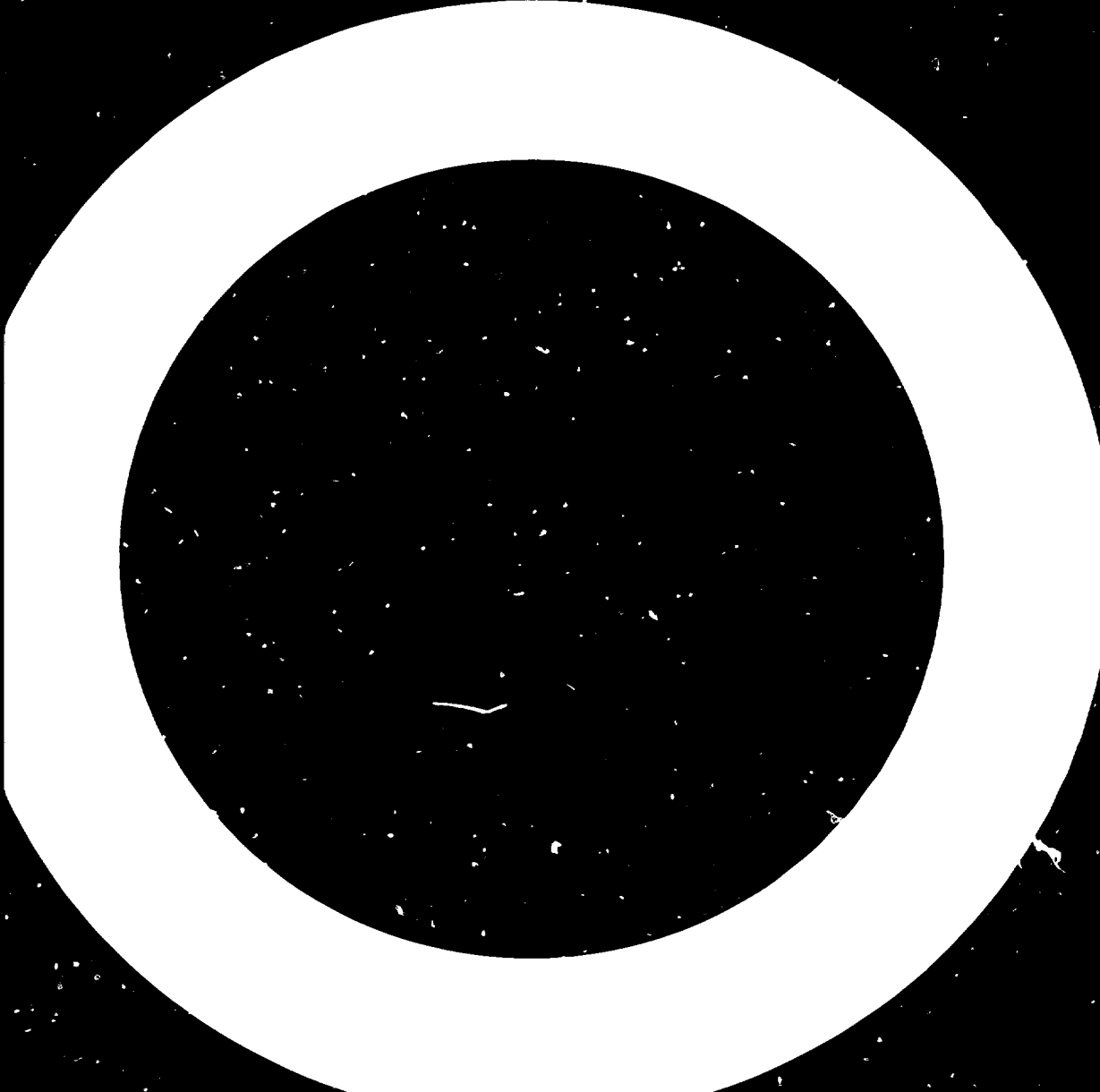
TECHNICAL PROFILES FOR PRODUCTION OF
PHARMACEUTICAL DOSAGE FORMS *

Prepared by

the UNIDO secretariat

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V.85-37748



Preface

The document "Technical profiles for the production of pharmaceutical formulations - dosage forms" was submitted to the Second Consultation on the Pharmaceutical Industry convened in Budapest, Hungary from 21-25 November 1983. This document has been completed and revised to include comprehensive guidelines with regard to site plans, building designs, section lay outs, process flow sheets, warehouse plans, equipment identification with indicative prices, etc.

It is hoped that the profiles included in this documents will be useful to the developing countries who wish to establish local pharmaceutical formulation units and would assist them in initiating necessary measures for the development of pharmaceutical industry.

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INTRODUCTION

To improve the availability of essential drugs for the health requirements of developing countries and to promote industrialization in the Pharmaceutical Sector, UNIDO has prepared a number of publications offering guidance to developing countries in establishment of units for production of pharmaceutical dosage forms (Contractual arrangements for the production of pharmaceutical chemicals, formulations and setting up of plants, Directory of sources of supply). The present document covering design, layout, process flow, equipment and other technical inputs, is expected to serve as a reference paper for phased setting up of industrial units initially commencing with pharmaceutical preparation for oral use and progressively incorporating production of parenteral dosage forms.

The following criteria for planning, design, construction and operation of model formulation units have been used:

- (i) The units are designed to enable the manufacture of most commonly used pharmaceutical preparations. These can be adapted to specific infrastructure;
- (ii) expansion in capacity of plants can be easily adopted, the designs have adequate provision for capacity adjustments and increases;
- (iii) the units are designed with options for automatic, semi-automatic and manual operations;
- (iv) the units fulfil GMP requirements.

It is, however, stated that the proposals referred to herein are guidelines and would need to be appropriately modified depending upon specific conditions and requirements.

TECHNICAL INFORMATION

In order to maintain segregation and functional identity between major operation areas, the main civil structure has been designed with six independent operational blocks, i.e. Buildings B1, B2, B3, B4, B5, B6.

Building

- B1 is designed for the manufacture of pharmaceutical dosage forms,
- B2 to locate the offices, quality control laboratories and social services,
- B3 for vaccines with segregated areas for bacterial and viral types,
- B4 to locate the animal house with provision for future conversion to specific pathogen free (SPF) animals, in compliance with GMP rules,
- B5 for processing of sterile antibiotic salts with independent provision for sterile change rooms and warehousing,
- B6 for the production of bulk drugs (pharmaceutical chemicals).

Power house, utilities area and guard room (gate office) are provided in separate buildings. Reserve area is in the center of the site to enable unforeseen plant expansion activities.

In this document details relating to only buildings B1, B2 and some services are covered, i.e. manufacturing and packaging of pharmaceutical formulations, warehouse; quality assurance laboratories, offices, conference room including library, canteen, cloakrooms, sanitary facilities; boiler house, water treatment, compressed air, effluent treatment, internal transport facilities, fire fighting and workshop facilities.

A simplified critical path method (CPM)/pert flow chart illustrates the major steps to be taken in the implementation of a project, important interrelations between the steps and an average duration which is normally necessary to follow up the project activities (Annex I).

Also included are:

- Basic data for a project (Annex II)
- Site plan, building- and department layout with cross sections (Annex IV,V,VI,XIV)
- Flow diagrams and flow sheets (Annex XI, XII)
- List of equipment/machinery with indicative capacity and price (Annex XIII)
- Specimen drawing of airconditioning layout for the sterile area for manufacturing, e.g. antibiotics (Annex IX)
- Organization chart (Annex III)

Process information

For each dosage form the following details are given:

- Appendix XI - Manufacturing and packaging flow diagrams
- Appendix XII - Equipment flow sheets
- Appendix XIII - Equipment list with an indicative list of suppliers, capacity- and energy consumption range, with an indication of price.

Working conditions

- Single shift work with 8 hours per day
- 240 working days per year
- Capacity increase by a second shift with enlargement of the warehouse space and infrastructure if need be.

More details relating to construction criteria, utilities, general air-conditioning for buildings B1, B2, B3, B4, B5 and B6 would be prepared subject to availability of resources.

Basic data for Building 1

The building is designed to locate facilities for manufacturing and packaging of granules, powders, tablets, oral and non-oral liquids, topical and ophthalmic ointments, injectables (parenterals), antibiotics and intravenous fluids on a ground floor basis with annual outputs as detailed in the "Basic document data for manufacturing and packaging of pharmaceutical dosage forms" (Annex II).

Organization chart

The set-up of personnel requirements is illustrated in Annex III.

Equipment selection

The following characteristics of the major production equipment have been taken into consideration:

- Choice of up-to-date models
- Choice of equipment having a moderate automation
- Alternative use of semi-automatic equipment and manual operations, more particularly in the packaging department
- Ensuring compliance with GMP standards - National and WHO.

General layout

The site plan UNIDO No. 85.4.001 (Annex IV) explains the proposals pertaining to layout of the factory.

The main building B1 is designed to allow future expansion work in two directions. A further doubling of that capacity is feasible, or the space is available for new activities. The warehouse has a large loading and unloading yard suitable for trailer type trucks.

Goods receipt and despatch as well as facilities for factory personnel have been separated.

Circulation of goods, in general, free of crossings.

A car parking area has been foreseen, which is fenced but outside the factory premises for better control of the personnel.

Site utilization

For this example the full site utilization amounts to 56% (Annex IV). The normal range varies between 40 and 60%, depending on scarcity or cost of land.

Wind direction in relation to building location at site

The main wind direction is a decisive factor for the location of the air intake, normally on the roof of a building. The proper placing of the buildings at site is another important decision. Particularly, the animal house must be located on the lee side of the main buildings. In regions with two main wind directions a compromise must be found.

Topography

A slightly sloped site offers the opportunity to place the services in a basement, normally under the manufacturing and packaging area. Calculations have indicated that such a solution is approximately 10% cheaper in building costs than the proposed solution (Annex V).



In regions with monsoon or heavy rain falls it is advisable to place the building's main floor at least on plinth level, if not at truck platform height. Instead of storm water pipes open drains/ditches may be used.

Construction of building - Structural Unit - Grid system

The basic elements influencing the determination of a grid system of a factory are:

- vehicles for internal transport
- pallets
- furniture for laboratories
- furniture for offices.

Studies about model factories have shown that the distance of building columns is mainly dependent on the size of the pallet in use. All other elements can be matched accordingly. An exception is the automated warehouse with high altitude, where other criterias are relevant.

Pallet sizes commonly used are:

- 80 x 120 x 15 cm ("European" pool pallet)
- 120 x 120 x 15 cm (drum pallet, "Chemie Palette")
- 40" x 40" x 6" ("English" pallet)

In the pharmaceutical industry the majority of goods is conveniently stored and moved on the "European" type pool pallet or on a half size pallet 80 x 60 x 15 cm, which is normally adopted for internal transport only.

Taking above into consideration, the grid basis is 1.3 m with a minimum column distance for all buildings = $4 \times 1.3 \text{ m} = 5.2 \text{ m}$ or 17 feet:*)

- | | | |
|---|-----------------|-------------|
| - | 5.2 m x 5.2 m | (17' x 17') |
| - | 5.2 m x 10.4 m | (17' x 34') |
| - | 5.2 m x 15.6 m | (17' x 51') |
| - | 5.2 m x 20.8 m | (17' x 68') |
| - | 10.4 m x 10.4 m | (34' x 34') |
| - | 20.8 m x 20.8 m | (68' x 68') |

Planning a new site, it is advisable for the sake of flexibility and future extensions to choose the distances between the buildings also as a multiple of above column distances.

Building and room layouts

The first phase of activities will take place, besides in a power house, gate house and utilities area, in the two main buildings, namely:

- Manufacturing, packaging and warehouse - building B1
- Management and services - building B2.

The manufacturing area in building B1 is sub-divided into the following departments:

- Tablets, powders and granules
- Ointments
- Syrups
- Injectables and eye drops

*) In some instances the column distance may be chosen up to $4 \times 1.5 \text{ m} = 6.0 \text{ m}$.

- Intravenous infusions
- Antibiotics
- Packaging

The covered area for manufacturing and packaging operations is some 4,600 sq.m. + 420 sq.m. corridor, with an effective room height of 4.5 m.

A technical floor exists on top of the production area which houses the air conditioning ducts, steam-, water- and electrical-network. The covered area is 5000 sq.m. with an effective height of 2.2 m.

The warehouse is located on one side of the production building with an approx. area of 3,000 sq.m. and an effective height of 6.5 m.

The management and services are located in building B2, consisting of two floors: the covered area of the ground floor is 1400 sq.m., effective height 3.0 m. The covered area of the first floor is 700 sq.m., effective height 3.0 m.

A separate section is provided to house utilities such as: Water reservoir, water softening plant, steam generation plant, compressed air generation, refrigerator compressors, plant maintenance workshop, laundry, solid waste incinerator and waste water treatment plant. Provision may be made for a segregated store to keep hazardous and explosive chemicals. In certain countries a bonded area for alcoholic material is required by law, or it is custom to include a prayers area.

The electric cables will be laid underground, while other services will be on pipe racks.

WAREHOUSE AND MATERIAL HANDLING

Additional basic data for determining the size of the warehouse

Maintenance of 3-6 months stock for raw materials, up to 3 months for finished goods is foreseen and for packaging material 3-6 months stock is anticipated, all depending on supply possibilities and economic lot sizes.

According to the basic document data as outlined in Annex II, the raw material weight excluding water varies between approximately min. 95 and max. 130 tons/year.

Generally, the average total weight of packaging material for small packs is about 1.70 times, and for large packs about 0.75 times the weight of the finished pharmaceutical dosage form in a package.

Hence, the storage quantities are

	min.tons/store	max.tons/store
- Raw material = 3-6 months	<u>23.3</u>	<u>65.0</u>
- Packaging material = 3-6 months	<u>113.0</u>	<u>339.0</u>
- Finished goods = 3 months	<u>213.2</u>	<u>337.6</u>

The requirement of storage space to accommodate these quantities would vary, under the consideration that in practice only 50 to 75% of the available pallet places are utilized, between min. 3700 and max. 7700 pallet places.

<u>Material handling at the ramp:</u>	<u>min.pallets/year</u>	<u>max.pallets/year</u>
- Raw material = 0.3 tons/pallet	310	433
- Packaging material = 4500 packs/pallet	3849	4800
- Finished goods = 9000 packs/pallet (Materials related to buildings B3 - B6 are supposed not to be stored in the warehouse B1)	1924	2400
	-----	-----
Total pallets handled at the ramp =====	6083 ====	7633 ====
	<u>min.pallets/day</u>	<u>max.pallets/day</u>
daily handling of pallets at the ramp (240 days/year) =====	25 ====	32 ====

Material handling between warehouse, manufacturing and packaging:

Movements from and to the warehouse = 30-40/day. This means every 16-12 minutes one movement with an average weight of 145 - 300kg. For the warehouse layout and type of racks used see Annex VI .

DESCRIPTION OF THE CIVIL ENGINEERING WORKS

Foundations

Foundations will be chosen according to soil testing which should be carried out prior to selection of the construction site. In some instances piling may be necessary.

Structure

The buildings explained in the design are suitable to be either pre-fabricated or concrete cast on site. Various combinations of the two systems are feasible, for instance, main structure cast on site and peripheral walls prefabricated. The choice will arise from economic considerations and the existence of a factory for prefabricated beams and pallets within a reasonable distance from the site on which the factory will be built.

An other alternative is the building in steel construction, with double roof, particularly for the warehouse, depending on climatic conditions and availability of cement or steel.

Internal partitions

Different types of internal partitions are foreseen:

- conventional masonry walls for the subdivision of the main areas;
- mobile walls for non-sterile areas, if not too expensive;
- double masonry walls, with air ducts inserted for the areas where large air conditioning volumes must be extracted from the lower level of the room;
- double windows, flushed doors and windows, avoiding settling of dust particles.

Finishing and application of coating materials on walls, floors and ceilings

See enclosed Annex VII .

Rain, sewage and industrial waste water drain system

The rain water will be drained through cement pipework or open drainings. (If required, this can be collected into tanks in order to use it for fire fighting after proper treatment.)

The sewage water will be drained into a special network to a biological treatment plant. Grease traps must be foreseen to minimize the adverse effects in the biological process.

The drains of quality assurance laboratories and production departments will be piped into an effluent pretreatment tank before transportation into the biological treatment plant. Chemical treatment will be required when the factory is completed with a multipurpose synthesis plant.

The vaccines area drains will be sterilized before being put into the biological treatment plant.

Windows

In the manufacturing areas, the windows must be flush with the inner side of the wall for minimum of dust settlement and ease of cleaning.

Experience shows that windows in the façade, properly dimensioned (height not more than 90 cm) and perfectly shielded against sun radiation, create an enormous positive effect on the working staff. It further reduces electricity spending. With adequate measures in the construction of the windows, the air conditioning losses can be kept within acceptable limits. Windows in the warehouse are to be kept to a minimum such that safe movement and identification of goods is guaranteed without artificial light. Excessive radiation yields to bleaching of printed matter. The windows should be placed near the ceiling because of goods storage along the wall. Corridor windows serve as control and visitor presentation.

SANITARY AND SOCIAL SERVICES

For the sake of cleanliness in pharmaceutical activities a proper layout of the locker area is important. Ideally, staff working in sterile product areas should actually leave the dress in standard lockers, take a shower and put on sterile clothes in an adjacent change room. Since normally this postulate cannot be met, due to layout and other reasons, the compromise could also be: change clothes to white laboratory coats in the standard locker room and change again to sterile clothes in a second change room incorporated into the sterile complex.

In distances not more than 40 to 80 m, WC facilities should be provided.

Where applicable, "Asian" toilets will have to be provided.

A minimum of 1 toilet for about 20 individuals should be provided if not more. Local conditions and laws should determine actual requirement for WCs, urinals, wash basins, etc.

During lunch time, a complete change of clothes to and from the canteen must be assured.

For lunch and smoking breaks in the morning and afternoon, one or several rest rooms, conveniently located next to manufacturing and packaging areas will avoid uncontrolled sojourns in the WC rooms.

UTILITIES (B1, B2 and related services)

Availability of infrastructure such as energy, water, disposal of waste, etc. has been considered.

Electricity (Voltage, frequency and electrical equipment as per specifications of the particular country) - Annex VIII

- Power sub-station: (20 kV to 380 V: 2 x 750 kVA transformers + extension)
- Distribution system for 380 V and 220 V supply, or local standard
- Stand-by generator: 60-400 kVA (depending on reliability of grid)
- Voltage stabilizer system (where required)
- Explosion proof fittings (where required)
- Safety devices.

Fresh water

- Main supply: 75-100 cu.m/day (depending on water reservoir)
- Storage tanks, underground: 400-500 cu.m. divided into 2 parts, overhead 150 cu.m, or the installation of two booster pumps (normally Diesel engine driven)
- Pressurised water circulation system: 3-4 bar

Warm water

The installation of a heat exchanger on the technical floor is foreseen, with capacity up to 300,000 Kcal/h and a temperature between 50° and 60°C.

Demineralized water

Up to 6 cu.m/h at full capacity with 4-5 cu.m storage tank and circulation in the pipe system. To be produced in the manufacturing area. Pipes and tank in stainless steel.

Distilled water

Distilled water will be produced by means of thermo-compression, beginning with 50L/h up to a maximum of 500 L/h, when intravenous infusions are manufactured.

Chilled water (required e.g. for multipurpose plant)

150 cu.m/h, 12°C - 7°C in closed circuit to be produced in the power house area.

Compressed air (dry, oil free)

30-70 cu.m/h at 7-8 kg/sq.cm per compressor. 2 compressors of the silent box type, air cooled. Pipes in copper or stainless steel.

Gas

- Public supply or generator or steel cylinders
- Oxygen and Nitrogen (located outside the buildings of consumption).

Vacuum

Normally generated at the spot of need.

ELECTRICAL INSTALLATIONS

Distribution to utilization points will be carried out by cables installed on the technical floor. All electric switchboards for the production departments may be located there or in the walls of the respective corridors

Branches to utilization points and switches for each room will be fitted in the walls (Annex VIII).

Light intensity, 1 m above floor:

Manufacturing	300-400 lux
Packaging	400-500 lux
Corridors	200 lux
Offices	300 lux
Laboratories	300-400 lux

AIR CONDITIONING SYSTEM

The air conditioning layout must be tailor made to requirement of the factory, but consisting of standardized elements available on the market. Three systems are generally used:

- Central air conditioning with only one set of main equipment, but large ducts over long distances. It is recommended for small to medium size plants.
- Decentralized air conditioning for room groups with identical or similar air requirements. Several so called package units are placed over each room group with small and short ducts. This system is applicable for all plant sizes.
- A combination of both types is feasible with decentralized air handling units but only one refrigeration compressor.
- Window air conditioner without any ducts for small rooms, mostly offices or laboratories.

- Two types of air heating are applied:
 - . One duct with a heating box, heated by steam and located near the air discharge (diffuser). It is the cheaper solution but the temperature regulation may lie only in the range of $\pm 5^{\circ}\text{C}$.
 - . "Dual duct" with one carrying cold, the other carrying hot air. A mixing box before the discharge to the room prepares the required air temperature with an accuracy of $\pm 1^{\circ}$ to 2°C . It is more expensive because of 2 ducts and the insulation of the hot air duct.
- Special air handling/conditioning is required for dehumidified rooms (e.g. capsule filling) or cool rooms, etc.

In the schematic drawing as shown for instance in Annex IX for a sterile area, the following guidelines have been followed:

- The FDA regulations have been taken into account.
- No production rooms are in direct contact with the outside, no unfiltered air can flow into the rooms and no spent air could escape towards the outside without filtration from contaminated rooms.
- To save energy, part of air is recycled, except for some areas with explosion danger, e.g. tablets coating, or with offensive smells, e.g. animal house, which is fully extracted to atmosphere through filters.
- Canteen, offices and laboratories are conditioned with fan coils and primary air.

The air conditioning calculation (thermal loads, heat gains or losses through the wall, personnel) and the thermohygroscopic internal conditions will follow the Ashrae rules with some exceptions, where special rel. humidity conditions are required.

Recommended air temperatures in summer and winter time, relative humidity, air changes, as well as the type of air for each room category is specified in Annex X.

NB: ASHRAE = American Society of Heating, Refrigeration and Air-conditioning Engineers
SWKI = Schweizer Verein von Wärme- u. Klima-Ingenieuren
VDI = Verein Deutscher Ingenieure

FIRE PROTECTION

For fire protection the following is foreseen:

- An independent water pipe ring with exclusive self-operating pump having diesel motor
- A water reservoir possibly fed from rain water drain system and/or clean discharge from the factory, capacity not less than 300 cu.m.
- A multipoint water distribution system
- A sprinkler fire extinguisher system or smoke detector alarm system for the warehouse

- Foam and/or carbon tetrachloride extinguishers for the whole plant
- An automatic fire detection system

MAINTENANCE AND REPAIR WORKSHOP

Fully equipped for general maintenance, minor repair/parts replacement and reconditioning of equipment and laboratory instruments. (Annex XV).

WASTE DISPOSAL SYSTEM

- Disposal of plant waste, garbage by incinerator, etc.
- Effluent treatment and disposal system with degreasing, separate sewer feed systems, biological process, sludge treatment.

INTERNAL TRANSPORT FACILITIES

- Hand trolleys
- Fork lift trucks
- Shipping conveyor

QUALITY CONTROL FACILITIES

- In process control
- Analytical control
- Biological control
- Chemical control
- Physical control

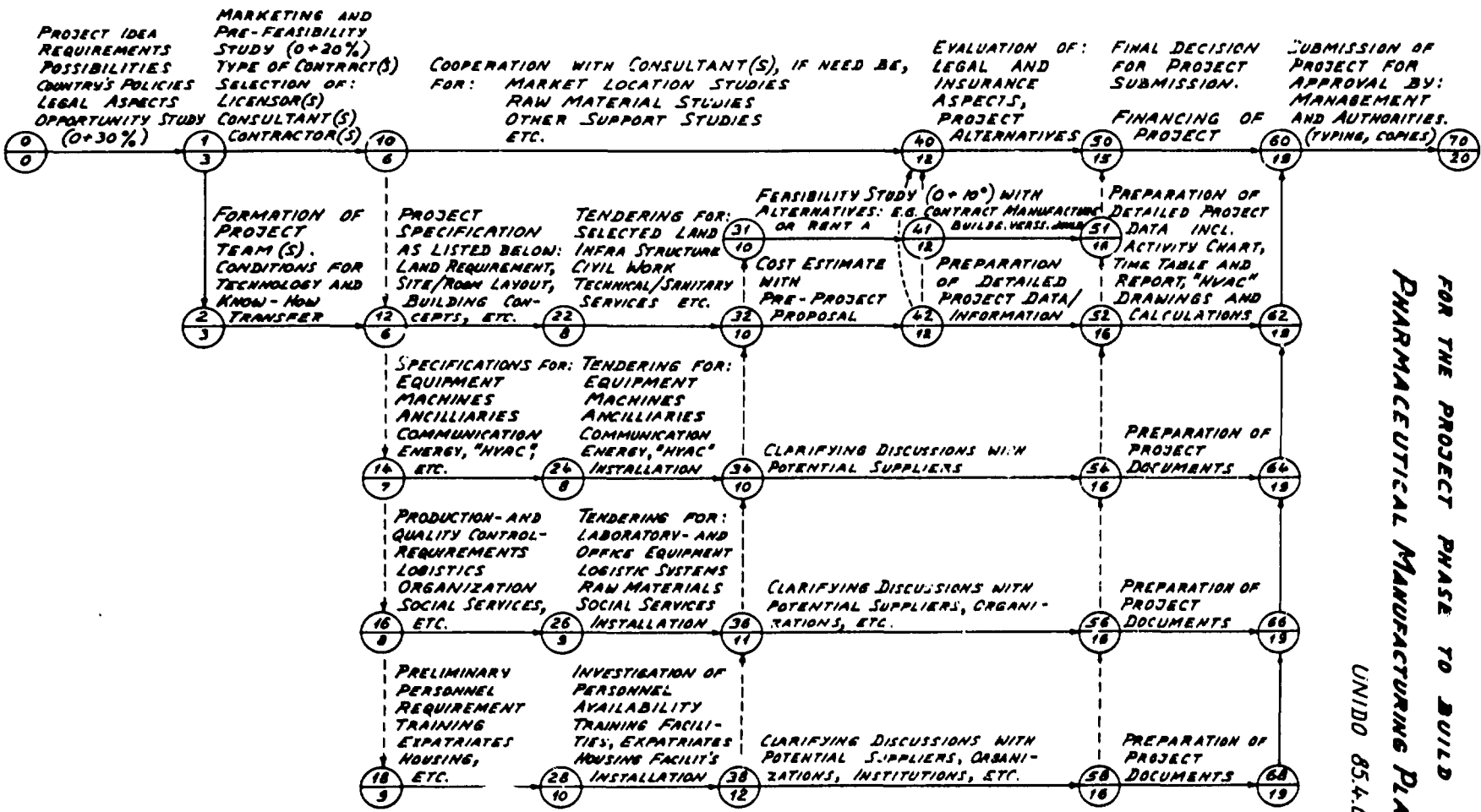
A project, in general, is based on data and assumptions which are a selection of possible alternatives with regard to capacity forecast, site selection, sequence of building extension, etc. Each aspect has a direct impact on investment, return on investment and pay-back time.

A feasibility study should include e.g.:

- financial aspects on alternative sites
- building according to the final capacity or in steps (first for oral dosage forms, later for sterile medicines)
- predominantly mechanized operations as against manual execution (mainly in the packaging section)
- sensitivity study (operational costs under varying plant utilization)
- impact on changing raw material costs, taxation or interest rates
- etc.

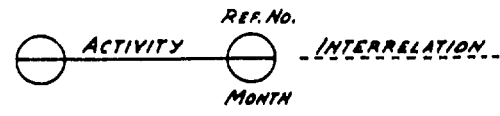
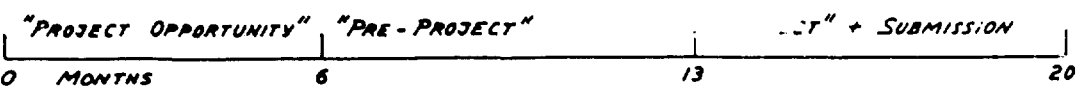
The introduction of computer systems for the execution of production planning, administrative and technical services may be already considered at the planning phase. The actual realization could be postponed until the plant has reached normal operational conditions or the office work should be extended beyond available staff capacity. Certain computer areas must be specially air-conditioned.

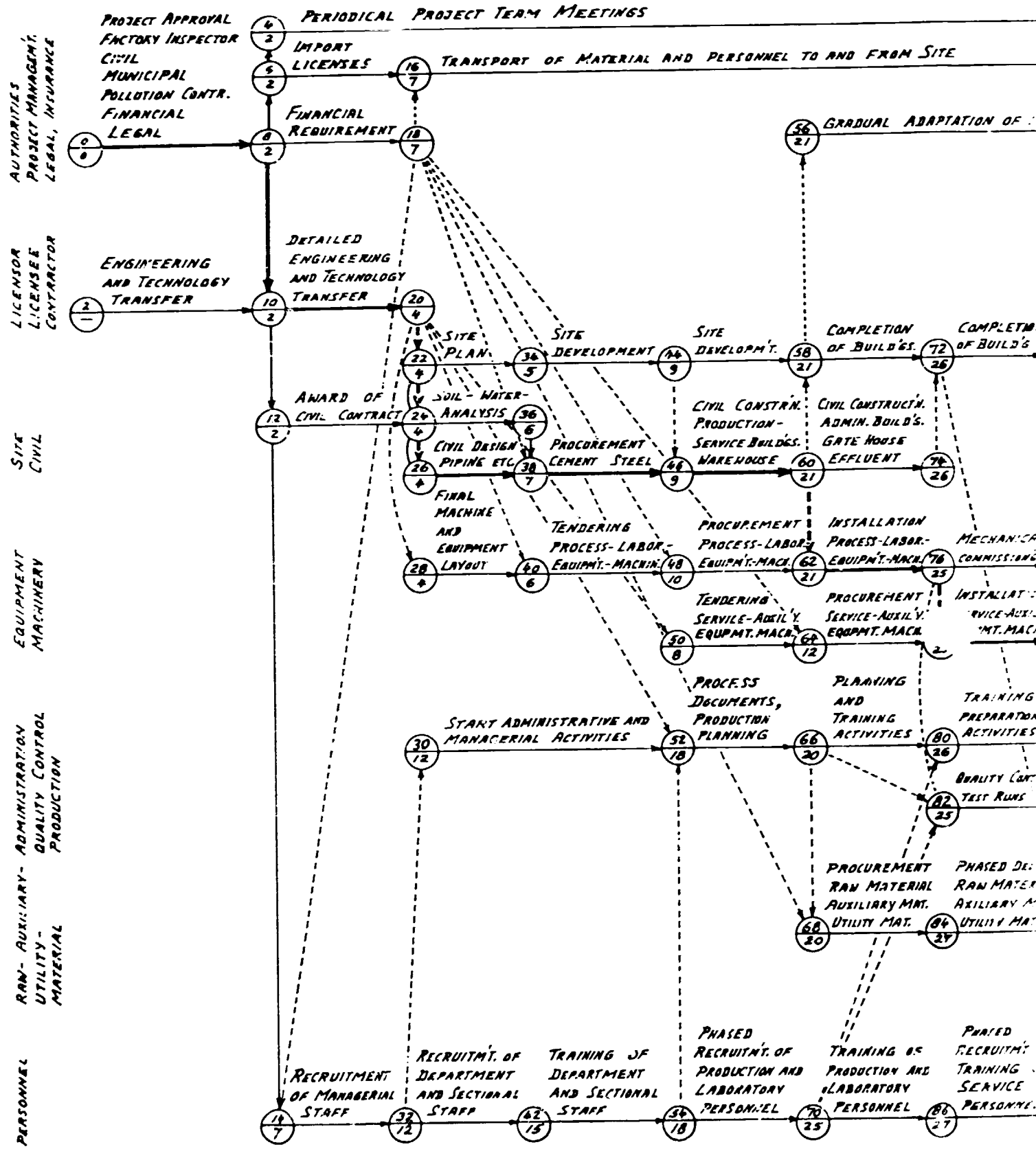
PROJECT MANAGEMENT: AUTHORITIES INSURANCE LEGAL CONSULTANT(S)
 LICENSEE LICENSEOR CONTRACTOR(S) CONSULTANT(S)
 EQUIPMENT MACHINERY ANCILLIARIES
 ADMINISTRATION PRODUCTION LOGISTICS SOCIAL
 PERSONNEL TRAINING



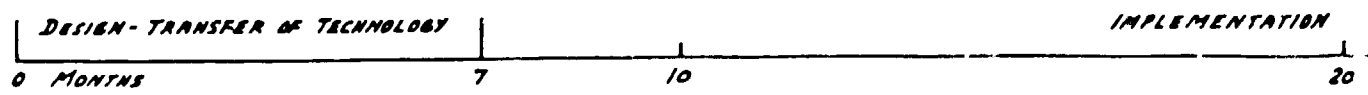
CPM-PERT ACTIVITY AND TIME CHART
 FOR THE PROJECT PHASE TO BUILD A
 PHARMACEUTICAL MANUFACTURING PLANT
 UNIDO 85.4.018

INDICATIVE TIME SCHEDULE FOR THE ... ATION OF THE PROJECT

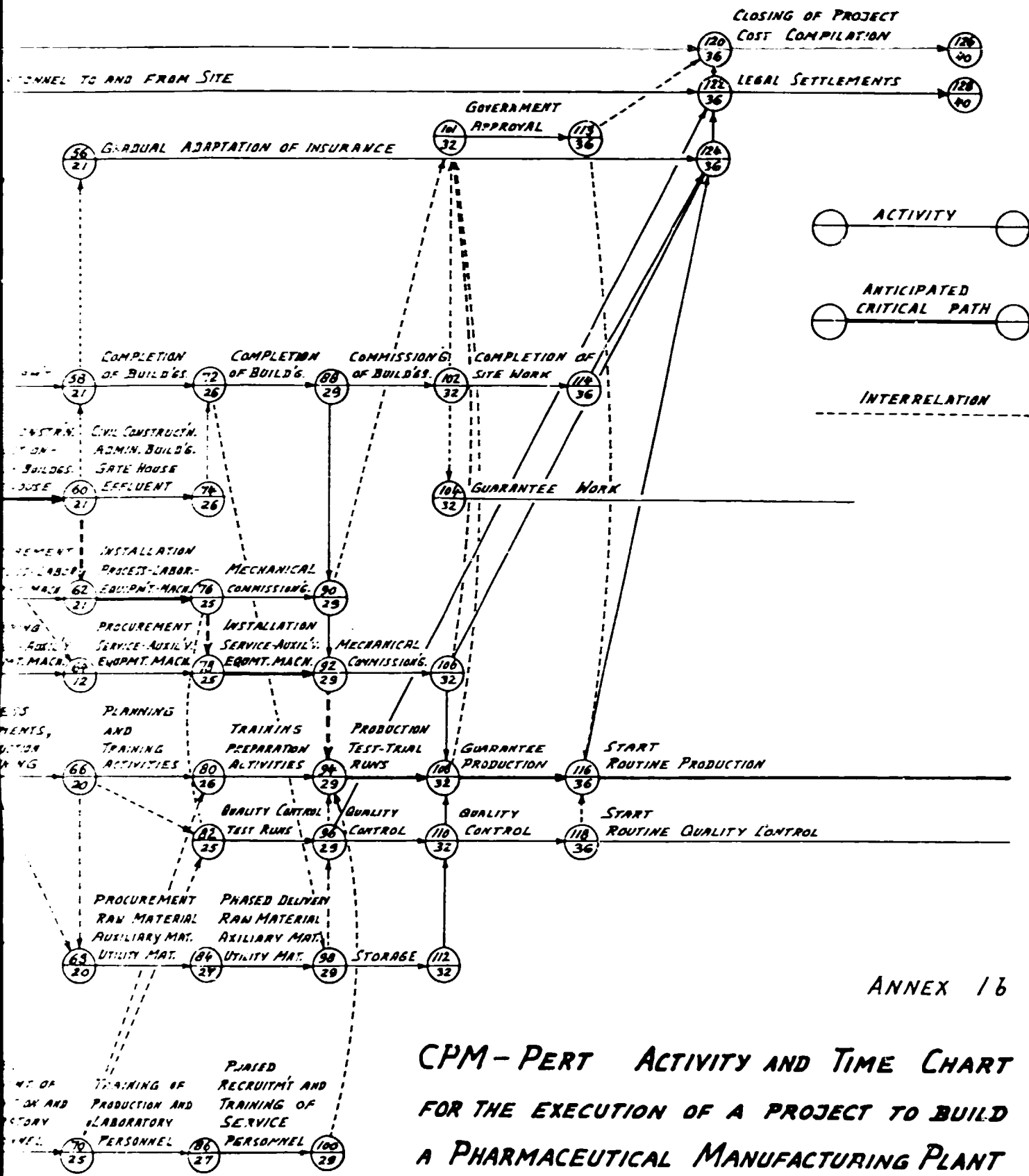




INDICATIVE TIME SCHEDULE FOR THE EXECUTION OF THE PROJECT



SECTION 1

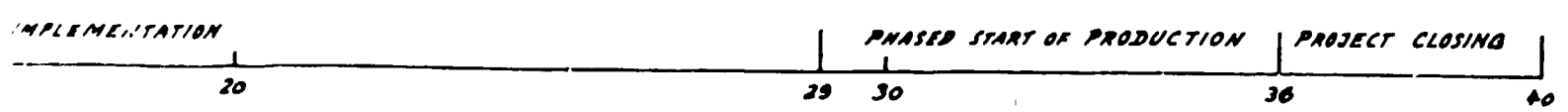


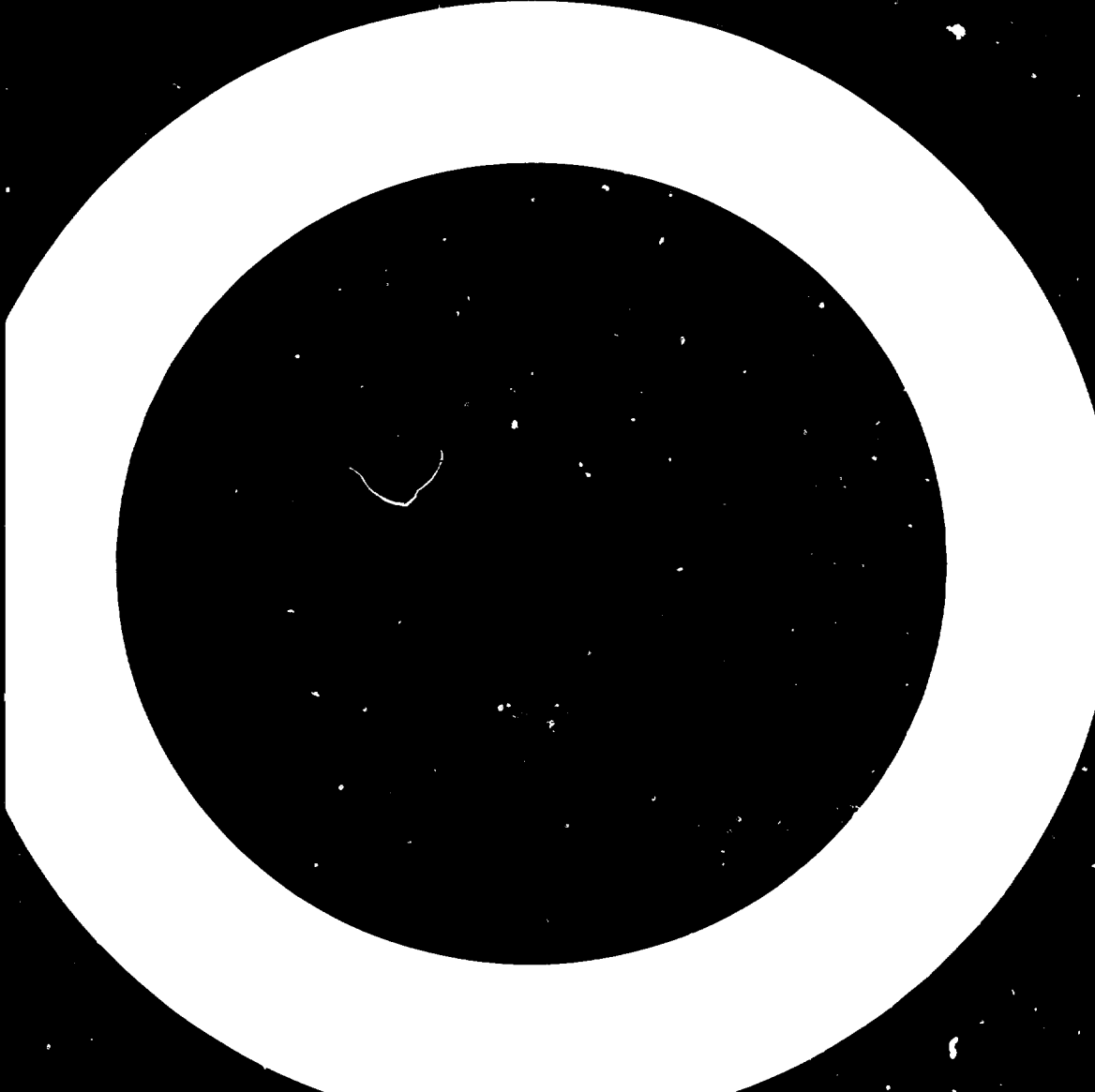
ANNEX 16

CPM-PERT ACTIVITY AND TIME CHART FOR THE EXECUTION OF A PROJECT TO BUILD A PHARMACEUTICAL MANUFACTURING PLANT

UNIDO 85.3.003

OF THE PROJECT





ANNEX II

BASIC DOCUMENT DATA FOR MANUFACTURING AND PACKAGING OF PHARMACEUTICAL DOSAGE FORMS

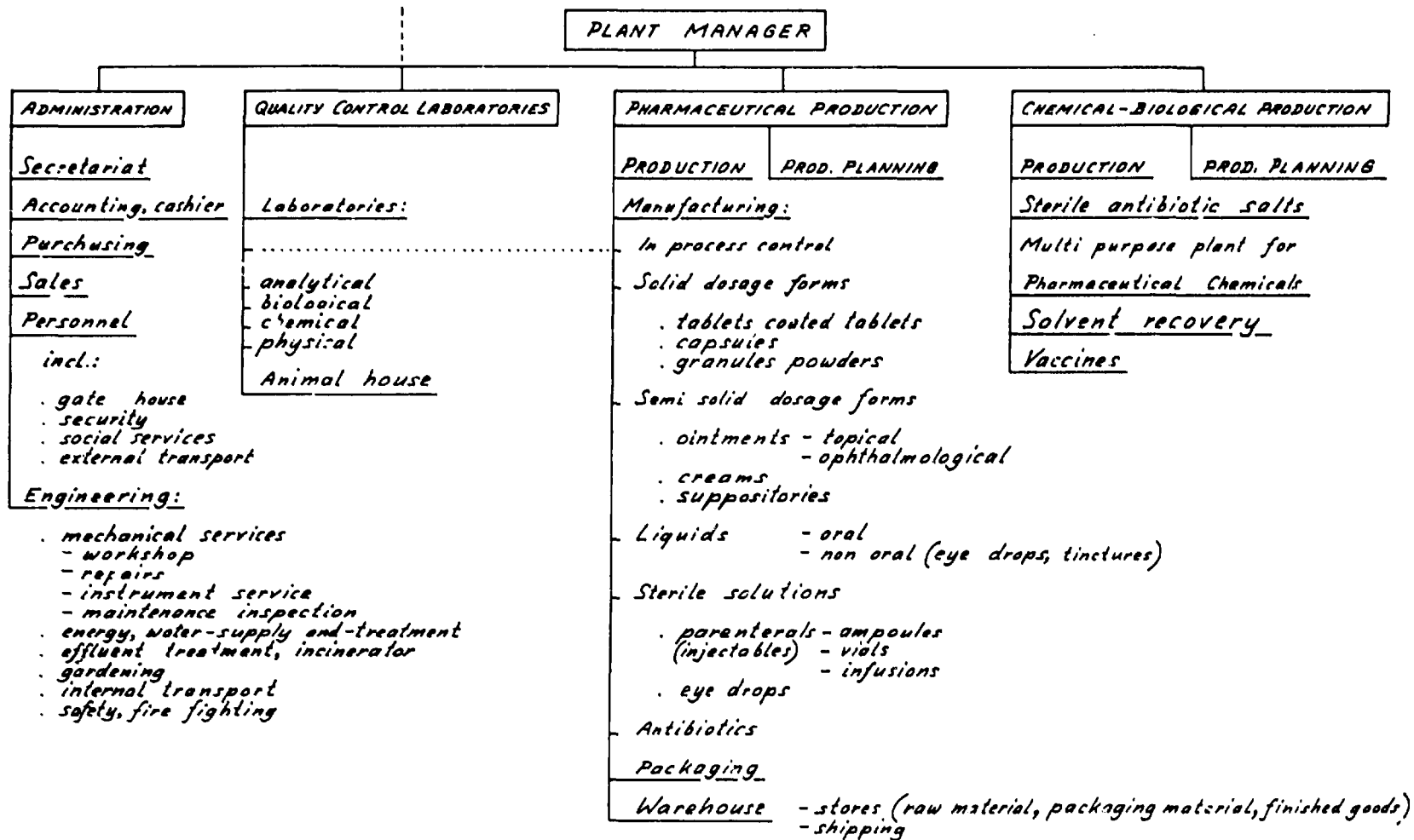
Dosage form	Units/quantities per year	Units per pack	Million packs/year		Tons/year	
			min.	max.	min.	max.
Tablets (T) - 0.3g/T and 50% coated T	100-120 millions	30 T	3.3	4.0	30	36
Hard gelatin capsules (C) - ~0.5g/C	10- 20 millions	10 - 20 C	0.5	2.0	5	10
Powders and Granules (packs) - ~10g/pack	2- 3 millions	10 sachets	0.2	0.3	20	30
Ointments - ~5-15g/tube	5-6000 kg	1 tube	0.3	1.2	5	6
Oral liquids (syrups) - ~ 50-100 ml/pack	50'000 l	1 bottle	0.5	1.0	50	50 *)
Non-oral liquids (eye drops) - ~10ml/pack	0.6 millions	1 bottle	0.6	0.6	6	6 *)
Parenterals - Ampoules (A) - ~ 3ml/A	0.6 millions	3-5 A	0.12	0.2	1.8	1.8*)
- Vials (V) - ~ 10ml/V	1.2 millions	1 V	1.2	1.2	12	12 *)
- Infusions (I)- ~ 500ml/I	0.5-1.0 millions	1 bag/bottle	0.5	1.0	250	500 *)
Water for injection - ~ 3ml/A, V	5.6 millions	1 A or V	5.6	5.6	16.8	16.8*)
Antibiotics (V) - ~ 1g/V	4.5 millions	1 V	4.5	4.5	4.5	4.5
Total			17.32	21.6	401.1	673.1

*) These quantities include treated water which is not stored in the raw material section of the warehouse. The raw material quantities amount to approximately 95 - 130 tons.

NB. Working conditions:

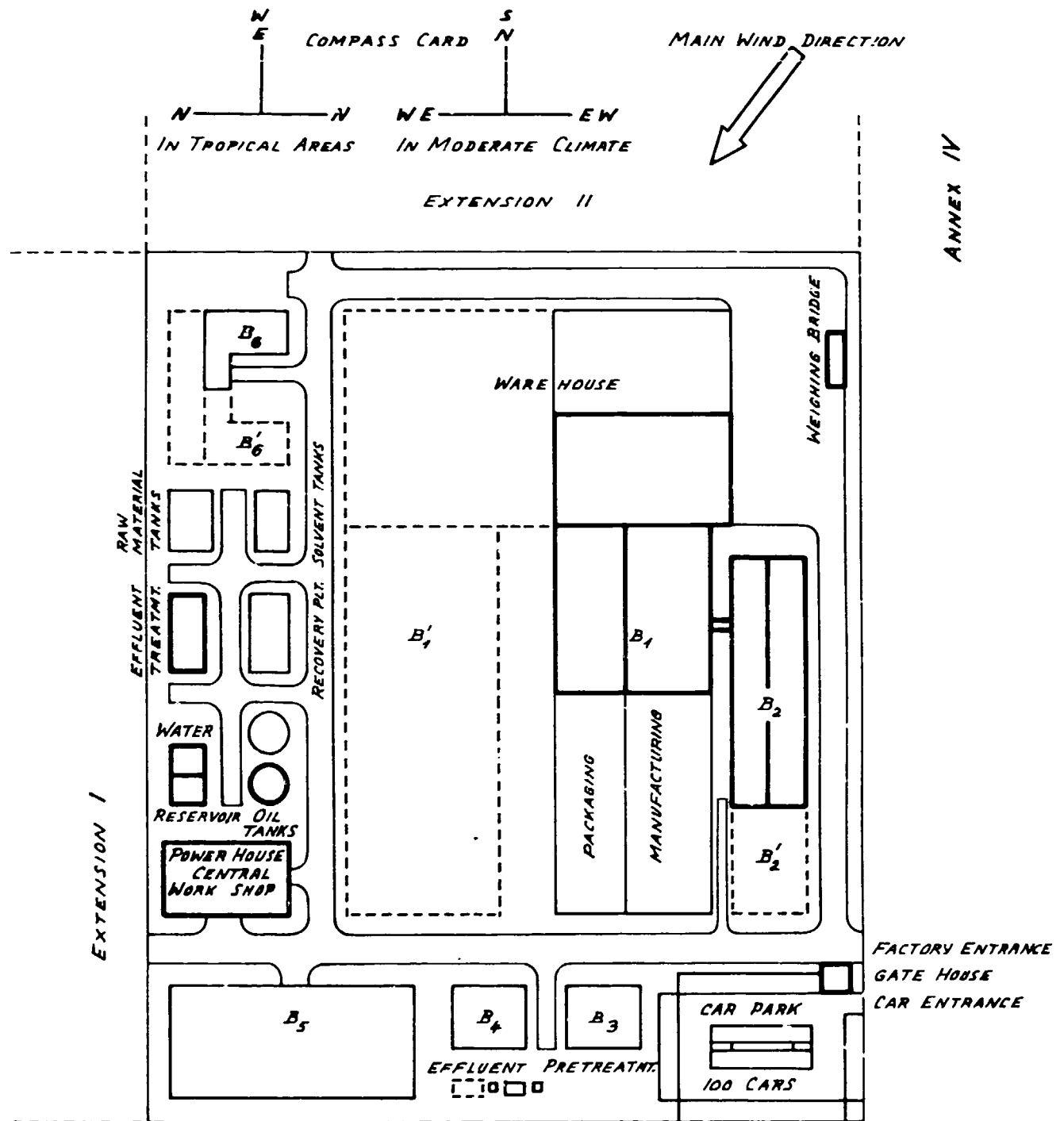
- 240 working days per year
- one shift per day
- 8 hours per shift with 7 hours effective working time

PROPOSED ORGANIZATION CHART (ANNEX III)



ANNEX IV
SITE PLAN AND SITE UTILIZATION

Covered site area	sq.m.
B1 - Manufacturing + packaging	4620
- Corridor	420
- Warehouse	3000
B2 - Annex building: ground floor (administration + laboratory)	1400
(first floor = 700 sq.m + reserve)	-
Extension:	
B'1 - Manufacturing + packaging	4620
- Corridor	420
- Warehouse	3600
B'2 - Annex building: ground floor (administration + laboratory)	650
(first floor = 650 sq.m.)	-
B3 - Vaccines production	350
B4 - Animal house	350
B5 - Sterile antibiotic salts	2100
B6 - Multipurpose plant for pharmaceutical chemicals	450
Extension:	
Boiler house incl. central workshop	720
Raw material tank area	190
Solvent tank area	150
Oil tank area	215
Fresh water reservoirs	230
Raw material and solvent recovery	220
Effluent treatment plants	280
Weighing bridge	30
Gate house	65
Car park (24.5 sq.m./car x 100 cars)	2450
<hr/>	
Total	27,400
Site area = 205 x 238 m	48'790
Site utilization	56%
=====	===



ANNEX IV

- B₁ PRODUCTION OF PHARMACEUTICAL DOSAGE FORMS
- B₂ ADMINISTRATION, LABORATORIES AND GENERAL SERVICES
- B₃ MANUFACTURE OF VACCINES
- B₄ ANIMAL HOUSE
- B₅ PROCESSING OF STERILE ANTIBIOTIC SALTS
- B₆ PRODUCTION OF BULK DRUGS (PHARMACEUTICAL CHEMICALS)

SITE = 238 x 205 m = 48'790 sq. m

ASSUMPTION: FLAT OR SLIGHTLY SLOPED TOPOGRAPHY

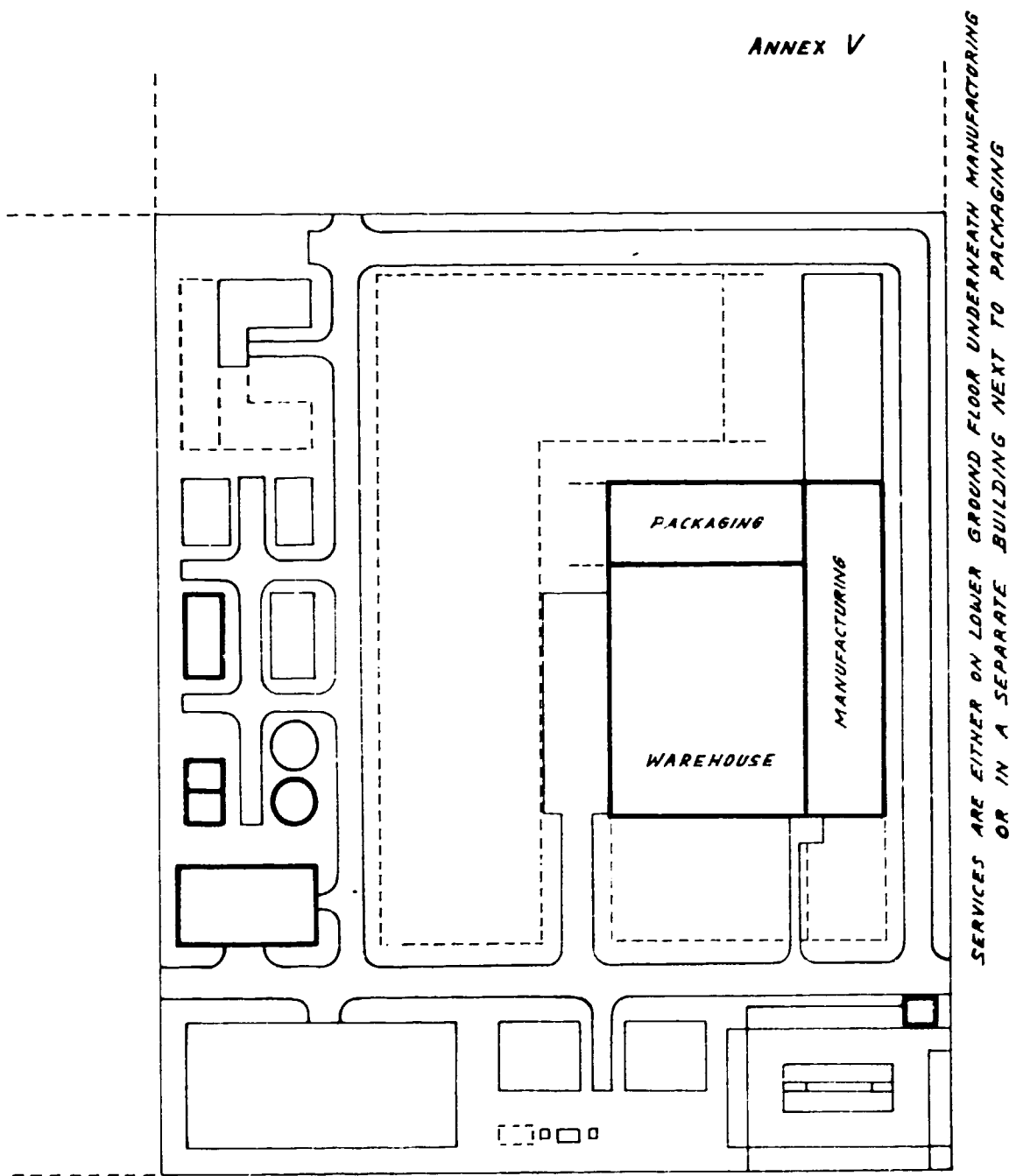
POSSIBLE STAGES OF REALIZATION:

SITE PLAN

SCALE = 1 : 1600

UNIDO 85.4.001

ANNEX V



POSSIBLE STAGES OF REALIZATION: —
- - -

SITE PLAN

FOR ALTERNATIVE LAYOUT

SCALE • 1 : 1600

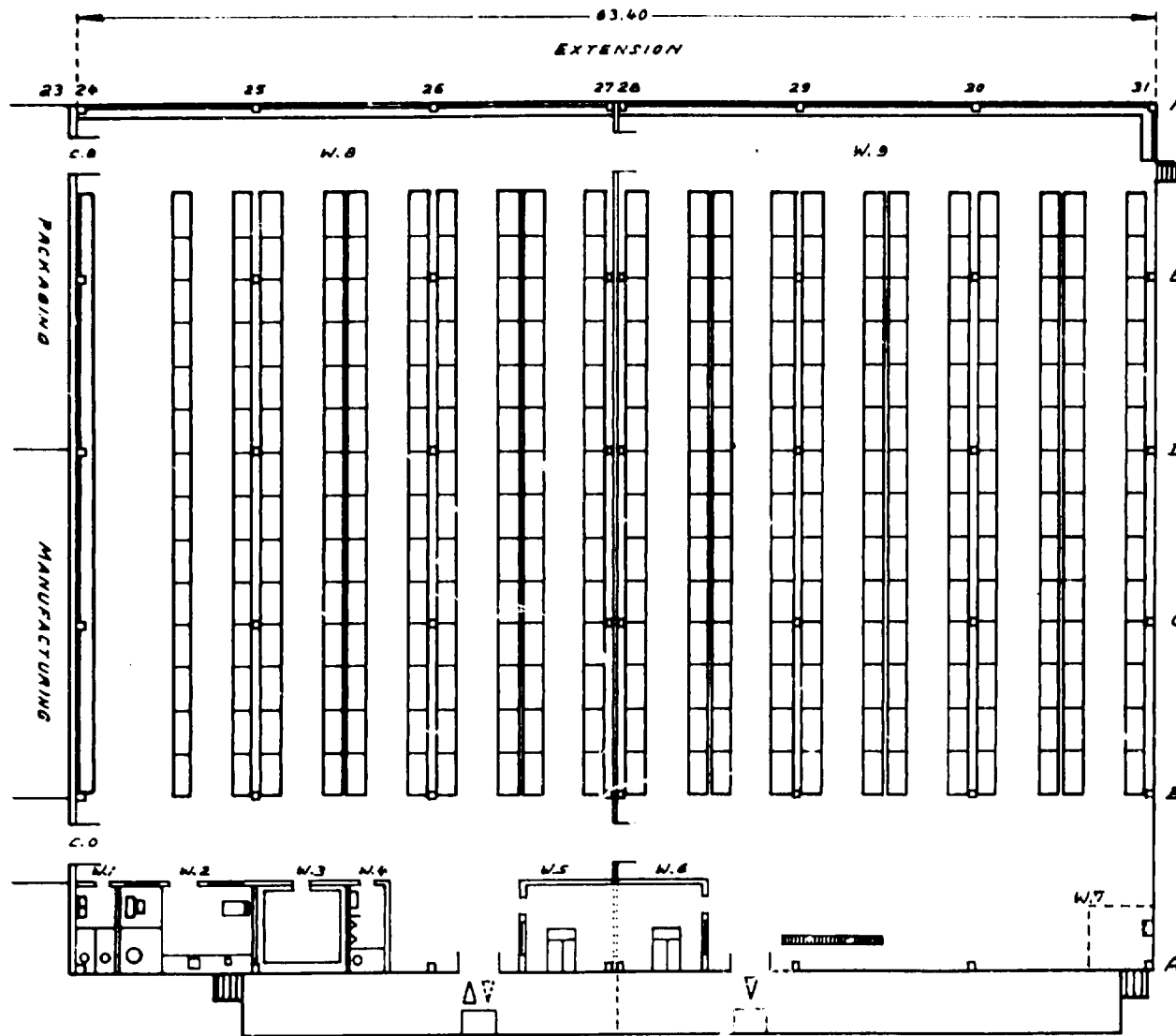
UNIDO 85.4.016

FOR FURTHER INFORMATION SEE SITE PLAN - UNIDO 85.4.001

SCALE = 1:400

UNIDO B5.4.002

WAREHOUSE



ANNEX VI a

POSSIBLE STAGES OF REALIZATION:
COLUMN 24-27 AND 28-31

FIRE WALL BETWEEN 23/24 AND 27/28

- ROOM 1 WC FOR WOMEN
 2 WEIGHING PRE-SIFTING/MILLING
 3 COOL STORE WITH REFRIGERATOR
 4 WC FOR MEN INCL. TRUCK DRIVERS
 5 WAREHOUSE OFFICE
 6 SHIPPING OFFICE
 7 FORK LIFT TRUCK CHARGING PLACE

STORAGE

PALLET PLACES FOR "EUROPEAN" POOL PALLETS
 120 x 80 x 15 CM

ASSUMPTION:

600 PALLETPL. 4 STOREYS HIGH = 2400 PP

324 PALLETPL. 5 STOREYS HIGH = 1620 PP

WALL SHELVES: 100 m x 60 cm x 3 m HIGH
 FLOOR SPACE FOR QUARANTINE AND SHIPPING

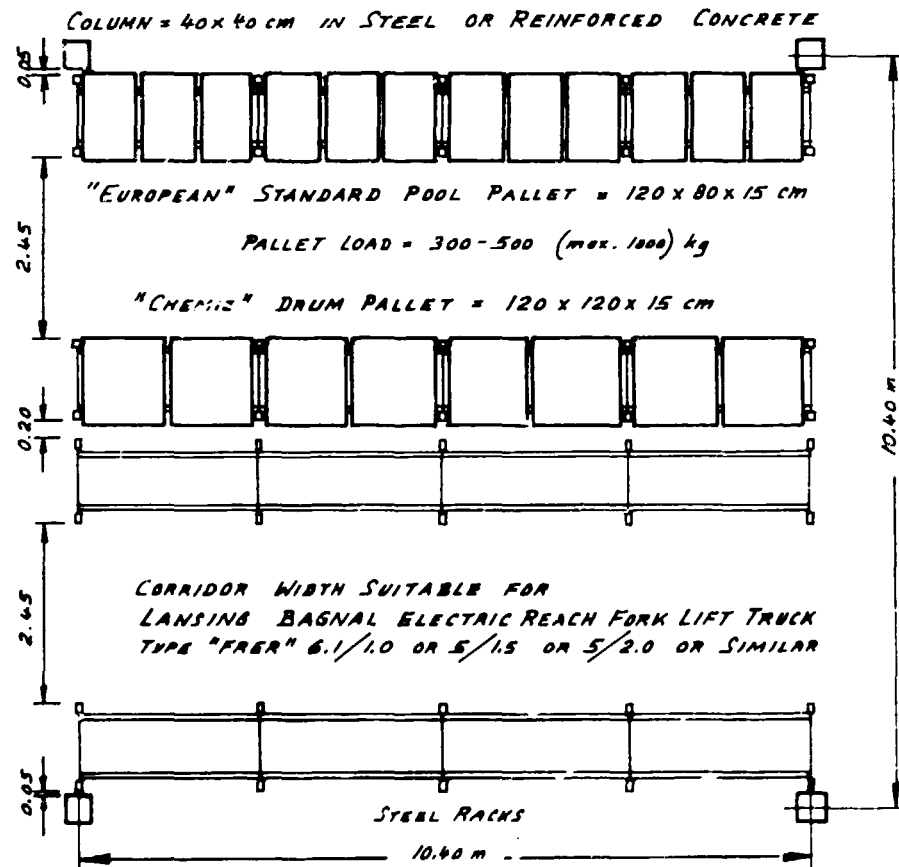
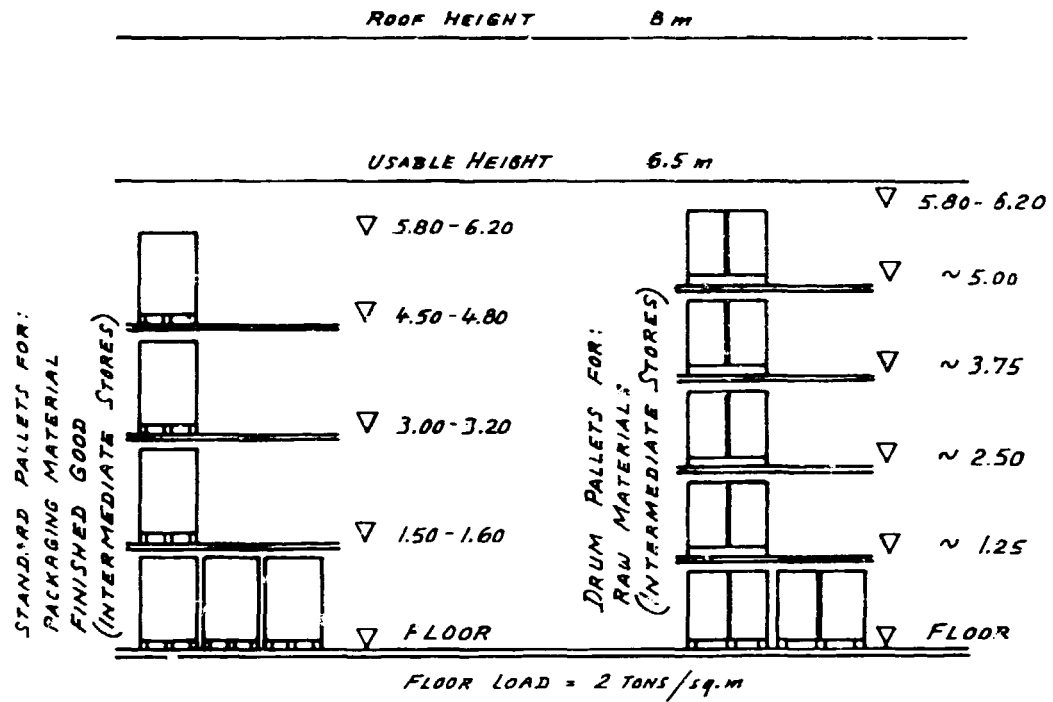
WAREHOUSE AREA

BUILDING: 53 x 64 m = 3392 sq. m

USABLE AREA: 52 x 63 m = 3276 sq. m

TRANSPORT FACILITIES

- 1 ELECTRIC REACH FORK LIFT TRUCK
- 1 ELECTRO-HYDRAULIC HAND FORK LIFT TRUCK
- 3 PALLET HAND TRUCKS

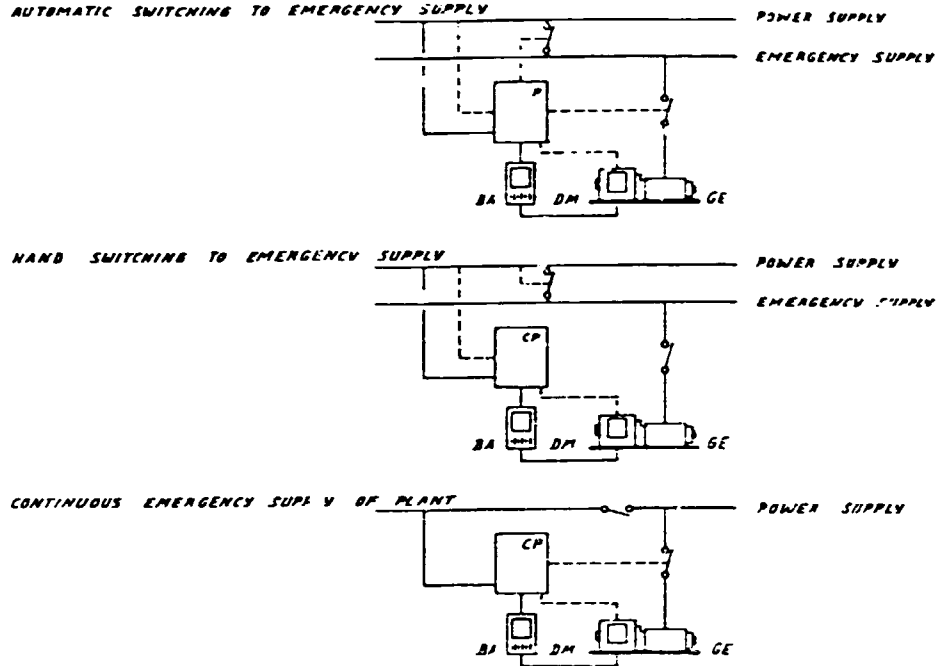


CHARACTERISTIC WAREHOUSE DIMENSIONS

ANNEX VII - Recommended room finishing

AREAS	WALLS	FLOORS	CEILINGS	NOTES
Tablets, granules, capsules Ointments Oral liquids Animal house	Welded PVC sheets, polyurethan or epoxy resins	Concrete with hard top cover or terrazzo	Epoxy or polyurethan resin coating	All floors, walls and ceiling junctions must be rounded and filled. Floor load = 1 ton/sq.m.
Antibiotics Injectables and eye-drops Intravenous infusions Vaccines	Welded PVC sheets	Pressed and welded PVC tiles or epoxy covering on concrete	False ceilings for sterile areas	Special arrangements for clean illumination. Floor load = 0.8 tons/sq.m.
Offices Laboratories Canteen Change rooms	Epoxy or polyurethan resins	Ceramic grès or artificial stone slabs	Epoxy or polyurethan resin coating	Floor load = 0.4 tons/sq.m.
Freeze-dryer rooms and packaging area	Polyurethan coating	Artificial stone slabs or concrete with hard top cover	Epoxy or polyurethan resin coating	Floor load = 1 ton/sq.m.
Corridors Raw materials distribution	Welded PVC sheets or painted plaster	Artificial stone slabs, clinker slabs or concrete with hard top cover	False ceiling made of PVC shooks, epoxy or polyurethan resin coating	Floor load = 1 ton/sq.m.
Warehouse Powerhouse	Anti-dust coating	Concrete with hard-top cover or artificial stone slabs	Anti-dust coating	In the warehouse the floor load must not be less than 2 tons/sq.m.
Cool store	Insulated walls with moisture protection on the outside of the wall	Insulated floor with concrete and hard top cover	Insulated ceiling with moisture protection on the outside of the wall	

POSSIBILITIES OF EMERGENCY POWER SUPPLY



LEGEND

- MT1 - M PANEL WITH AIR LOAD DISCONNECTING SWITCH AND FUSES
- MT2, MT3 - M.V. PANEL WITH SMALL AIR VOLUME CIRCUIT BREAKER
- MT4, MT5 - M.V. PANEL WITH SMALL AIR VOLUME CIRCUIT BREAKER - EXTENSION
- CPP - CENTRAL POWER PANEL
- SL - LIGHT SWITCHBOARD
- SP - POWER SWITCHBOARD
- SAC - AIR CONDITIONING UNIT POWER SWITCHBOARD
- R - REACTIVE POWER COMPENSATION PANEL (FROM mag-676 TO mag-65 AVERAGE)
- SPH - POWERHOUSE POWER SWITCHBOARD
- SRC - REFRIGERATION COMPRESSOR POWER SWITCHBOARD
- SRR - BARGE COMPRESSOR POWER SWITCHBOARD
- TR1, TR2 - POWER TRANSFORMER: 20000/300/200Y 50Hz 2.750 MVA CAPACITY OR LOCAL STANDARD
- TR3, TR4 - POWER TRANSFORMER EXTENSION

ASSUMPTION: SIMULTANEITY FACTOR = 50%

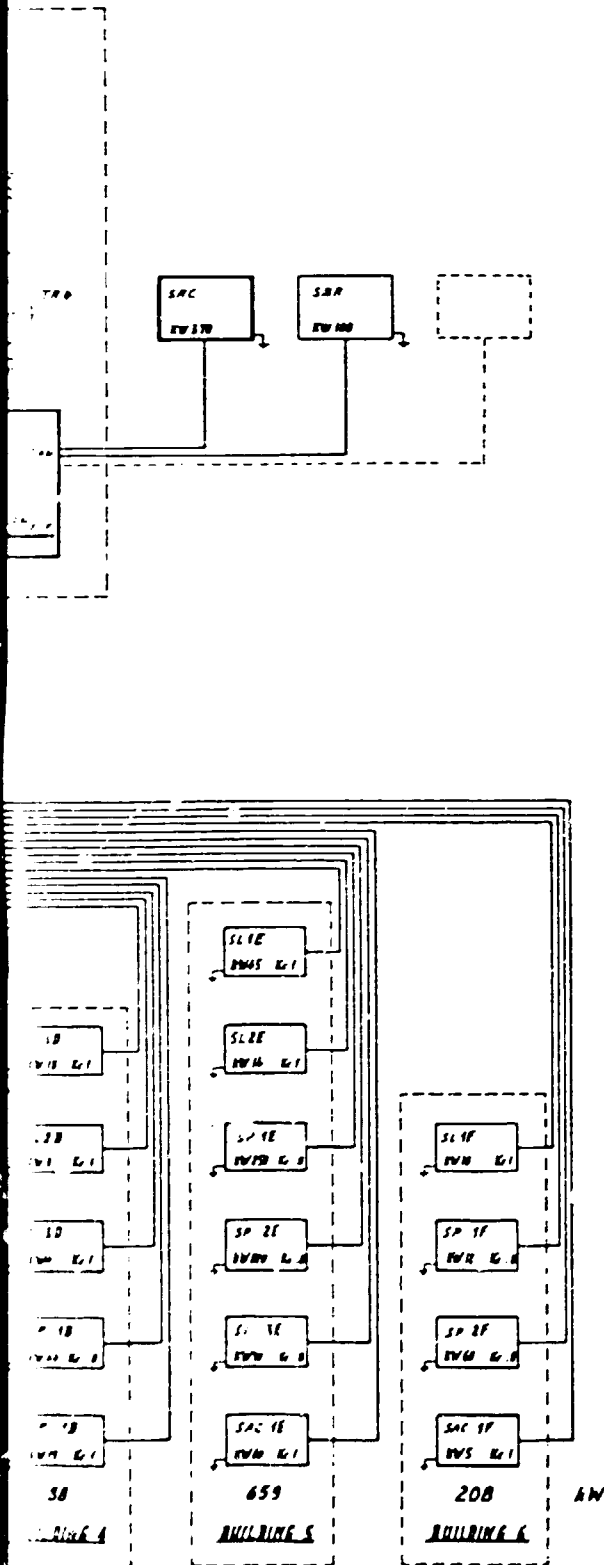
- BA - BATTERY
- CP - CONTROL PANEL
- DM - DIESEL MOTOR
- GE - GENERATOR

POSSIBLE STAGES OF REALIZATION:

HIGH- AND LOW- VOLTAGE POWER SUPPLY

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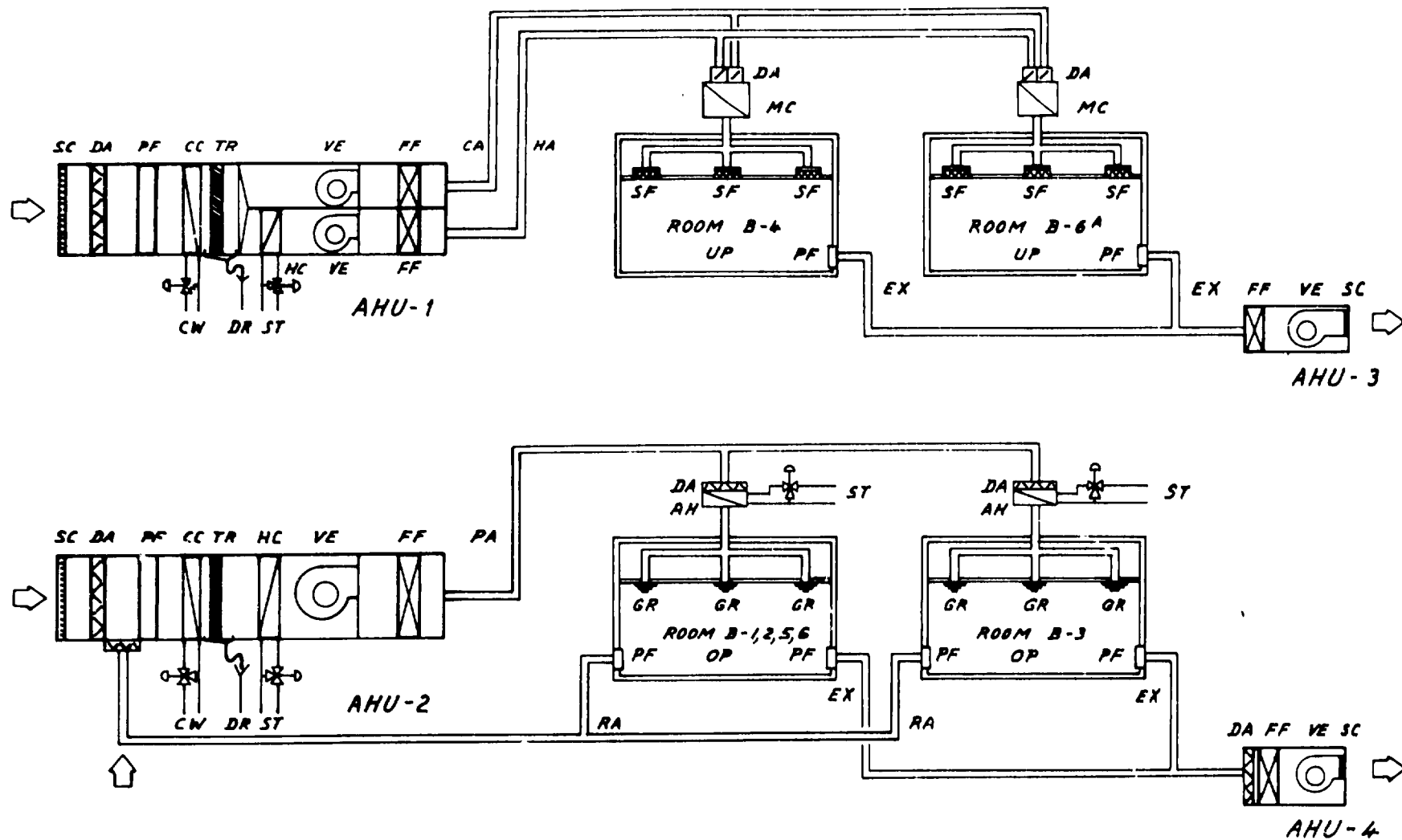
SECTION 2



EXPLANATIONS TO SCHEMATIC DIAGRAMS OF AIR CONDITIONING

(See also layout for antibiotics)

AH	After-heater	
AHU-1	Air handling unit with dual duct system for precision room conditioning	
AHU-2	Air handling unit for standard room conditioning	
AHU-3	Exhaust air unit for antibiotics contaminated room air	
AHU-4	Standard exhaust air unit with the possibility of partial reuse of room air	
CA	Cool air supply	
CC	Cooling radiator	
CW	Cooling- or chilled water, or brine	
DA	Damper	
DR	Drain	
EX	Exhaust air	
FF	Fine filter according to need and specifications in Annex X	
HA	Hot air supply	
HC	Heating radiator	
GR	Gril	
MC	Mixing chamber	
OP	Over pressure in room	
PA	Preconditioned air supply	
PF	Pre filter according to need and specifications in Annex X	
RA	Room return air	
SC	Screen to protect air intake and air exhaust from birds, insects, etc.	
SF	Sterile ("HEPA") filter according to need and specifications in Annex X	
ST	Steam	
TR	Trap to eliminate the water drops from the dried air	
UP	Under pressure in room	
VE	Centrifugal air ventilator	
Room	B-1, -2, -5	Cloak rooms
	B-6	Lock
	B-3	Washing room
	B-4	Antibiotics blending and filling room
	B-6A	Antibiotics preparation room



SCHEMATIC DIAGRAMS OF AIR CONDITIONING

FOR BLENDING AND FILLING OF ANTIBIOTICS

UNIDO 85.4.017

FOR EXPLANATIONS SEE EXTRA PAGE

RECOMMENDED CONDITIONS OF AIR WITHIN A PHARMACEUTICAL MANUFACTURING PLANT (ANNEX Xa)

AREA	TEMPERATURE		RELATIVE HUMIDITY %	AIR CHANGES VOL./h	DIN ⁵⁾ 241B5/241B4	SWKI ⁵⁾ 68-3	ASHRAE ⁵⁾ 52-76 %	ASHRAE 52-68 %	DOP-TEST MIL. STD. 202 %	OIL MIST TEST DIN-AEROSOL 1 %	US FEDERAL STD. 290 3 CLASS
	SUMMER °C	WINTER °C									
WAREHOUSE	4	>16 ± 2	1)	—	SCREENS AGAINST BIRDS AND INSECTS	—	—	—	—	—	—
COOL ROOMS	15 ± 2	15 ± 2	DRY WALLS	—	EU2-EU3	G2-G3	88	—	—	—	—
COLD STORE (REFRIGERATOR)	4 ± 1	4 ± 1	—	—	—	—	—	—	—	—	—
LABORATORIES	MAX. 28 ²⁾	20 ± 2	60 ± 10	2-4	EUS	F1	96	—	—	—	—
OFFICES	MAX. 28	20 ± 2	60 ± 10	1-4	EUS	F1	96	—	—	—	—
SOCIAL AREAS	MAX. 28	20 ± 2	60 ± 15	1-2	EU2-EU3	G2-G3	88	—	—	—	—
(SANITARY ROOMS)	1)	20 ± 2	60 ± 15	2-4	EU2-EU3	G2-G3	88	—	—	—	—
MANUFACTURING:											
TABLETS	24 ± 2	20 ± 2	50 ± 10	3-5	EUS-EU7	F1-F2	96	82	—	—	—
CAPSULES	24 ± 2	20 ± 2	30 ± 5	3-5	EUS-EU7	F1-F2	96	82	—	—	—
POWDERS	24 ± 2	20 ± 2	40 ± 5	3-5	EUS-EU7	F1-F2	96	82	—	—	—
LIQUIDS - ORAL	24 ± 2	20 ± 2	50 ± 10	3-5	EUS-EU8	F1-F3	96	82-95	—	—	—
OINTMENTS - TOPICAL	22 ± 2	20 ± 2	50 ± 10	3-5	EUS-EU8	F1-F3	96	82-95	—	—	—
SUPPOSITORIES	22 ± 2	20 ± 2	50 ± 10	3-5	EUS-EU8	F1-F3	96	82-95	—	—	—
PARENTERALS - GENERAL	22 ± 2	20 ± 2	40 ± 10	10-20	EU7-EU8	F2-F3	96	82-95	—	—	—
INFUSIONS - GENERAL	22 ± 2	20 ± 2	40 ± 10	10-20	EU7-EU8	F2-F3	96	82-95	—	—	—
ANTIBIOTICS - GENERAL	22 ± 2	20 ± 2	40 ± 10	10-20	[EUS-8] + Q	[F1-F3] + S1	96	82-95+	> 85	96.7	100'000
STERILE ROOMS - GENERAL	22 ± 2	20 ± 2	40 ± 10	10-20	OR R	OR S2	96	82-95+	> 95	99.2	10'000
					OR S	OR S3	96	82-95+	> 99.97	> 99.97	100
FILLING OF:											
EYE-DROPS AND - OINTMENTS,	22 ± 2	20 ± 2	40 ± 10	LAM. FLOW	↓	↓	↓	↓	↓	↓	↓
STERILE POWDERS AND SOLUTIONS	22 ± 2	20 ± 2	40 ± 5	LAM. FLOW	↓	↓	↓	↓	↓	↓	↓
LAMINAR FLOW	22 ± 2	20 ± 2	40 ± 5	500-1000	[EUS-8] + S	[F1-F3] + S3	96	82-95+	> 99.97	> 99.97	100
PACKAGING	24 ± 2	20 ± 2	50 ± 5	4-6	EUS-EU7	F1-F2	96	82	—	—	—
TECHNICAL AREAS/ROOMS	1)	16 ± 5	1)	—	SCREEN IN ROOM OPENINGS	—	—	—	—	—	—
ELIMINATION OF:											
CROSS CONTAMINATION	—	—	—	SPOT	[EUS-8] + [Q,R,S]	[F1-F3] + [S1-S3]	96	82-95+	> 85->99.97	96.7->99.97	100'000 - 100
FILTRATION OF:				VENTILATION							
POLLUTED EXHAUST AIR ⁴⁾	—	—	—	OR ROOM	[EUS-8] + [Q,R,S]	[F1-F3] + [S1-S3]	96	82-95+	> 85->99.97	96.7->99.97	100'000 - 100
(FOR ANTIBIOTICS = "ZERO LIMIT") ³⁾	—	—	—	EXHAUST	[EU7-8] + [(R), S]	[F2-F3] + [(S2)-S3]	96+	95+	> 95->99.97	99.2->99.97	10'000 - 100
ANIMAL HOUSE	22 ± 2	21 ± 2	60 ± 5	4-6	SCREEN IN EXHAUST DUCTS	—	—	—	—	—	—

1) NORMAL OUT DOOR CLIMATIC CONDITIONS

2) MAX. DIFFERENCE TO OUT DOOR TEMPERATURE SHOULD NOT EXCEED 6°-8°C

3) TWO STEP PREFILTRATION AS AND WHEN REQUIRED

4) APPLICABLE FOR SPECIAL CASES ONLY. NORMALLY USE BAG-FILTERS AS DESCRIBED ON FOLLOWING PAGE.

5) FOR EXPLANATION SEE TEXT

ANNEX X8: FILTER SPECIFICATIONS FOR VARIOUS GRADES OF EFFICIENCY (REPRESENTATIVE BUT NOT EXCLUSIVE VALUES)

	GRADE DIN-24185/84		THEORETICAL FLOW CAPACITY	ACTIVE FILTER SURFACE	NOMINAL FACE VELOCITY	MAX. NORMAL OPERATING TEMP. (ADMISSIBLE REL. HUMID.)	SHORT TIME OVER-TEMPERAT.	PRESSURE DROP		SERVICE LIFE IN NORMAL AIR POLLUTION	FILTER MEDIUM
	SNKI-68-3		CU.M/H	SQ.M	M/SEC	°C	°C	INITIAL mbar	REG. FINAL mbar	h	
PRE-FILTERS	EU-2/3	G-2/G-3	~ 2000 - 4000	~ 1 - 2	~ 3 - 3.5	~ 80	~ 100	~ 0.6	~ 1.6	~ 5000	CELLULOSE/SYNTHETIC FIBER
	EU-3	G-3	~ 2000 - 4000	~ 1 - 2	~ 3 - 3.5	~ 80	~ 100	~ 1.3	~ 2.5	~ 4000	CELLULOSE/SYNTHETIC FIBER
	EU-5/6	F-1	~ 2000 - 4000	~ 2 - 4	~ 3 - 3.5	~ 70	~ 80	~ 1.4	~ 2.8	~ 10'000	CELLULOSE PAPER
	EU-7	F-2	~ 2000 - 4000	~ 3 - 6	~ 3 - 3.5	~ 70	~ 80	~ 1.5	~ 3.0	~ 9000	GLASS FIBER PAPER OR GLASS/NYLON WEB
	EU-8/9	F-3	~ 2000 - 4000	~ 4 - 8	~ 3 - 3.5	~ 70	~ 80	~ 1.8	~ 3.2	~ 7000	GLASS FIBER PAPER OR GLASS NYLON WEB
STERILE-OR "HEPA"-FILTERS	Q	S-1	~ 60 - 100	1.6	~ 0.21	~ 70 (85%)	~ 80	~ 0.7	~ 1.8	DEPENDENT ON FREQUENCY OF CHANGING PREFILTERS AND SEQUENCE OF PREFILTERS	CELLULOSE
			~ 2000	~ 10	~ 1.5	~ 70 (100%)		~ 1.2	~ 8		GLASS FIBER
	R	S-2	~ 60 - 100	~ 1.7	~ 0.21	~ 70 (85%)	~ 80	~ 0.3	~ 1.0		CELLULOSE
			~ 2000	~ 16	~ 1.5	~ 70 (100%)		~ 1.2	~ 8		GLASS FIBER
	RR-R		~ 600 - 700	~ 10	~ 1.0	~ 90 (100%)		~ 1.5	~ 4		GLASS FIBER
	S	S-3	~ 75 - 120	~ 1.3	~ 0.28	~ 135 (100%)		~ 1.7	~ 4.4		GLASS FIBER
			~ 2000 - 3000	~ 18 - 36	~ 1.35 - 2.25	~ 70 (100%)		~ 2.5	~ 8		GLASS FIBER
RR-S		~ 600 - 700	~ 10	~ 0.8	~ 90 (100%)		~ 2.5	~ 6	GLASS FIBER		
BAG FILTER ^{1) 2)}			~ 1000 - 2000	~ 5 - 30		~ 70 (<100%)					COTTON OR FELT 350-500g/sq.m

1) TO BE CLEANED BY HAND, MECHANICALLY OR COMPRESSED AIR

2) EFFICIENCY = 98.3-99.8% MEASURED BY TEST DUST WITH RANGE OF GRAIN SIZES: 0-5 μm = 39%

5-10 μm = 18%

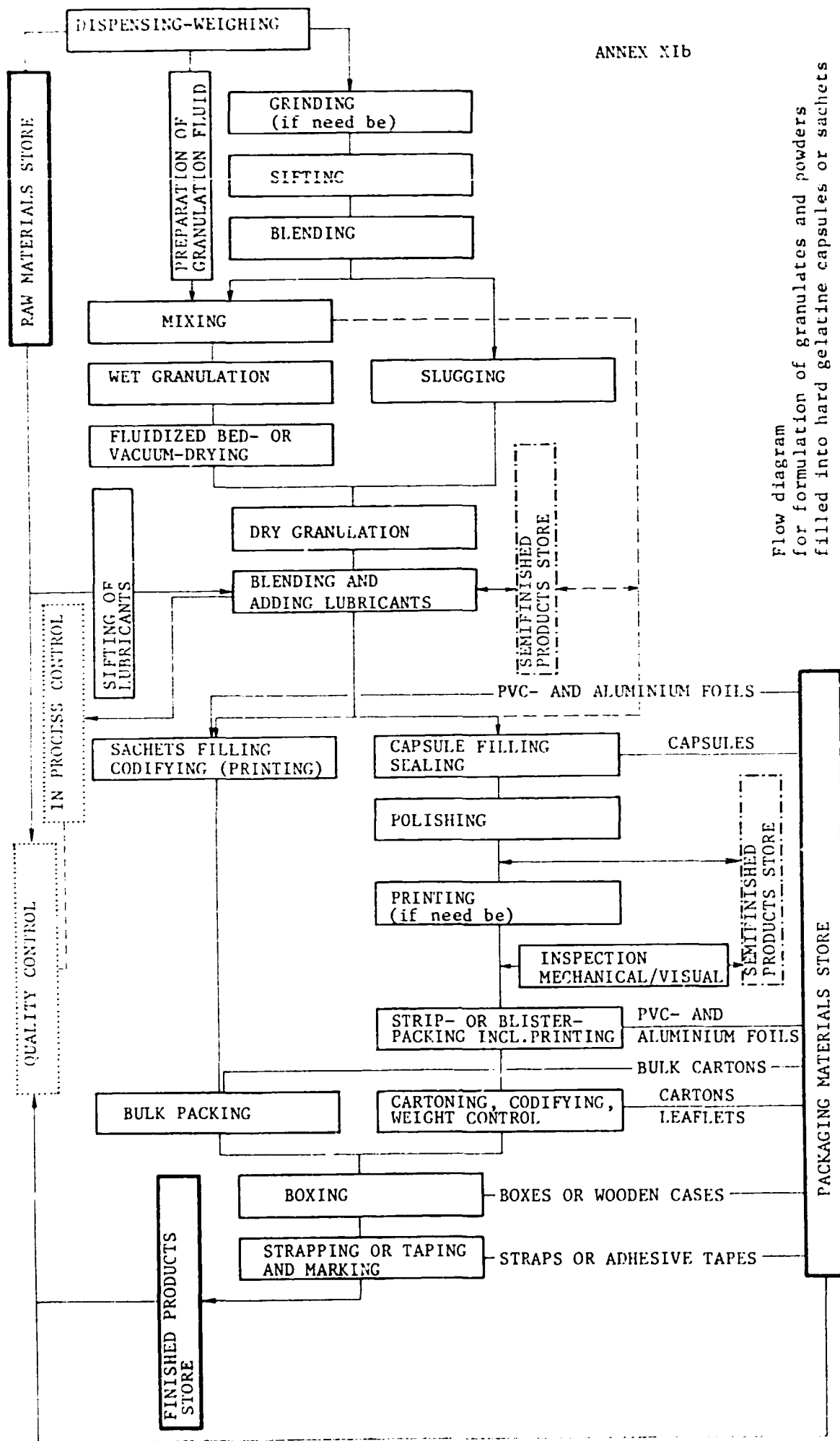
10-20 μm = 16%

20-40 μm = 18%

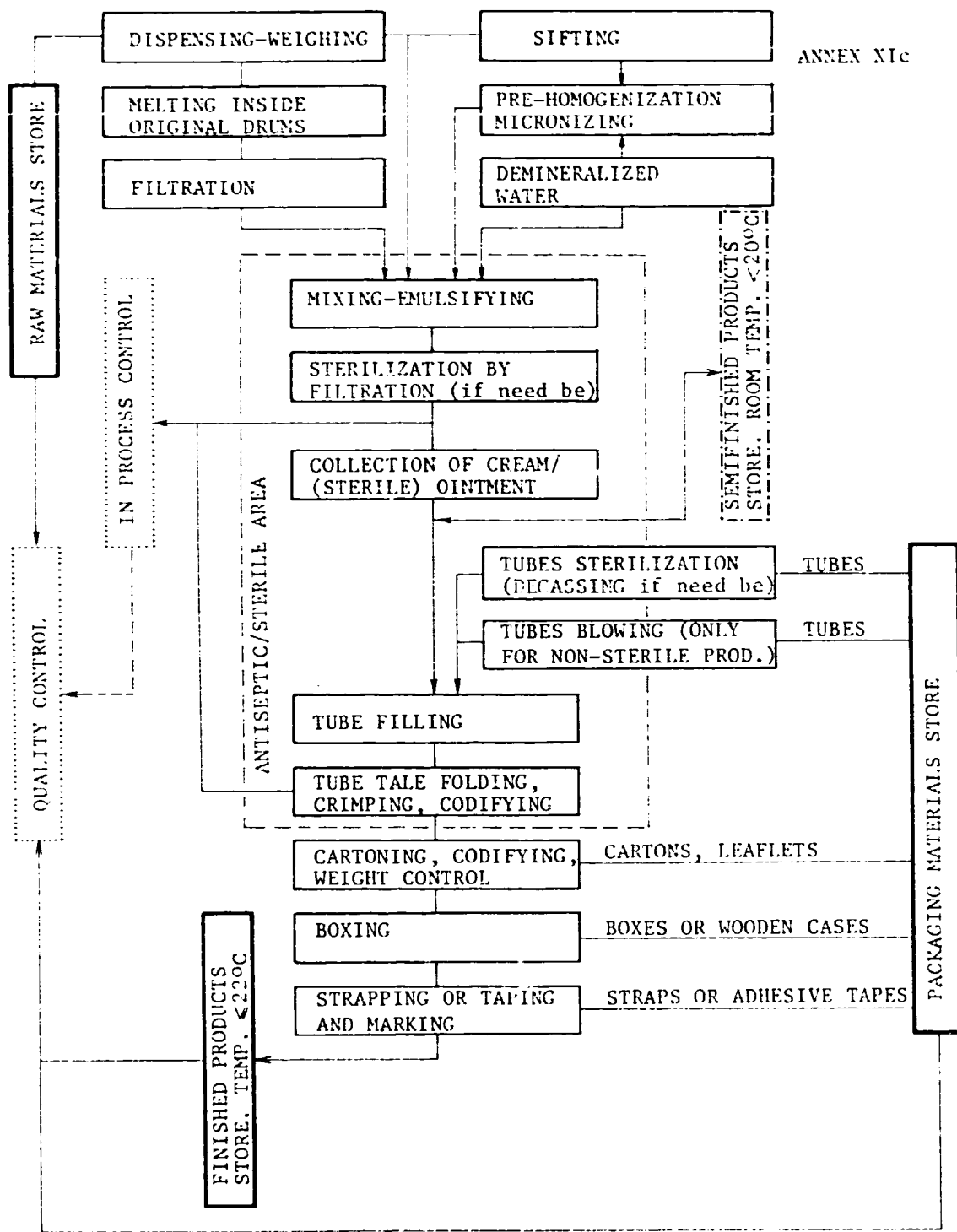
40-80 μm = 9%

PS: FOR SPECIAL CASES OF POLLUTED EXHAUST AIR SEE PREVIOUS PAGE Xa

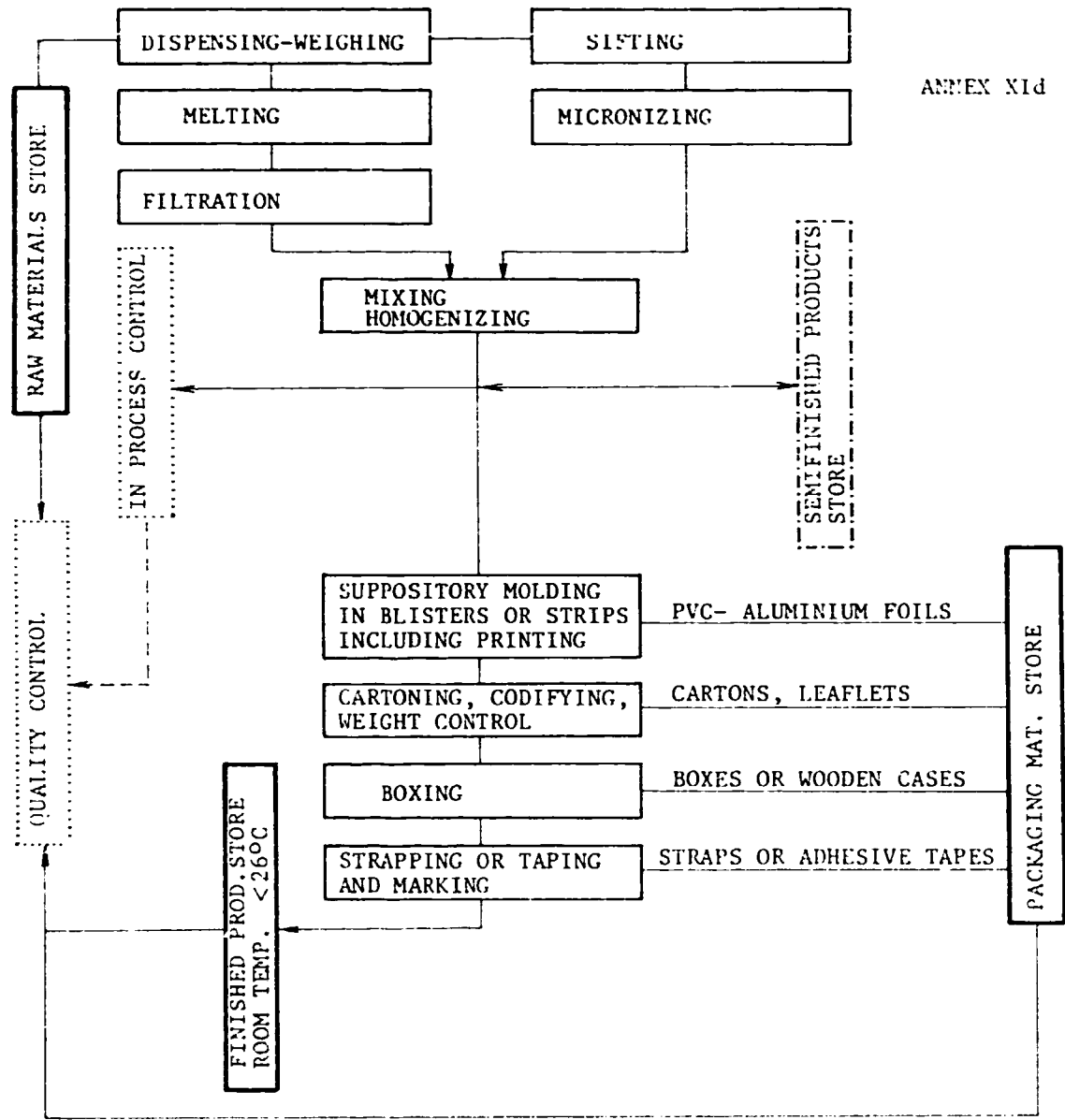
ANNEX XIb



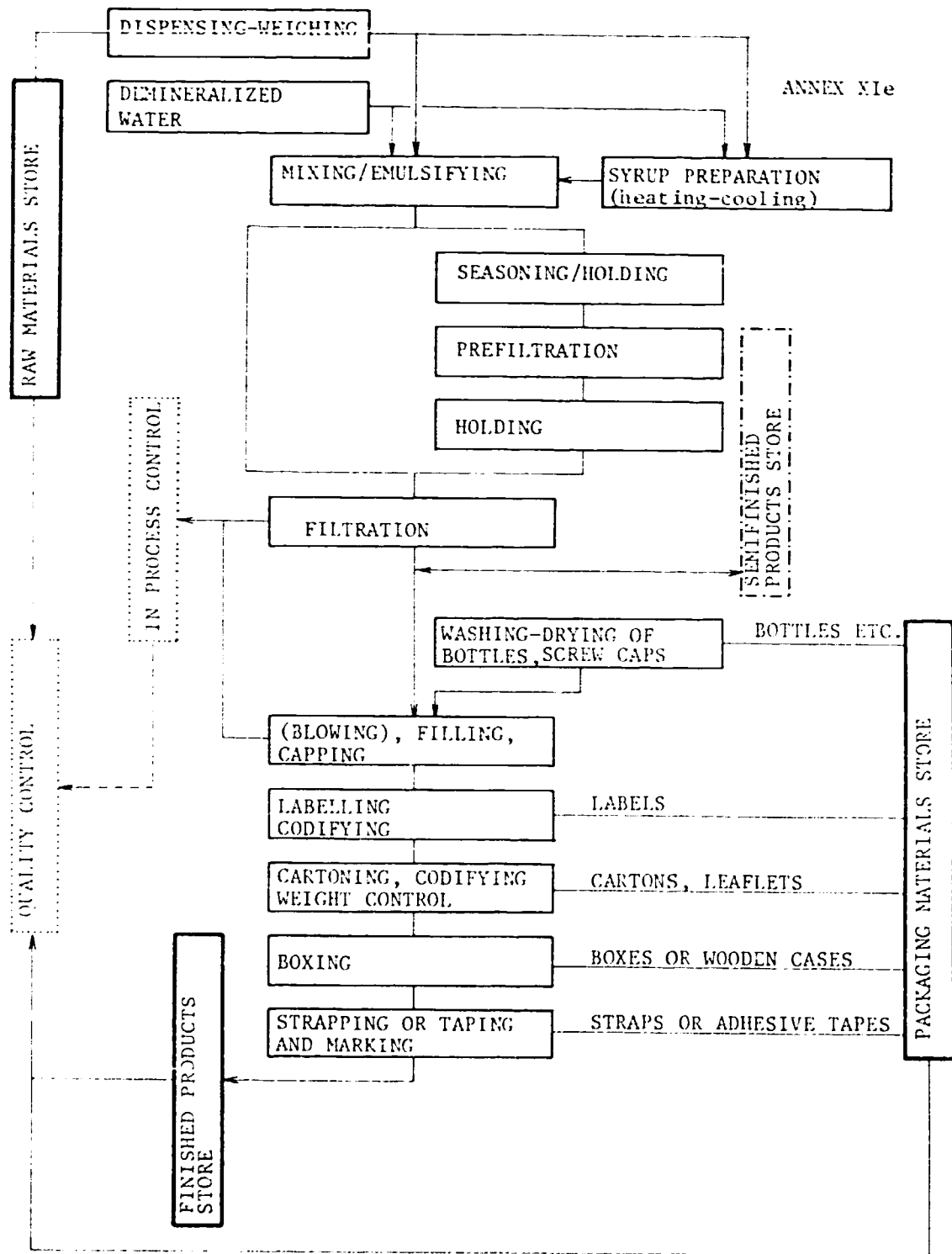
Flow diagram for formulation of granulates and powders filled into hard gelatine capsules or sachets



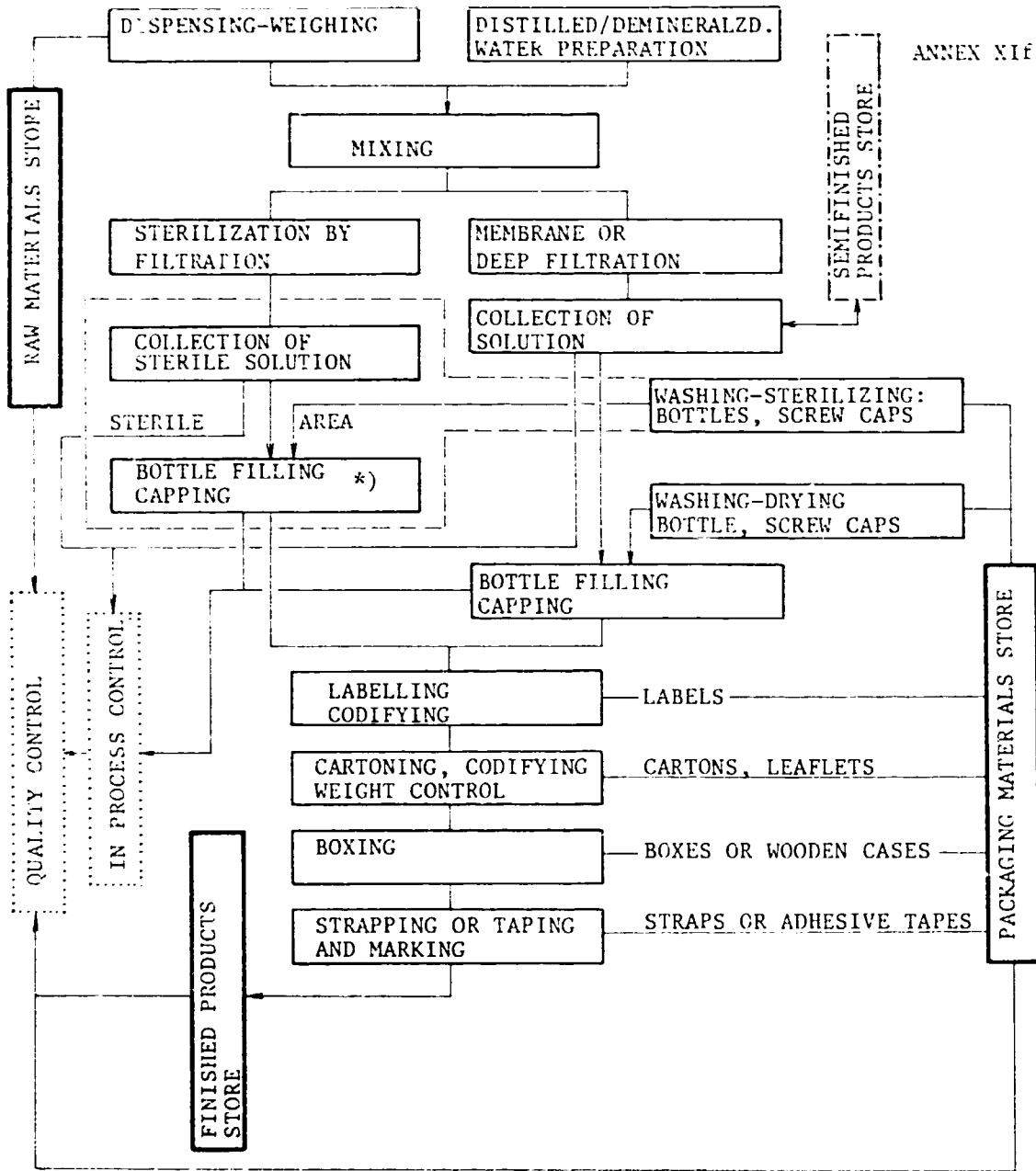
Flow diagram
for manufacture of creams, sterile and non sterile ointments



Flow diagram
for manufacture of suppositories

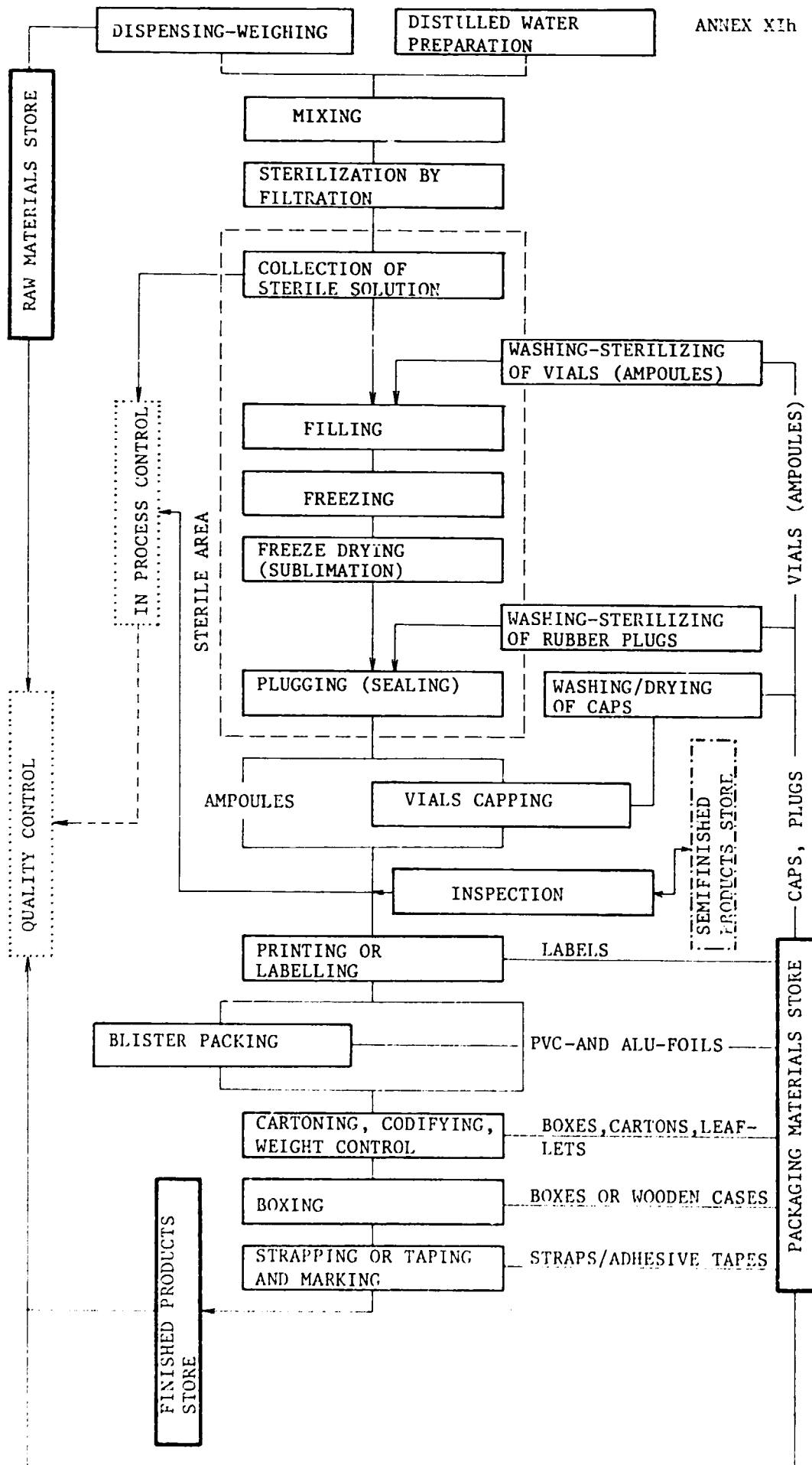


Flow diagram
for manufacture of oral liquids

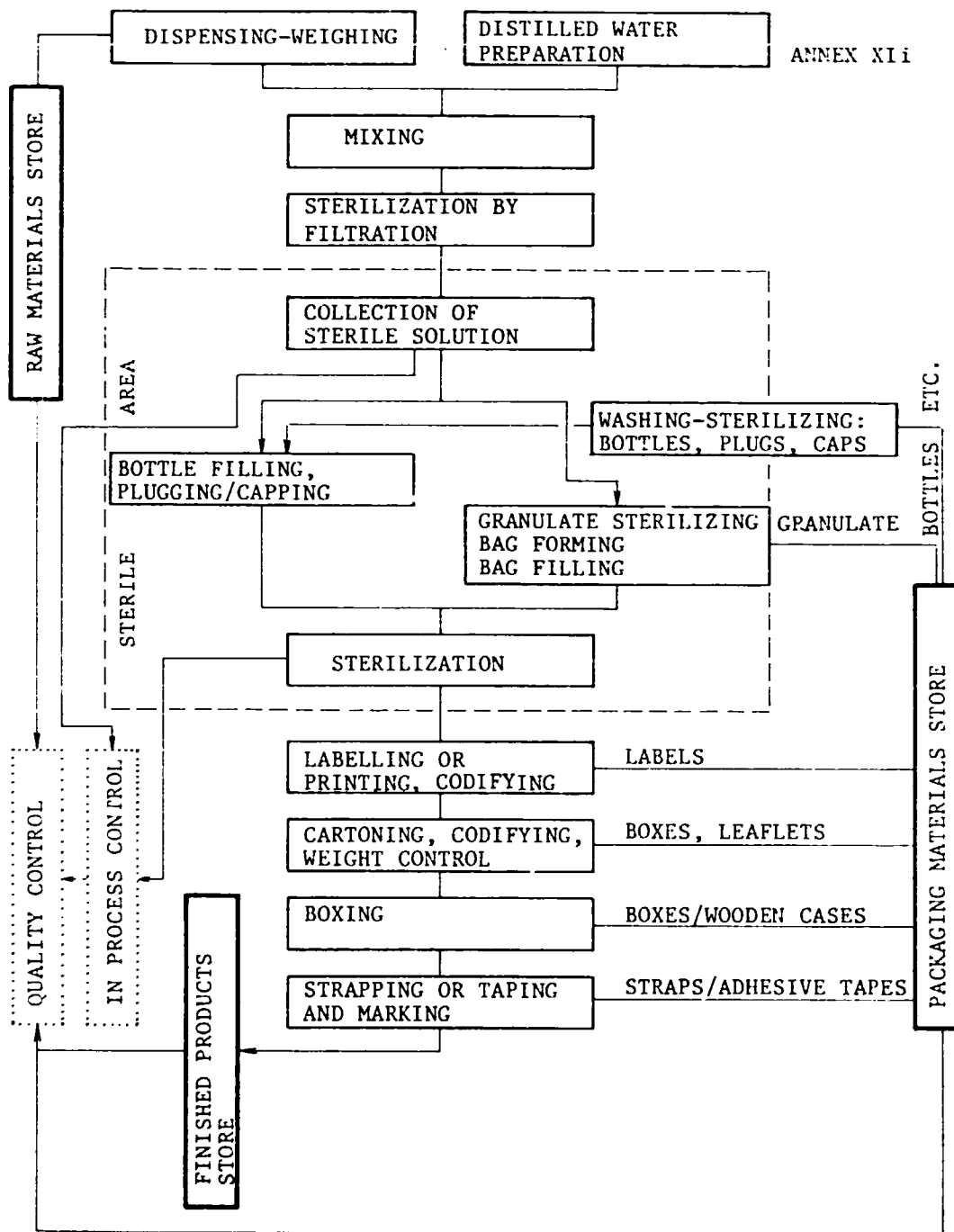


*) For quantities larger than 3 million units per year an alternative would be bottle forming from sterile granulate and filling, in one and the same machine

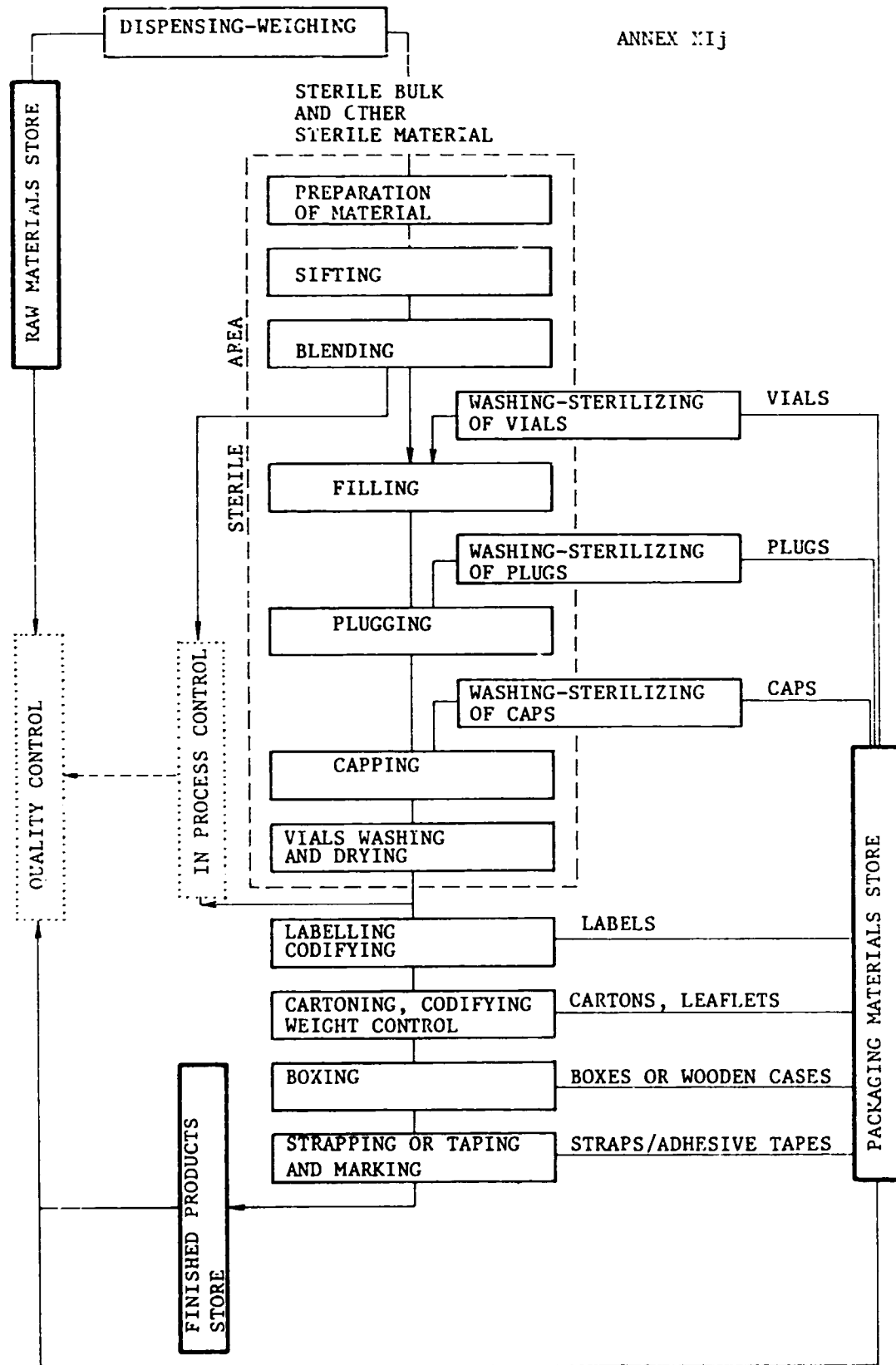
Flow diagram
for manufacture of non-oral liquids
(eye drops, tinctures)



Flow diagram for manufacture of freeze dried parenterals

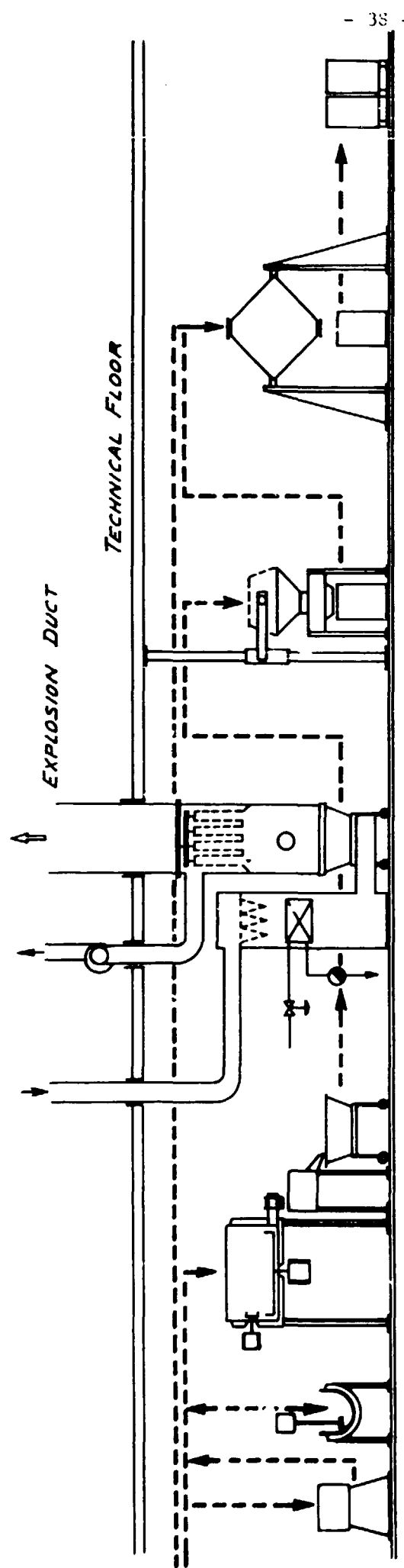


Flow diagram
for manufacture of intravenous infusions



Flow diagram
for blending and filling of antibiotics

FLOW SHEET FOR FORMULATION OF TABLETS



SEMI-FINISHED PRODUCTS STORE

BLENDING
SAMPLES TO IN PROCESS CONTROL

GRANULATE SIFTING

FLUID BED DRYING
ALTERNATIVE:
TRAY-OR VACUUM-DRYING

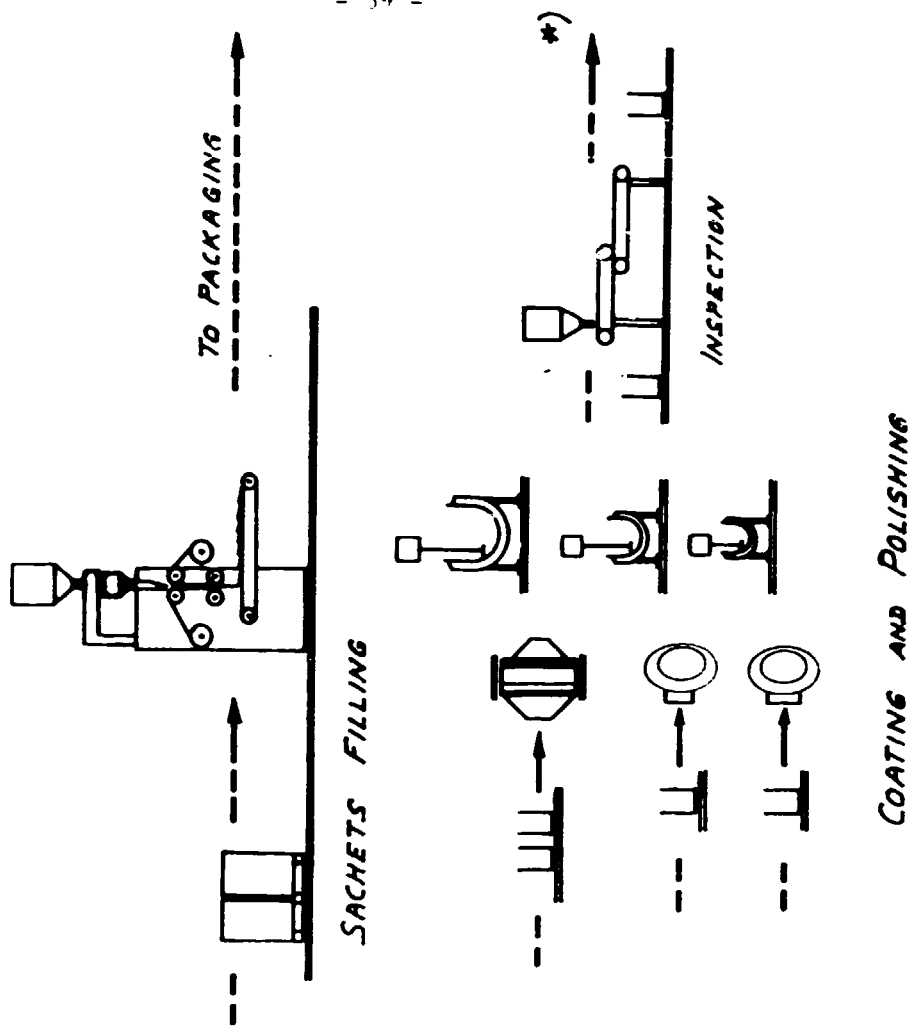
GRANULATE BOWL

WET GRANULATION

MIXING

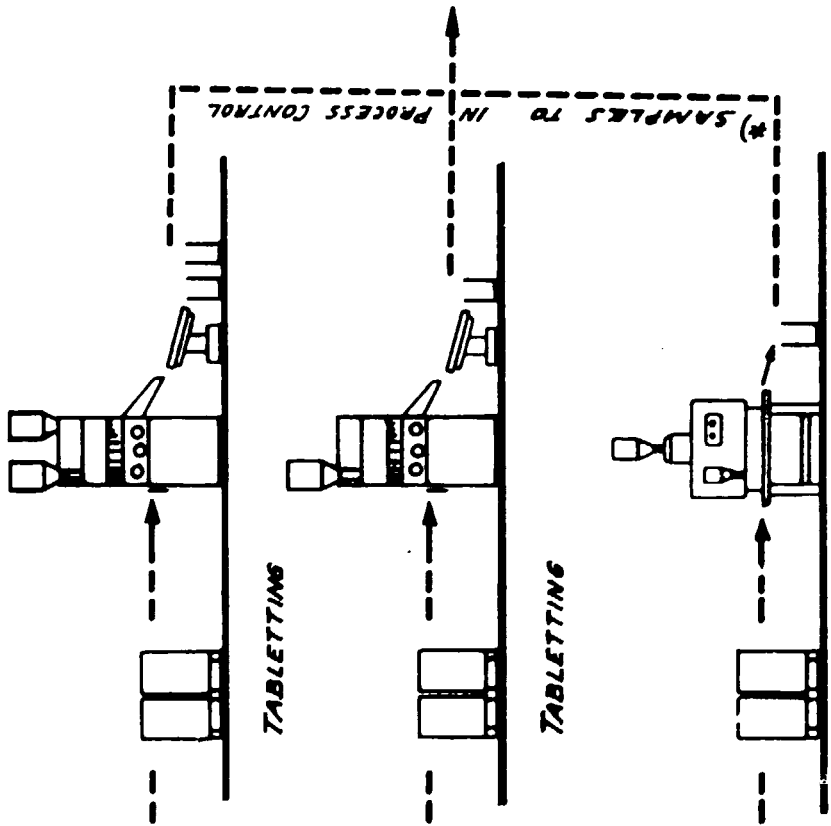
PREPARATION OF
GRANULATION FLUID

GRINDING - SIFTING



COATING AND POLISHING

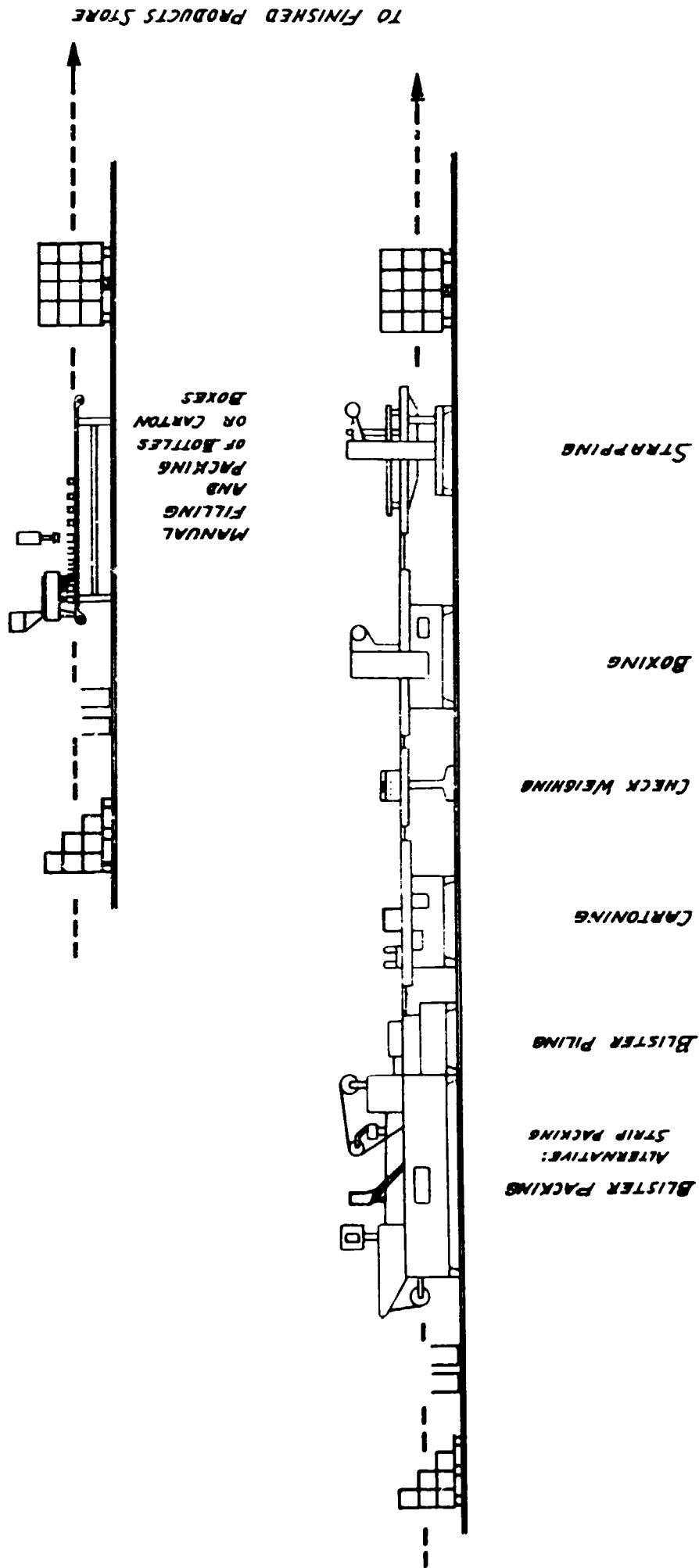
*) TO SEMIFINISHED PRODUCTS STORE OR DIRECT FILLING ON THE STRIP-OR-BLISTER-PACKING MACHINE

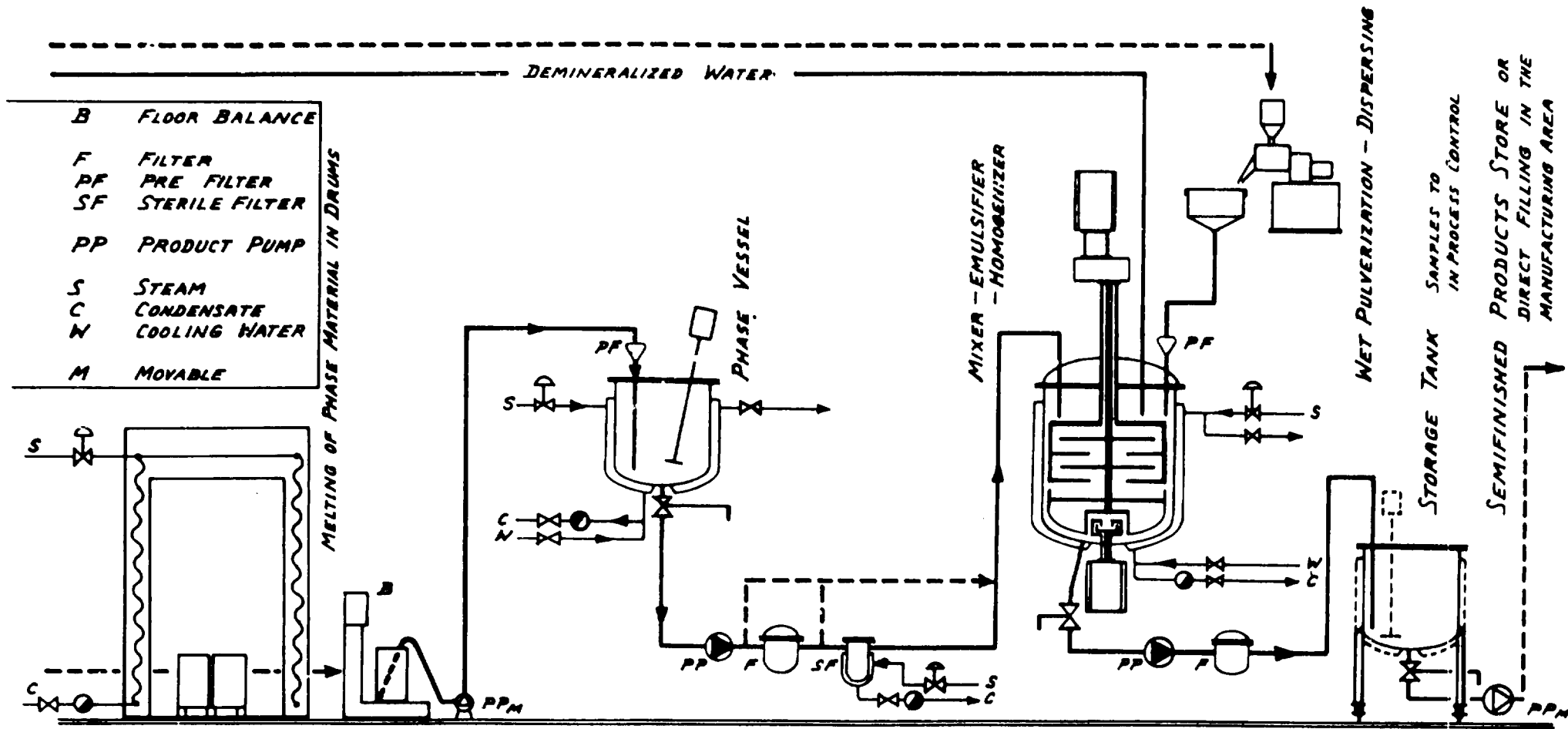


TABLETTING

FLOW SHEET FOR TABLETTING, COATING AND FILLING OF CAPSULES AND SACHETS

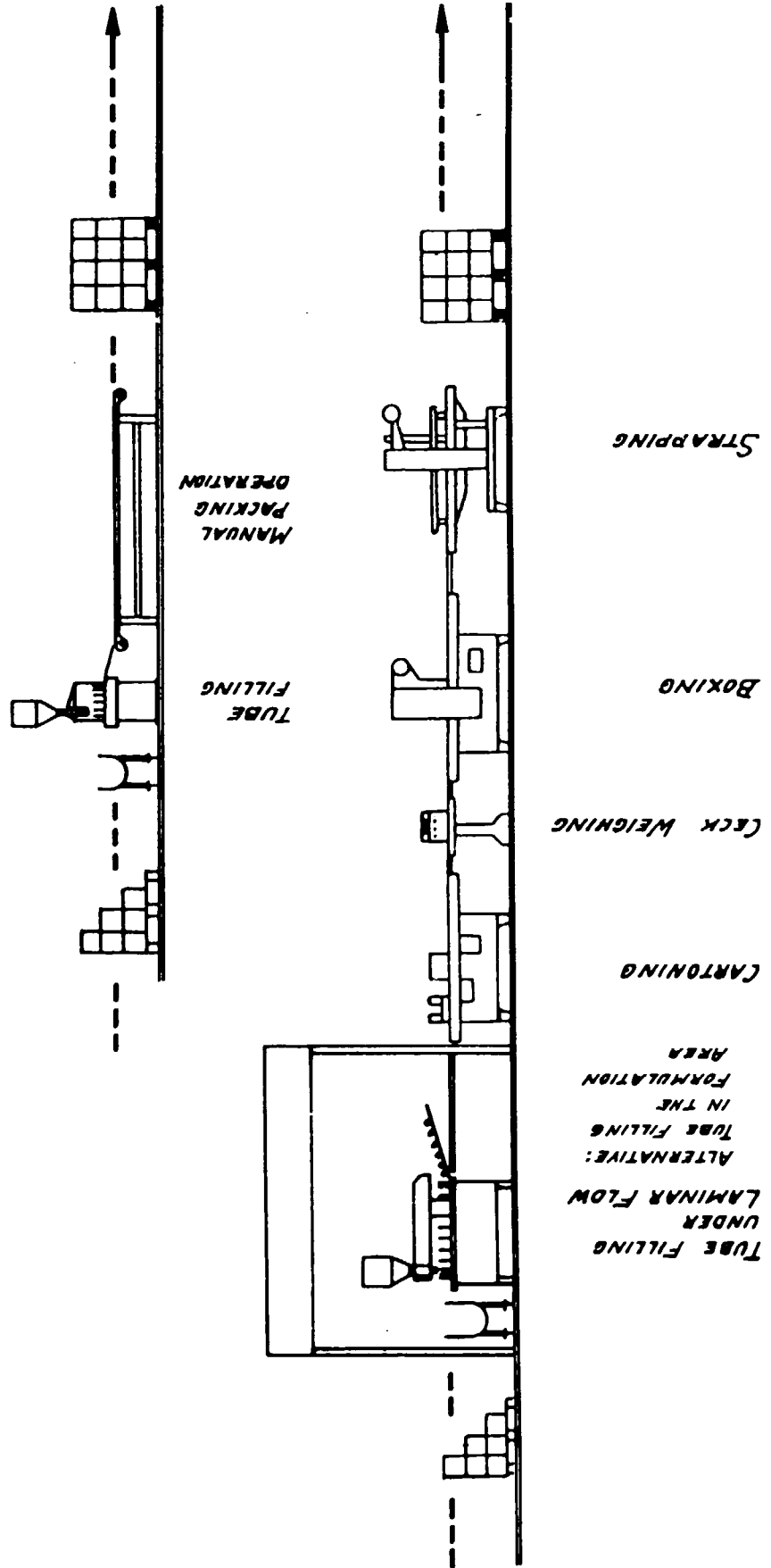
FLOW SHEET FOR FILLING AND MACHINE - OR MANUAL - PACKING
OF SOLID DOSAGE FORMS

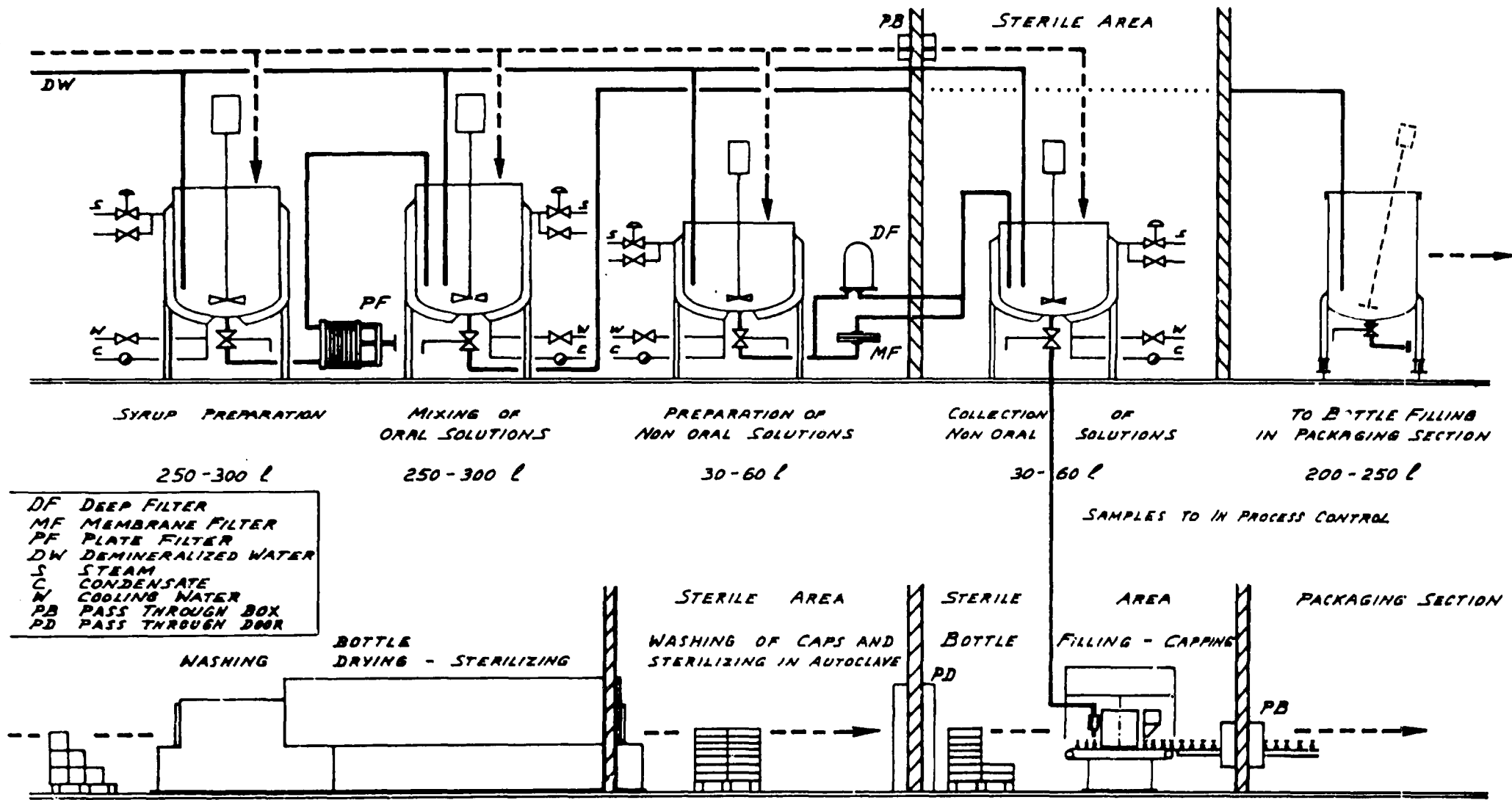




FLOW SHEET FOR MANUFACTURE OF CREAMS, TOPICAL AND OPHTHALMIC OINTMENTS

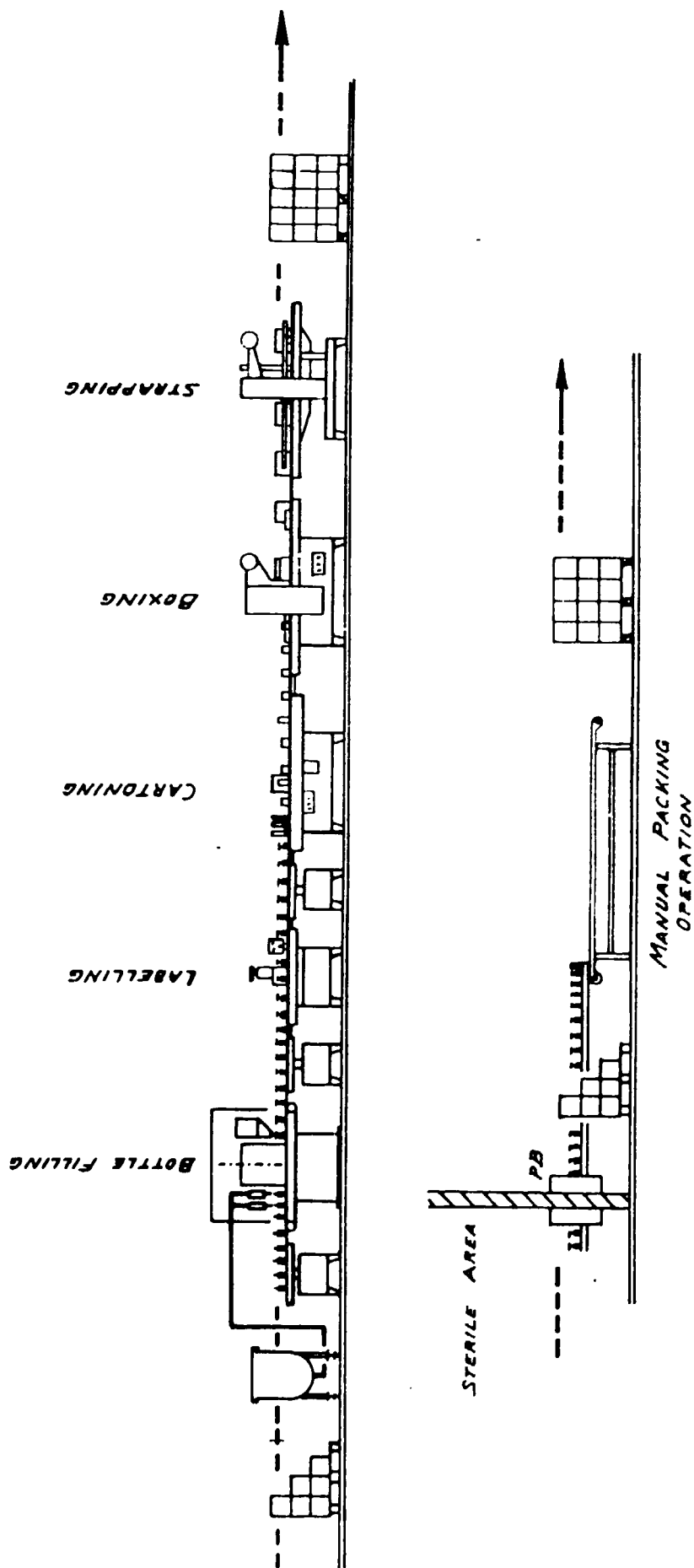
FLOW SHEET FOR FILLING AND MACHINE- OR MANUAL- PACKING
OF CREAMS TOPICAL AND OPHTHALMIC OINTMENTS

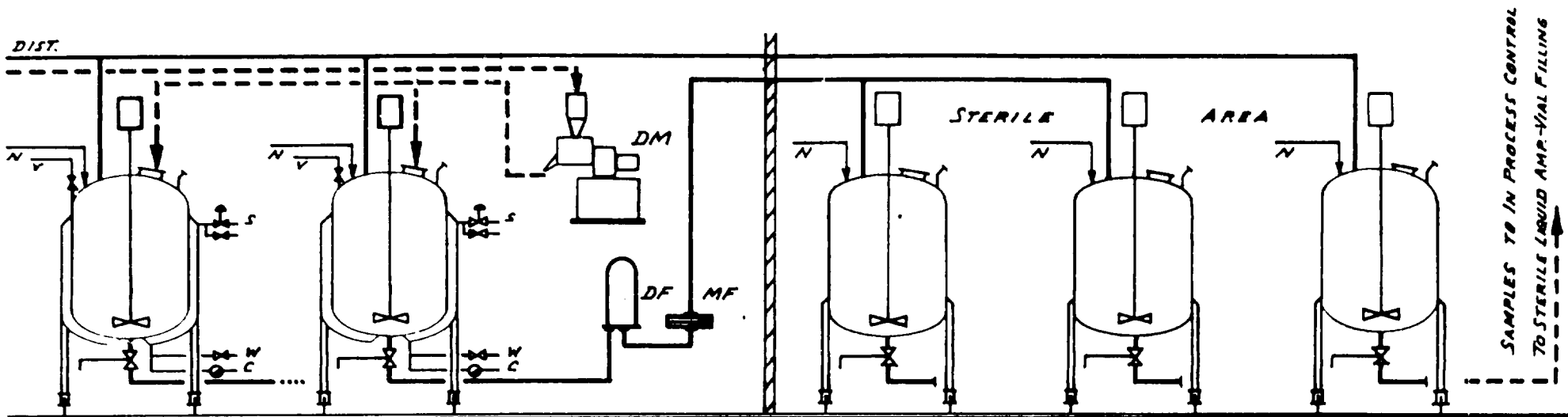




FLOW SHEET FOR MANUFACTURE OF ORAL AND NON ORAL SOLUTIONS
INCL. STERILE FILLING

FLOW SHEET FOR FILLING AND MACHINE- OR MANUAL- PACKING OF ORAL LIQUIDS
AND MANUAL PACKING OF NON ORAL LIQUIDS





PREPARATION - MIXING VESSELS

60 l

60 l

STORAGE VESSELS

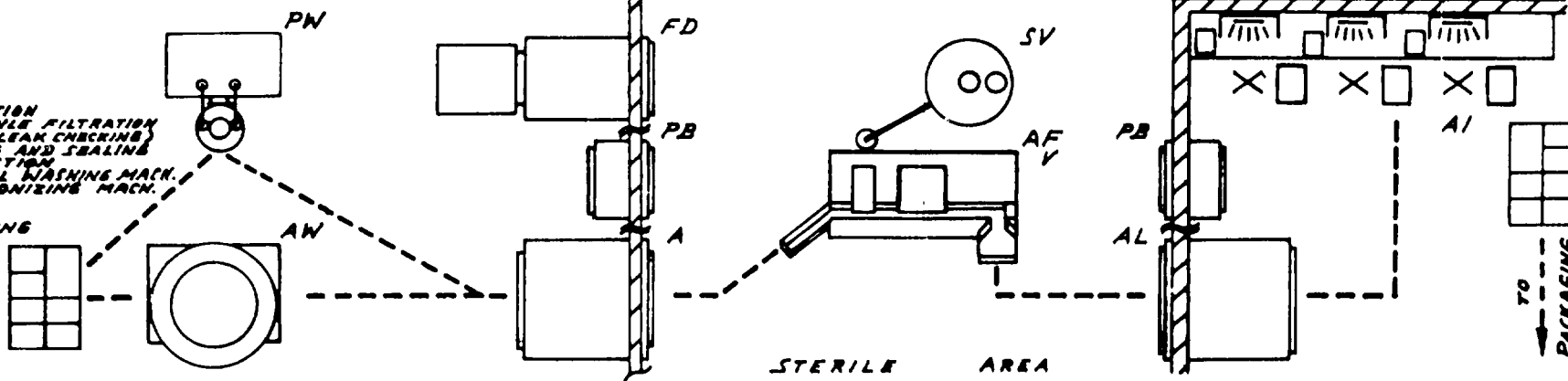
60 OR 160 l

60 OR 160 l

STORAGE VESSEL FOR DISTILLED WATER

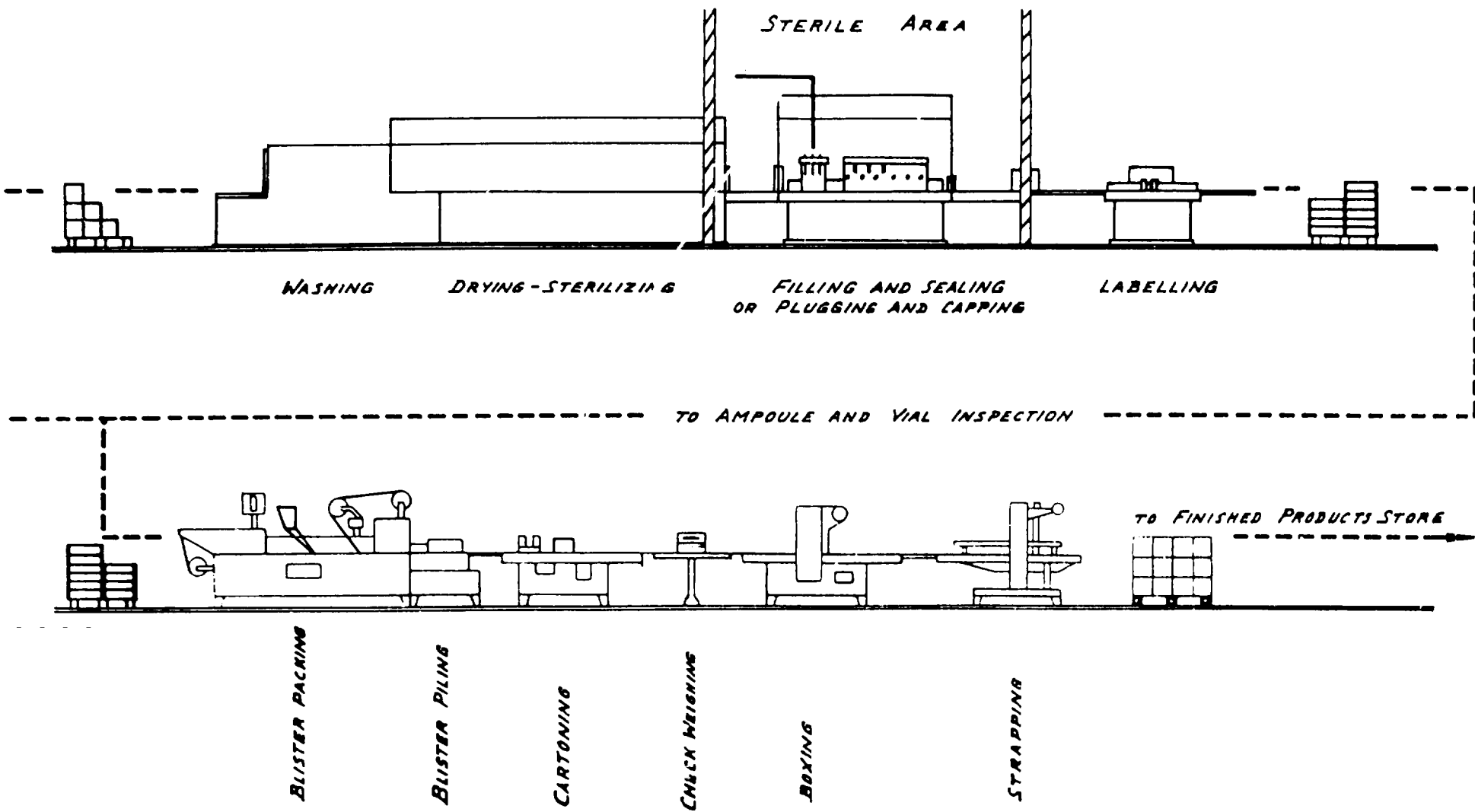
100 l

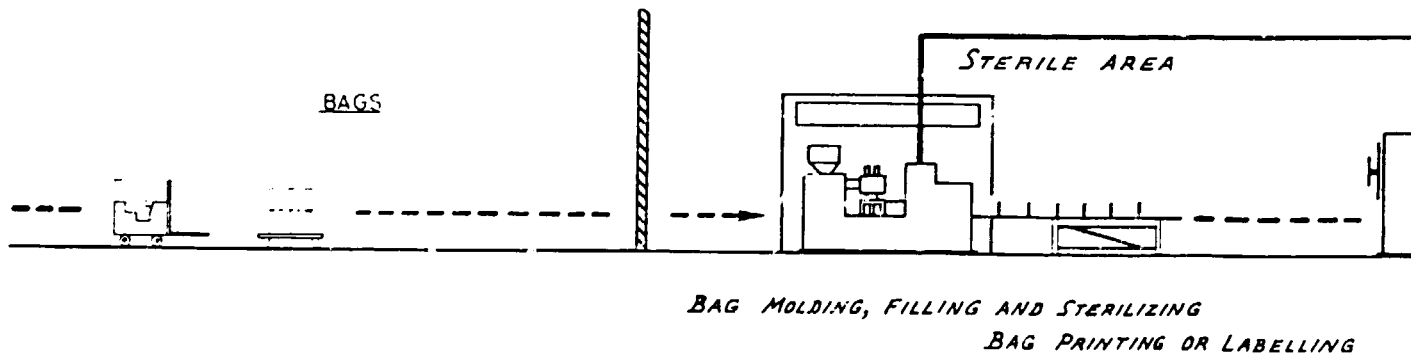
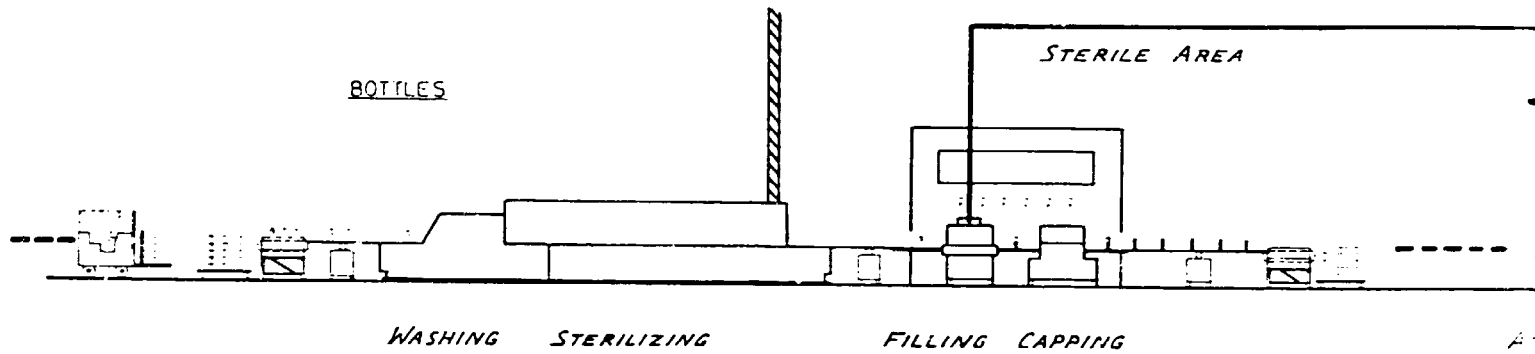
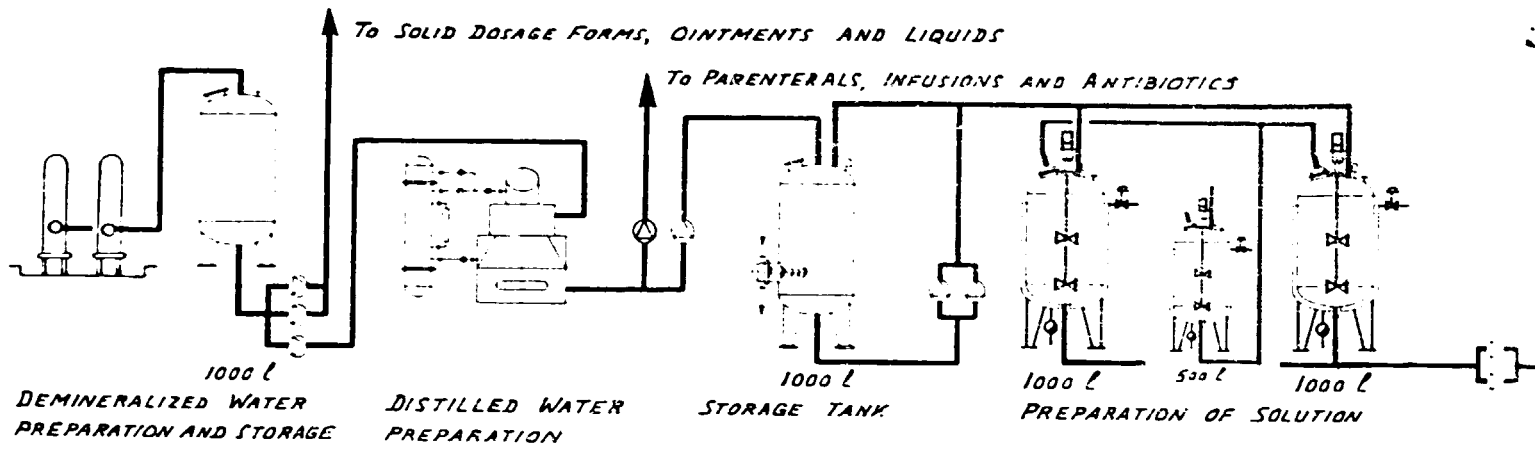
- S STEAM
- C CONDENSATE
- W COOLING WATER
- DIST. DISTILLED WATER
- N NITROGEN
- V VACUUM
- DF DEEP-PRE FILTRATION
- MF MEMBRANE-STERILE FILTRATION
- AL AUTOCLAVE (WITH LEAK CHECKING)
- AF AMPHOLE FILLING AND SEALING
- AI AMPHOLE INSPECTION
- AW AMPHOLE AND VIAL WASHING MACH.
- DM DISPERSING-MICRONIZING MACH.
- FD FREEZE DRIER
- PB PASS THROUGH BOX
- PW PLEW-CAP WASHING AND STERILIZING EQUIPMENT
- SV STORAGE VESSEL
- Y ALTERNATIVE: VIAL FILLING, PLUGGING AND CAPPING MACH.



FLOW SHEET FOR MANUFACTURE AND FILLING OF PARENTERALS

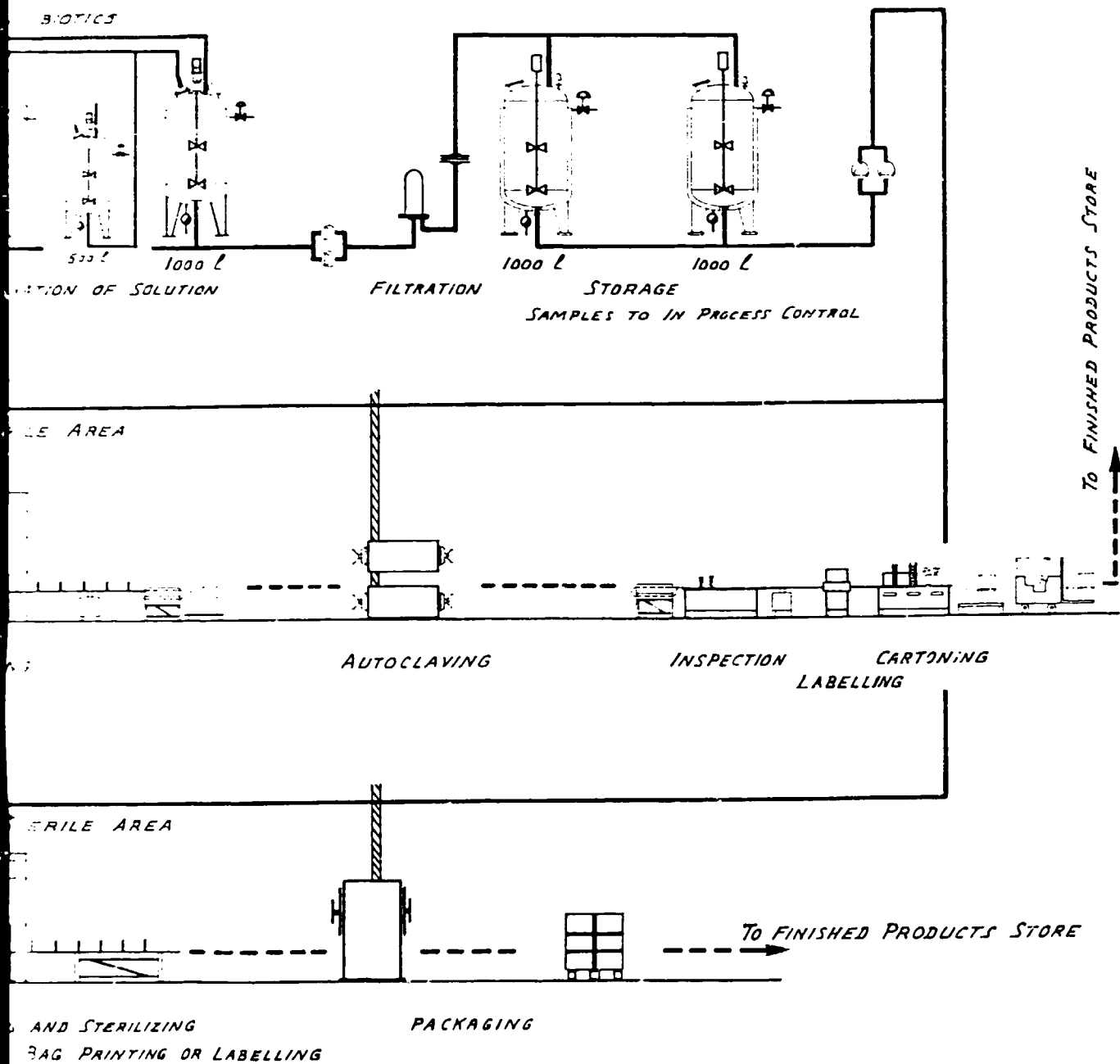
FLOW SHEET FOR WASHING, DRYING, STERILIZATION, FILLING AND SEALING OF AMPDULES OR PLUGGING AND CAPPING OF VIALS, FILLED WITH STERILE LIQUID FOR INJECTION. PACKAGING OF ALL PARENTERALS - EXCLUDING INFUSIONS





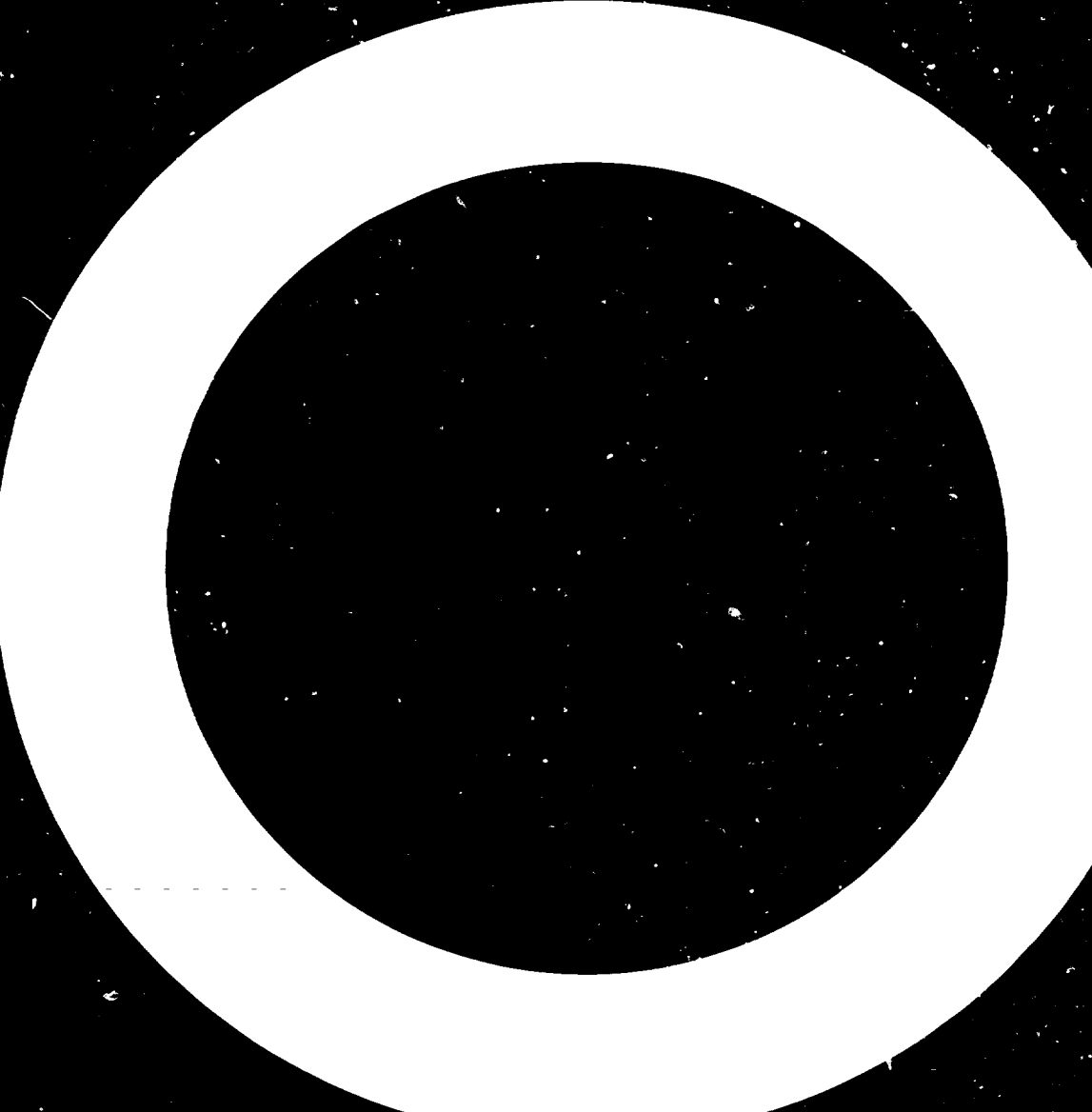
SECTION 1

FLOW SHEET FOR PREPARATION, FILLING AND

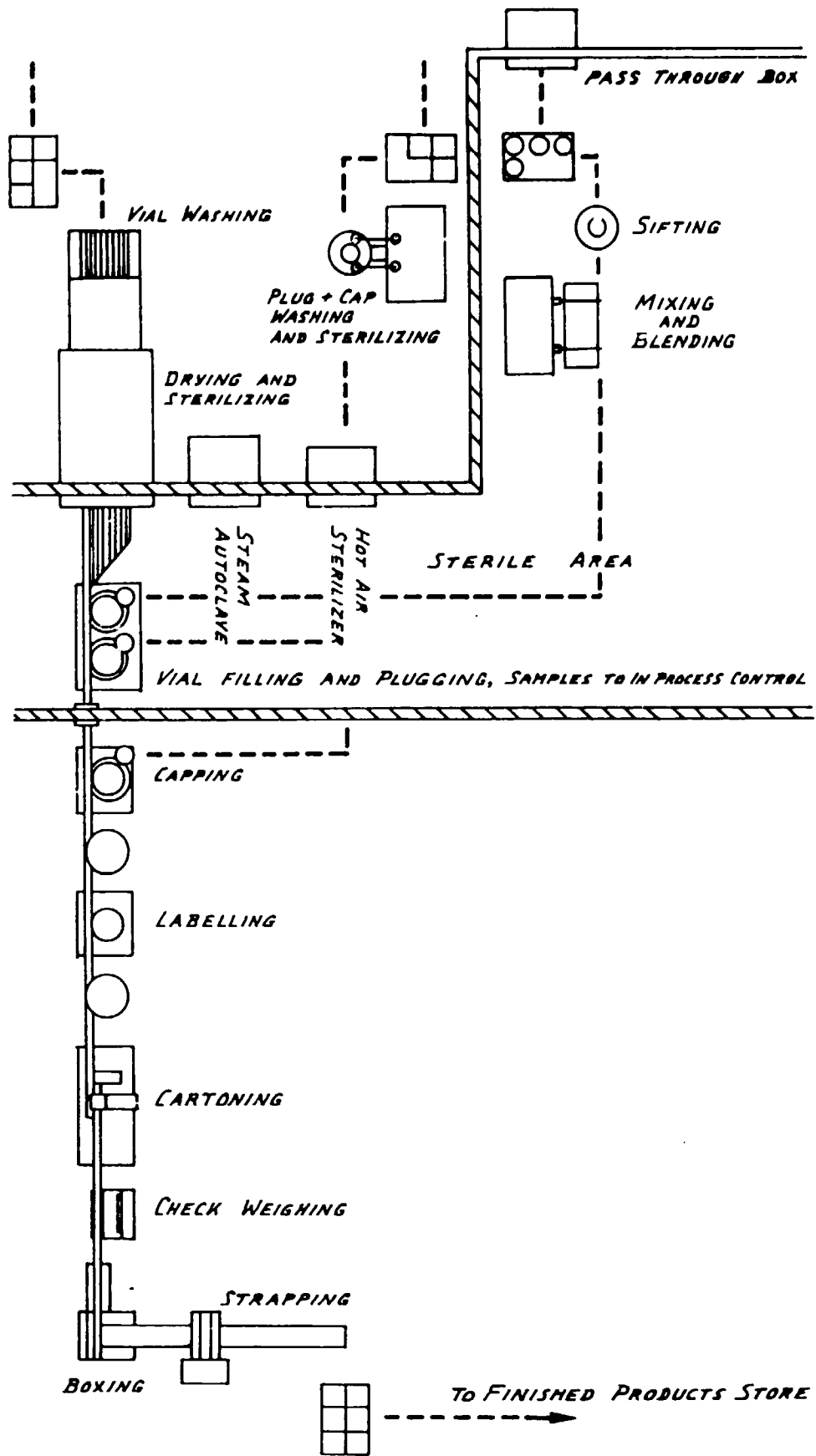


SECTION 2

PREPARATION, FILLING AND PACKING OF INFUSIONS



FLOW SHEET FOR BLENDING, FILLING AND PACKING OF ANTIBIOTICS



ANNEX XII K

ANNEX XIII: INDICATIVE MAJOR EQUIPMENT/MACHINE LIST FOR THE PHARMACEUTICAL FORMULATION AND PACKAGING PLANT

giving capacity range, approx. energy consumption, approx. price range (including one set of operating tools), number required for production as outlined in ANNEX II, and some possible suppliers: These sheets also cover requirements of furniture, fixtures and personnel conveniences installations.

Room	Item	Description of equipment/machines, possible suppliers and their contry of origin ¹⁾	Parts in contact with the product ²⁾	Capacity	Approx.energy consumption	Approx.price range in US\$ ³⁾	No.
1	2	3	4	5	6	7	8
<u>MANUFACTURING and PACKAGING</u>							
<u>Solid dosage forms:</u>							
1-4	101	Grinding and slugging machine: ALEXANDER WERK (D), FITZPATRICK(GB, USA), FREWITT(CH), HUTT(D), MANESTY(GB)	CrNi	150-1500kg /h	0.75-5.5kW	9'000-15'000	1
	102	Mechanical sifter, movable, variable mesh sizes 12-120: ALLGAIER(D), RUSSEL-FINEX (B), VIBROWEST(I)	CrNi	300-1000kg /h	0.4-1.5kW	4'000-6'000	1
	103/4	Preparation of granulation fluid in a vessel, jacketed (tiltable), with stirrer: COMBER(I), PRESS INDUSTRIA(I), SEITZ(D), THERMA(CH), and bakery equipment suppliers	CrNi	10-60 l	1-2.5kW steam=1-4bar or 10-15kW	5'000-20'000	1-2
	105	High speed mixer with chopper, mech. discharge to wet granulation: DIERKS(D), FIELDER(GB), LOEDIGE(D)	CrNi/CrNiMo	300-600 l	20-48kW	70'000-80'000	1
	106	Planetary mixer with spare bowl: AM.MACHINE (USA), BAKER PERKINS(GB), COLLETTE(B), MOLTENI(I), SPANGENBERG(D)	CrNi	100-200 l	6-7kW	35'000-45'000	1

- 1) The supplier's country is indicated by its abbreviated letter symbol.
 2) Either stainless steel with: Cr-chromium, Mo-molybdenum, Ni-nickel, Ti-titanium, or other materials as specified.
 3) Price = ex works, value about mid 1985.

1	2	3	4	5	6	7	8
	107/7.1	Wet granulating machine with mesh sizes Ø 3-8mm: AESCHBACH(CH), ALEXANDER WERK (D), COLTON(USA), FREWITT(CH), MANESTY (GB), VIANI(I). Alternative=oscillating system.	CrNi	200-1000kg /h	0.75-4kW	15'000-20'000	1
7-6	108/9	Fluid bed drier, product container + 1 spare, flame proof motor for ventilation; price depending on optionals: AEROMATIC(CH), GLATT(D), STOKES(USA)	CrNi	60-180kg/ batch	15-22kW steam=1-4 bar 150-300kg/h compr.air=6bar	90'000-100'000	1
	110	Container lifting device: AEROMATIC(CH), GLATT(D)	mild steel	150-250kg	1.2-1.5kW	16'000-20'000	1
	111	Tray drier: AERG(CH), GLATT(D), MANESTY(GB), COLTON(USA)	CrNi/galv.steel	60-120kg	1-4kW steam=3bar 50-150kg/h	15'000-35'000	1
	112	Alternative=vacuum drier for drying under exclusion of oxygene: ITALVACUUM(I), MANESTY(GB), ANGELO PILOTA(I)					
	113	Dry granulating machine with knifeedged, rotating blades, different screen sizes, variable speed: DANIONI ITALO(I), FITZ- PATRICK(GB, USA)	CrNi	500-1500kg /h	4-5.5kW	15'000-20'000	1
	114	Alternative: oscillating granulation machine with different screen sizes: COLTON(USA), FREWITT(CH), MANESTY(GB)	CrNi	500-1000kg /h	0.75-1.1kW	9'000-16'000	1
	115	Blending equipment: ENGELSMANN(D), ANGELO PILOTA(I), PATTERSON-KELLEY(USA)	CrNi	400-600 l	3-5kW	15'000-25'000	1
	116	Drum blender: BACHOFEN-"Turbula"(CH), ENGELSMANN(D), MANESTY(GB)	CrNi	60-200 l	0.4-2.2kW	2'500-26'000	1

1	2	3	4	5	6	7	8
T-11	117	Rotary tableting machine, 15-25 stations, for CrNi/brass 3-25 mm T Ø, max.compression=100kN (~ 10 tons): COLTON(USA), FETTE(D), HATA(J), KIKUSUI(J), KILIAN(D), KORSCH(D), MANESTY(GB), STOKES (USA)		up to 130'000T/h	1.5-7.5kW	25'000-80'000	1
	118	Rotary tableting machine, 12-20 stations for 3-28mm TØ, max.compression=40-60kN (~ 4-6 tons): HATA(J), KILIAN(D), MANESTY (GB), STOKES(USA)	CrNi/brass	up to 60'000T/h	0.75-3kW	25'000-35'000	1
	119	Special tableting machine for dry coating: KILIAN-"Prescoter"(D), MANESTY-"Drycota" (GB)	CrNi/brass	15'000-50'000T/h	1.5-2.5kW	50'000-75'000
	120	Special tableting machine for double layer compression: KILIAN-"Prescoter"(D)	CrNi/brass	14'000-40'000T/h	2.3kW	50'000-60'000
	121.1, etc.	Tableting tools for various tablet forms and face shapes, one set consisting of one upper-, one lower-punch and one die: COLTON(USA), KILIAN(D), KRÄMER(CH), MANESTY (GB), STOKES(USA)	special tough steel with hardened punch tip and die bore 1)	12-25 sets - per machine +2-5 sets as spare		100-250 per set 2)3)
	.	1) Alternative: tool steel, hardened surface and chromium plated punch face.					
		2) price dependent on steel quality and surface treatment, free gliding or guided punches, diameter of tablet, shape (flat, curved, bevelled edge, etc.) and embossing and/or brake line(s) on tablet face.					
		3) number dependent on different diameters and shapes of the product mix.					

1	2	3	4	5	6	7	8
	122/3	Tablet dedusting device, normally supplied with tableting machine or e.g. by KRAEMER (CH)	CrNi	according to tabl. machine output	0.5kW	2'000-3'000	2
	124	Tablet punches and dies polishing equipment: KRAEMER(CH), MANESTY(GB)			0.3kW	5'500	1
	125	Tablet tool measuring devices: micrometer, slide gauge, etc.	CrNi	tablet diameter, punch length	-	200-400	1
1-7	126/7	Preparation vessel, jacketed, with stirrer for coating solutions: COLLETTE (B), DIESEL(D), PELLEGRINI(I), MANESTY (GB), SEITZ(D), etc.	CrNi	60-160 l	0.5-1kW steam=3bar or up to 5.5kW	6'000-15'000	2
	128/9	Coating pan for standard coating with hot air blower: BRUCKS(D), MANESTY(GB), PELLEGRINI(I). (Polishing in coating- or special-drum).	CrNi or copper	50-130kg end weight	0.5-3kW	8'000-12'000	2
	130/1	Film- and large quantity coating with spraying system and air conditioned ventilation: FREUND-LOEDIGE(J-D), MANESTY-"Accela-Cota"(GB), PELLEGRINI(I)		100-300kg end weight	4.5-12.5kW	50'000-120'000	1-2
	132	Drying of coated tablets in ventilated drums: MEISSNER and WURST(D). Alternative=drying in coating pans or tray driers	CrNi	120-200 l per drum, 8-10 drums per system	~3.5kW	~ 20'000	1
1-12	133	Printing of coated tablets (if required): HARTNETT(USA), MARKEM(USA)	CrNi/plastic	60'000- 1'000'000 CT/h	0.4-0.8kW	35'000-70'000	1
	134	Coated tablet inspection belt system: PELUI/CITUS(CH/F), GLATT(D), MASCHIMPEX (D)	CrNi/plastic	80-100kg/h	0.2-1.4kW	10'000-25'000	1

1	2	3	4	5	6	7	8
T-14	135	Capsule filling machine: BOSCH/HOEFLIGER + KARG(D), MG-2(I), ZANASI(I) For vacuum and spot ventilation - additional	CrNi/brass	4000-50'000 C/h for sizes Nr. 5-000	2-3.5kW 1.5-2.5 kW	15'000-80'000	1
	136	Capsule polishing in drum mixer with salt: BACHOFEN-"Turbula"(CH), ENGELSMANN(D), MANESTY(GB)	CrNi	60-200 1	0.4-2.2 kW	2'500-26'000	1
	137	Capsule inspection belt system: PELUI/CITUS(CH/F)	CrNi/plastic	up to 50'000 C/h	1.5kW	20'000	1
	138	Capsule printing (if needed): HARTNETT(USA), MARKEM(USA)	CrNi/plastic	40'000-800'000 C/h	0.4-0.8 kW	35'000-70'000	(1)
T-10	139	Granulate/powder filling machine for bottles: BOSCH/HOEFLIGER+KARG(D), PERRY(USA), ZANASI(I). Alternative: by hand	CrNi/brass	3000-7000 bottles/h	0.5-3kW	20'000-30'000	1 and
	140	Bottle/vial cap inserting+closing machine: AMPACK(CH), BOSCH/HOEFLIGER+KARG(D), KING(GB), LAKSO(USA), ZANASI(I). Alternative: by hand	CrNi/brass	according to filling machine	0.5-0.7kW	6'000-16'000	1
	141	Granulate/powder filling machine for sachets: ACMA(I), BOSCH/HOEFLIGER+KARG(D), 2M di M. MARCHESINI(I), SOTECO/IMA(I)	CrNi/brass	4000 sachets/h	3kW	20'000-50'000	or 1
	142/3	Tin filling and sealing device: KING(GB)	aluminium, CrNi or surface treated steel	by hand	-	300	1-2

1	2	3	4	5	6	7	8
T-5		In process control laboratory:					
	144	- tablet friabilator: ENGELSMANN(D), ROCHE(CH)			light	500	1
	145	- tablet hardness tester: SCHLEUNIGER(CH)			light	1'000	1
	146	- tablet disintegration tester: SOTAX(CH), VANDERKAMP(USA)			0.75kW	2'500	1
	147	- microscope: LEITZ(D)			light	2'500	1
	148	- water bath : HAAKE(D), SALVIS(CH)			3kW	1'700	1
	149	- moisture tester: BRABENDER(D)			1.2	5'000	1
	150	- optical precision balance: GIBERTINI(I), METTLER(CH), SAUTER(D)	CrNi	0-2kg	light	900-1'300	1
	151	- laboratory cabinet: BRABENDER(D), GALLO(I), HAAKE(D), VILLA(I), SALVIS(CH)		100-1601	1.5-3kW	800-1'500	1
	152	- laboratory bench, lavabo, compressed air					
	153	- set of sieves	CrNi		-	250	1
T-1	160	Washing and drying machine for bottles: GILOWY(D), NERI(I), PROT(I), ZANASI(I).	CrNi	up to 3000 bottles	~ 10kW	25'000-35'000	1
	161	For drying use tray drier or extra machine as an alternative		/h			
	162	Cap cleaning device/machine This room is used also for cleaning of equipment and machines.	CrNi	up to 3000 caps/h	~ 2kW	3'000	1
P-6/7	163	Bottle filling machine for tablets, coated tablets, capsules (if not filled into strips or blister packs): KING(GB), LAKSO(USA); (For powders: BOSCH/HOEFLIGER+KARG(D), PERRY(USA), ZANASI(I))	CrNi (plastic)	4000-6000 bottles/h	~ 0.5kW	6'000-50'000	1
	(139)					(25'000- 50'000)	(.....)
	164	Cotton inserting machine: KING(GB), LAKSO(USA)	CrNi (rubber)	up to 6000 bottles/h	~ 1 kW	20'000-25'000	1
	165	Capping machine: FARMOMAC(I), KING(GB), LAKSO (USA)	CrNi (rubber)	2500-4800 caps/h	~ 1 kW	~ 10'000	1

1	2	3	4	5	6	7	8
	166	Pilfer proof swaging machine: FARMOMAC(I), HOLTZ(D)	CrNi	up to 6000 caps/h	2-2.5 kW	~10'000	1
	167	Labelling machine on paper-glue basis: BOSCH/STRUNCK(D), GNUDI(I), NERI(I), JOHANN WEISS(D)	CrNi/brass	up to 7000 labels/h	0.5-1.5 kW	15'000-30'000	(1)
	168	Labelling machine for adhesive label bands: HERMANN(D), GUHL+SCHEIBLER(CH), STE.PILOT(F), J. WEISS(D)	CrNi/brass	up to 7000 labels/h	1.0-2.5 kW	3'000-7'000	1
	169	Labelling machine with printing equipment: PRONTOHOT-HAPA(CH)	CrNi/rubber	5000-10'000 prints +labels/h	~4kW	75'000-85'000	(1)
P-5	170	Strip packing machine O. HAENSEL(D), IMA(I), UHLMANN(D)	PVC-aluminium or ACLAR or similar	up to 60'000T/h	2.1-2.6 kW	20'000-50'000	1
	171	Blister pack machine with printing device: BOSCH/HOEFLIGER+KARG(D), HARRO HOEFLIGER(D), IMA(I), UHLMANN(D)	PVC-aluminium or ACLAR or similar	up to 150'000T/h (9000-18000 blisters/h)	8-20 kW	70'000-90'000	(1)
	171.1	Do. but with transfer mechanism and attached cartoning machine	CrNi/brass	3000-5000 folding cartons/h	10-24 kW	100'000-160'000	1
	172	Small or semi automatic cartoning machine: BOSCH/HOEFLIGER+KARG(D), CAM(I), IWK(D), JONES(USA), 2 M di M. MARCHESINI(I), PETRI(D), UHLMANN(D)	CrNi/brass	up to 5000 folding cartons/h	1-5 kW	50'000-100'000	1

1	2	3	4	5	6	7	8
P-5 P-6/7	173/4	Check weigher: BOSCH/HOEFLIGER+KARG(D), COLLISCHAN (D), IWK(D), OPTIMA(D), TECNOEUROPA-ELETTROMECCANICA(I), UHLMANN(D)	plastic, rubber	up to 30'000 cartons/h, depending on size and weight	0.3-0.6 kW	14'000-20'000	1-2
	175/6	Bundling machine (if need be): AUCOUTURIER (F), CAM(I), GM(I), SOLLAS(NL), PESTER(D), UHLMANN(D)	CrNi/brass	900-2000 bundles/h	1-4 kW	15'000-40'000	1-2
	177/8	Case packer-"boxing" (if need be): CAM(I), LINGENFELDER(D)	CrNi/brass	600-700 cases/h	0.3-0.5 kW	13'000-25'000	1-2
	179/180	Strapping equipment - hand/machine: CYCLOP (USA), SIGNODE(D)	-	hand operated/ 300-600/h	-/0.6-1 kW	600/8'000	2
P-6/7	181	Conveyor belt working table for up to 10 packers, 5 m long: MASCHIMPEX(D), ROTZINGER(CH), STOECKLIN(CH), etc.	plastic, rubber	0.1-0.5 m/ sec. belt velocity	0.3-0.5 kW	6'000-12'000	1
T	182/3/4	Pallet hand truck: AB-BYGG(S), JUNG- HEINRICH(D), LANSING(GB), STOECKLIN(CH), TOYOTA(J), OM(I), etc.	(Nylon wheels because of floor load)	2000 kg	-	~ 500	3
T	185	Electro-hydraulic hand fork lift truck: AB-BYGG(S), JUNG-HEINRICH(D), STOECKLIN(CH)	(castor + fork wheels = Nylon because of floor load)	800 kg	battery or 2 kW	5'000-17'000	1
T-3		Semifinished products store: racks, shelves, pallets					
T-3, etc.		General: furniture, 1 telephone, 1 type- writer, wash basins, warm and cold water, compr.air/6 bar, steam/3 bar or hot water					

1	2	3	4	5	6	7	8
T-4/8	186/7	Floor balance (with spot ventilation): AVERY(GB), BIZERBA(D), BUSCH(CH), TOLEDO (USA). *) Alternative = movable	mild steel or CrNi	100-250 kg ^{*)} (+ pre load)	(light)	1'500-5'000	2
T-4/7/ 11/12	188/91	Table balance: AVERY(GB), BIZERBA(D), BUSCH (CH), TOLEDO(USA)	CrNi	30-50 kg (+ pre load)	(light)	1'000-4'000	4
T-4/7/ 11	192/3/4	Precision balance: GIBERTINI(I), METTLER(CH), SAUTER(D)	CrNi	0-2 kg	(light)	900-1'300	3
T-2/9		Corridors for technical service and spot ventilation					
		<u>Semi-solid dosage forms:</u>					
		A) Creams, sterile (antiseptic) - non sterile ointments:					
0-3	201	Disintegration/dispersing/wet pulverization machine: BACHOFEN W.A.(CH), COFIN(I), MARCO (USA)	CrNi/CrNiMo	40-400 l	3.5-20 kW	8'000-22'000	1
	202	Phase vessel, jacketed, with stirrer, movable: DIESEL(D), FRYMA(CH), HAGEN+RINAU(D), KRIEGER(CH), SEITZ(D), etc.	CrNi	30-60 l	steam = 3 bar or up to 5.5 kW	7'000-12'000	1
	203	Screen filter: HANSEN(D), WALTHER(D), etc.	CrNi			~ 300	1
0-4	204	Preparation vessel, jacketed, with (variable speed) stirrer and (variable speed) emul- sifier (movable): DIESEL(D), FRYMA(CH), HAGEN+RINAU(D), KRIEGER(CH)	CrNi	100-120 l	10-16 kW steam = 3 bar cooling water	35'000-80'000	1
	205	Additional homogenizing with corundum rim and disk or toothed rim and rotor: FRYMA(CH), PREMIER(USA)	CrNiMo	120-500 kg /h	7.5-11 kW	15'000-20'000	(1)
	206	or by piston homogenization: MANTON GAULIN (USA), ZEHNDER(CH)	CrNiMo	50-500 kg/ h	1.5-2 kW	~ 5'000	(1)

1	2	3	4	5	6	7	8
207	Sterilization by filtration: AMF-CUNO(USA), BALSTON(GB)	CrNiMo/ kieselguhr /glass fibers or pure cellulose	pre filtr.= 600 l/h steriliza- tion = 300 l/h	- -		400-500 400-500	1 1
208	Collection vessel, jacketed, movable, with stirrer: DIESSEL(D), FRYMA(CH), HAGEN+RINAU(D), SEITZ(D);	CrNi	100 l	steam = 3 bar or up 5.5 kW		7'000-12'000	1
209	Alternative = CrNi stainless steel drums: MUELLER(CH/D), etc.	CrNi	50-100 l	-		200-300	4-6
210	Pump for creams, ointments: PONNDORF(D)	plastic hose	30-250 l/h	0.4-0.8 kW		~ 3'500	1
211	Shovel loading pump for creams, ointments: GRACO(USA)	CrNi or CrNiMo	up to 3000 kg/h	compr.air = 54 Ncu.m at 6 bar		~ 13'000	1
212	Ethylene oxide sterilizer: DMB(D), FEDEGARI(I), DE LAMA(I), TERRUZZI CHR.(I), 3M(USA)	CrNi	50-100 l	1-10 kW		15'000-30'000	1
213	Degassing in ventilated cabins: GLATT(D), LUWA(CH), MEISSNER+WURST(D), SKAN(CH), STERIL(I)		300-1000 l	1.5-2 kW		6'000-10'000	1
214	Tube filling with blowing, tale closing, crimping: COLTON(USA), COMADIS(I), GANZHORN+STIRN(D), IWK(D), NORDEN(S), TONAZZI(I)	CrNi	2000-4000 tubes/h	1-2 kW		12'000-30'000	1

1	2	3	4	5	6	7	8
1-2		In process control laboratory:					
	215	- oil and water emission testing apparatus: METTLER(CH)			-	~ 1'000	1
	216	- melting point apparatus: METTLER(CH)			0.1 kW	~ 1'500	1
	217	- apparatus for testing tube crimp tightness:			-	~ 1'000	1
	218	- water bath: HAAKE(D), SALVIS(CH)			3 kW	~ 1'700	1
	219	- optical precision balance: GIBERTINI(I), METTLER(CH), SAUTER(D)	CrNi	0-2 kg	light	900-1'300	1
	220	- laboratory cabinet for drying glassware/ utensils: DRABENDER(D), GALLO(I), HAAKE(D), VILLA(I), SALVIS(CH)		100-160	1 1.5-3 kW	800-1'500	1
	221	- laboratory bench, lavabo, compressed air					1
P-6	222	Tube labelling (which should be avoided!): PONY LABEL RIGHT(USA)	CrNi/brass	500-600 tubes/h	0.6 kW	~ 15'000	(1)
	223	Small or semi automatic cartoning machine: BOSCH/HOEFLIGER+KARG(D), CAM(I), IWK(D), JONES(USA), 2 M di M. MARCHESINI(I), PETRI (D), UHLMANN(D)	CrNi/brass	up to 5000 folding cartons/h	1-5 kW	50'000-100'000	(1)
	224	Alternative (for first phase of production): conveyor belt working table for up to 10 packers, 5 m long: MASCHIMPEX(D), ROTZINGER (CH), STOECKLIN (CH), etc.	plastic, rubber	0.1-0.5 m/ sec. belt velocity	0.3-0.5 kW	6'000-12'000	1
	225	Check weigher: BOSCH/HOEFLIGER+KARG(D), COLLISCHAN(D), IWK(D), OPTIMA(D), TECNO- EUROPA-ELEFROMECCANICA(I), UHLMANN(D)	plastic, rubber	up to 30'000 cartons/h depending on size and weight	0.3-0.6 kW	14'000-20'000	1
	226	Bundling machine (if need be): AUCOUTURIER (F), CAM(I), GM(I), SOLLAS(NL), PESTER(D), UHLMANN(D)	CrNi/brass	900-2000 bundles/h	1-4 kW	15'000-40'000	(1)

1	2	3	4	5	6	7	8
	227	Case packer - "boxing" (if need be): CAM(I), LINGEN-FELDER(D). Alternative = by hand	CrNi/brass	600-700 cases/h	0.3-0.5 kW	13'000-25'000	(1)
	228	Strapping by hand: CYCLOP(USA), SIGNODE(D)	-	up to 300 cases/h	-	~600	1
1-3	229	Floor balance: AVERY(GB), BIZERBA(D), BUSCH(CH), TOLEDO(USA). *) Alternative = movable	mild steel or CrNi	100-250kg ^{*)} (+ pre load)	(light)	1'500-5'300	1
	230	Table balance: AVERY(GB), BIZERBA(D), BUSCH(CH), TOLEDO(USA)	CrNi	30-50 kg (+ pre load)	(light)	1'000-4'000	1
0-1	231	Precision balance: GIBERTINI(I), METTLER(CH), SAUTER(D)	CrNi	0-2 kg	(light)	900-1'300	1
0	232	Pallet hand truck: AB-BYGG(S), JUNG-HEINRICH(D), LANSING(GB), OM(I), STÖCKLIN(CH), TOYOTA(S), etc.	(Nylon wheels because of floor load)	2000 kg	-	500	1
1-3		Semi finished products store: racks, shelves, pallets					
0		General: furniture, wash basins, warm and cold water, compr. air 6 bar, steam 3-8 bar or hot water					
0-1/2		For sterile production: sterile locker room, passage room for goods, sterile clothes					
1-4	233	Laminar flow cabin: GLATT(D), LUWA(CH), MEISSNER+WURST(D), SKAN(CH)		10 cu.m	3.5-4 kW	10'000-20'000	1
1-4	234/5	Pass-through box: GETINGE(S), DE LAMA(I), LEQUEUX(F), SCHAERER(CH), STERIL(I)	aluminium/CrNi	50-100 l	(2.5-4 kW) (+ steam = 3 bar)	2'000-30'000	1-2

1	2	3	4	5	6	7	8
(I?)		B) Suppositories:					
	250	Melting vessel: DIESSEL(D), ERWEKA(D), etc.	CrNi	30-120 1	steam=3 bar	7'000-18'000	
	251	Preparation vessel: DIESSEL(D), ERWEKA(D), PELLEGRINI(I), etc.	CrNi	30-120 1	10-16 kW steam = 3 bar, cooling water	35'000-80'000	
	252	Suppository molding in preformed aluminium foils: BOSCH/HOEFLIGER+KARG(D), CRESPI(I), SARONG(I)	aluminium	10'000- 20'000 suppos/h	12-15 kW	100'000-200'000	
	253	Suppository molding in molding forms and cooling chamber: ERWEKA/ERBO(D)	aluminium	3'000- 5'000 suppos/h	1.5-2 kW	15'000-25'000	
		<u>Oral and non-oral liquids:</u>					
L-7	301	Syrup-/liquid-preparation vessel, jacketed, with stirrer, fixed, inside surface = ground	CrNiMo	250-300 1	0.5-5 kW	6'000-15'000	1
L-10	302	with cover: DIESSEL(D), PRESSINDUSTRIA(I), SEITZ(D), STOECKLIN(CH)		30-60 1*)	0.5-3 kW	3'000-11'000	1
L-7	303	Mixing vessel, jacketed, with stirrer, fixed, inside - surface = ground; with cover: COLLETTE(B), DIESSEL(D), PRESSINDUSTRIA(I), SEITZ(D), STOECKLIN(CH)	CrNiMo	250-300 1	0.5-5 kW	6'000-15'000	1
				30-60 1*)	0.5-3 kW	3'000-11'000	1

*) optional = movable

1	2	3	4	5	6	7	8
I-7	305	Storage vessel, fixed (movable), inside surface = ground, with cover: DIESSEL(D), PRESSINDUSTRIA(I), SEITZ(D), STOECKLIN(CH). *) depending on products where seasoning is required.	CrNiMo	200-250 l	-		4'000-12'000 1 ^{*)}
I-10	306			30 - 60 l	-		2'000-7'000 1
I-7/10	307	Stirrer, movable: CHEMAPEC(USA), EKATO(D), IKA-JANKE+KUNKEL(D), MAVER(I), SICMI(I)	CrNiMo	for 250-300 l	1-5.5 kW		3'000-7'000 1
I-7/10	308	Transfer pump (centrifugal or rotary piston): ALBIN(S), FRYMA(CH), JOHNSON(S), MAAG(CH), SEITZ(D), STAMP(D)	CrNiMo	up to 5 cu.m/h	0.6-3 kW		2'000-5'000 1
I-7	309	Plate filter for clarification: AMF-CUNO (USA), FILTROX(CH), SEITZ(D)	CrNiMo/cellulose with kieselguhr/ pure cellulose	600-1200 l/h	-		500-5'000 1
I-10	310	Plate filter for sterilization: GELMAN(USA), SEITZ(D)	CrNiMo/polysulfon cellulose with kieselguhr without glas fiber	600-1200 l/h, sq.m.	-		2'000-5'000 1
I-6		In process laboratory together with preparation of sterile solutions.					
I-6/10	311/2	Bottle washing machine with recycled and fresh deionized water and clean, compressed air: BAUSCH+STROEBEL(D), BOSCH/STRUNCK(D), GILOWY(D), NERI(I), PROT(I), ZANASI(I)	CrNi	1000-1500 bottles/h	~ 10 kW		20'000-35'000 1
I-6/10	313/4	Bottle drying: BAUSCH+STROEBEL(D), BOSCH/STRUNCK(D), GILOWY(D), NERI(I), PROT(I), ZANASI(I). Alternative = drying of bottles in tray drier, or vacuum drier.	CrNi	1000-1500 bottl./h (100-300 kg glass/h)	5-15 kW		15'000-30'000 1
		Alternative to bottle washing: delivery of glass controlled bottles in dust-proof closed cases.					

1	2	3	4	5	6	7	8
L-7/13	315/6	Piston or vacuum filling machine (with bottle blowing), for different bottle sizes (and shapes), manual or mechanically operated: BAUSCH+STROEBEL(D), BOSCH/STRUNCK(D), CAPSULIT(I), COZZOLI(USA), FARMOMAC(I), KING(GB), MACOFAR(I), MARZOCCHI(I), SIOLI(I), US-BOTTLERS(USA)	CrNi(Mo)	up to 3000 bottles/h	0.2-1 kW	3'000-10'000	2
L-10	317	Screw cap cleaning/sterilizing equipment: COLUSSI(I), NERI(I), SIMEJA(D), ZANASI(I)	CrNi	40-80 l cleaning/sterilizing volume	3-9 kW	10'000-90'000	(1)
L-7	318	Screw cap capping machine (if not already included in the bottle filling machine): BOSCH/STRUNCK(D), FARMOMAC(I), KING(GB), ZANASI(I). Alternative = by hand device: AMPACK(CH)	(rubber/plastic)	2500-3500 caps/h	0.5-1 kW	5'000-15'000	(1)
L-13	319	ZANASI(I). Alternative = by hand device: AMPACK(CH)	rubber	1000-1500 caps/h	-	2'500-3'500	1
L-7	320	Pilfer proof swaging machine: FARMOMAC(I), HOLTZ(D)	CrNi	up to 6000 caps/h	2-2.5 kW	~ 10'000	1
P-7/8	321	Labelling machine on paper-glue basis: BOSCH/STRUNCK(D), GNUDI(I), NERI(I), JOHANN WEISS(D)	CrNi/brass	up to 7000 labels/h	0.5-1.5 kW	15'000-30'000	(1)
	322	Labelling machine for adhesive label bands: HERMANN(D), GUHL+SCHFIBLER(CH), STE.PILOT (F), JOHANN WEISS(D)	CrNi/brass	up to 7000 labels/h	1.0-2.5 kW	3'000-7'000	1
	323	Labelling machine with printing equipment: PRONTO PHOT-HAPA(CH)	CrNi/rubber	5000-10'000 prints+ labels/h	~ 4 kW	75'000-85'000	(1)

1	2	3	4	5	6	7	8
	324	Small or semi automatic cartoning machine: BOSCH/HOEFLIGER+KARG(D), CAM(I), IWK(D), JONES(USA), 2 M di M. MARCHESINI(I), PETRI(D), UHLMANN(D). Alternative = conveyor belt working table.	CrNi/brass	up to 5000 folding cartons/h	1-5 kW	50'000-100'000	1
	325	Conveyor belt working table for up to 10 packers, 5 m long: MASCHIMPEX(D), ROTZINGER(CH), STOECKLIN(CH), etc.	plastic, rubber	0.1-0.5 m/sec. belt velocity	0.3-0.5 kW	6'000-12'000	1
	326	Check weigher: BOSCH/HOEFLIGER+KARG(D), COLLISCHAN(D), IWK(D), OPTIMA(D), TECNO-EUROPA-ELETTROMECCANICA(I), UHLMANN(D)	plastic, rubber	up to 30'000 cartons/h	0.3-0.6 kW	14'000-20'000	1
	327	Bundling machine (if need be): AUCOUTURIER(F), CAM(I), GM(I), SOLLAS(NL), PESTER(D), UHLMANN(D)	CrNi/brass	900-2000 bundles/h	1-4 kW	15'000-40'000	(1)
	328	Case packer - "boxing" (if need be): CAM(I), LINGENFELDER(D). Alternative = by hand.	CrNi/brass	600-700 cases/h	0.3-0.5 kW	13'000-25'000	(1)
	329/30	Strapping by hand/machine: CYCLOP(USA), SIGNODE(D)	-	up to 600 cases/h	-	600/8'000	1-2
L-7	331	Floor balance: AVERY(GB), BIZERBA(D), BUSCH(CH), TOLEDO(USA). *) Alternative = movable	mild steel or CrNi	100-250kg ^{*)} (+ pre load)	(light)	1'500-5'000	1
L-7/10 /13	332-4	Table balance: AVERY(GB), BIZERBA(D), BUSCH(CH), TOLEDO(USA)	CrNi	30-50 kg	(light)	1'000-4'000	3
L	335	Pallet hand truck: AB-BYGG(S), JUNGHEINRICH(D), LANSING(GB), OM(I), STOECKLIN(CH), TOYOTA(J)	(Nylon wheels because of floor load)	2000 kg	-	500	1

1	2	3	4	5	6	7	8
L-7/13		Semifinished products store with shelves. General: furniture, 1 telephone (also for ointments), 1 typewriter, wash basin, warm and cold water, steam 3-8 bar or hot water, compr. air 6 bar					
L-11/2		For sterile production: sterile locker room, passage room for goods, sterile clothes					
L-13	336/7	Pass through box: GETINGE(S), DE LAMA(I), LEQUEUX(F), SCHAERER(CH), STERIL(I)	aluminium/CrNi	50-100 1	(2.5-4 kW) (+ steam = 3 bar)	2'000-30'000	1-2
	338	Laminar flow cabin: GLATT(D), LUWA(CH), MEISSNER+WURST(D), SKAN(CH)		~ 10 cu.m	3.5-4 kW	10'000-20'000	1
L-8	350-61	Demineralized water preparation complete: TH. CHRIST(CH), HAGER+ELSAESSER(D), MANGOLD(CH)	CrNi(Mo), glass	3-6 cu.m/h	~ 1 kW	250'000-350'000	1
	362	Stainless steel CrNi or glass piping					
	363	Storage tank for demineralized water, insulated, with heating coil	CrNi(Mo), glass	1000 1	steam = 3 bar	10'000-20'000	1
L-9	370-.....	Washing and drying equipment for cleaning of machines and equipment of the ointment, liquid and sterile sections					

1	2	3	4	5	6	7	8
		<u>Parenterals (ampoules and vials):</u>					
A-4	401	Mechanical sifter (if need be)	CrNiMo	300 kg/h	0.5 kW	~ 4'000	1
	402	Micronizing apparatus: BACHOFEN(CH), COFIN(I), MARCO(USA)	CrNiMo	2-40 l	3.5 kW	~ 8'000	1
	403/4	Preparation/mixing vessel, jacketed, closed or with fixed cover, surface inside and outside ground, with stirrer, movable, vacuum tight to 2 bar: DIESEL(D), ANGELO PILOTA(I), PRESS INDUSTRIA(I), SEITZ(D), STOECKLIN(CH)	CrNiMo(Ti)	60 l	0.5-3 kW	6'000-14'000	2
	405	Pre-filtration: AMF-CUNO(USA), FILTROX(CH), GELMAN(USA), DOMNICK-HUNTER(GB), MILLIPORE(USA), PALL(USA), SARTORIUS(D), SCHLEICHER+SCHUELL(D), SEITZ(D)	CrNiMo/cellulose with asbestos or kieselguhr, cellulose-nitrate or -tri-acetate, glass-fiber, mixture of cellulose ester	up to 1200 l/h	-	3'000-6'000	1
	406	Sterilization by filtration: GELMAN(USA), DOMNICK-HUNTER(GB), MILLIPORE(USA), PALL(USA), SARTORIUS(D), SCHLEICHER+SCHUELL(D)	CrNiMo/polysulfonate, cellulose-nitrate or -tri-acetate, PTFE, mixture of cellulose ester, nylon, teflon	up to 700 l/h	-	3'000-6'000	1

1	2	3	4	5	6	7	8
	407/8	Transfer pump with rotary piston system: ALBIN (S), FRYMA(CH), JOHNSON(S), MAAG(CH), SEITZ(D), STAMP(D)	CrNi(Mo)	up to 2 cu.m/h	0.6-1.5 kW	2'000-4'000	1-2
	409-411	Storage vessel, closed or with fixed cover, possibility to insert stirrer, movable, vacuum tight to 2 bar: DIESSEL(D), ANGELO PILOTA(I), PRESSINDUSTRIA(I), SEITZ(D), STOECKLIN(CH)	CrNiMo	60(-160)l	-	5'000-10'000	3(-2)
I-6		In process control laboratory:					
	420	- pH meter: METTLER(CH)			light	~ 800	1
	421	- viscometer: CONTRAVES(CH)			light	~ 7'500	1
	422	- microscope: LEITZ(D), REICHERT(A)			light	~ 2'500	1
	423	- water bath: HAAKE(D), SALVIS(CH)			3 kW	~ 1'700	1
	424	- optical precision balance: GIBERTINI(I), METTLER(CH), SAUTER(D)			light	900-1'300	1
	425	- refractometer			light	~ 3'000	1
	426	- autoclave with blue bath			light	~ 3'000	1
	427	- water distillation: BUECHI(CH)		~ 10 l/h	7.5 kW	~ 1'400	1
	428	- laboratory cabinet for drying glassware/utensiles: BRABENDER(D), GALLO(I), HAAKE (D), VILLA(I), SALVIS(CH)		100-160 l	1.5-3 kW	800-1'500	1
	429	- autoclave: DE LAMA(I), STIEFENHOFER(D)		60 l	steam = 3 bar		1
	430	- gas chromatograph: PERKIN ELMER(USA)					1
	431	- shaking apparatus:					
	432	- clean bench					
	433	- bench, wash basins					
	434	- tintometer					1

1	2	3	4	5	6	7	8
A-2	441	Ampoule washing machine with/without attached drying tunnel (*): BAUSCH+STROEBEL(D), BOSCH/STRUNCK(D), COZZOLI(USA), NERI(I), PROT(I), ZANASI(I). (*) Alternative = heat sterilization in autoclave. Due to the envisaged small production of ampoules and vials, the same equipment will be also used for vials.	CrNi/CrNiMo	1500-2500 A/h	1-12 kW	13'000-80'000	1
A-2/4	412/3						
	442	Washing and drying/sterilizing equipment for plugs and caps: COLUSSI(I), NERI(I), SMEJA(D), ZANASI(I)	CrNi	40-80 l sterilizing volume	3-9 kW	10'000-90'000	1
A-5	443	Ampoule and vial filling (and closing) machine: BAUSCH+STROEBEL(D), BOSCH/STRUNCK(D), COZZOLI(USA), MARZOCCHI(I), ZANASI(I). For closed stem ampoules, a special device is attached to the filling machine	CrNi	up to 2500 A,V/h	0.5-1 kW	12'000-35'000	1
	444	Code ring marking of ampoules (if need be) is also attached to the filling (and closing) machine.					
	445/6	Vial plugging and capping machine: BAUSCH+STROEBEL(D), BOSCH/STRUNCK(D), FARMOMAC(1), KING(GB), PERRY(USA)	CrNi/brass	up to 2500 V/h	0.5-1 kW	10'000-20'000	1-2
	447	Ampoule sterilization and blue bath control in autoclave: GETINGE(S), DE LAMA(I), LEQUEUX(F), SCHAERER(CH), STIEFENHOFER(D)	CrNi	up to 300 l	2-3 kW steam = 4-7 bar	25'000-45'000	1
A-8	448	Ampoule inspection machine: BOSCH/STRUNCK(D), EISAI/STRUNCK(J/D), ROTA(D). Alternative = hand-eye inspection	CrNi/plastic	up to 4000 A,V/h	0.8-2 kW	25'000-140'000	(1)
P-8/10	449	Labelling machine on paper-glue basis: BOSCH/STRUNCK(D), GNUDI(I), KING(GB), NERI(I), JOHANN WEISS(D)	CrNi/brass	up to 7000 labels/h	0.5-1.5 kW	15'000-30'000	(1)

1	2	3	4	5	6	7	8
450	Labelling machine for adhesive label bands: HERMANN(D), GUHL+SCHIEBLER(CH), STE.PILOT (F), JOHANN WEISS(D)	CrNi/brass	up to 7000 labels/h	1.0-2.5 kW	3'000-7'000	1	
451	Labelling machine with printing equipment: PRONTOHOT-HAPA(CH)	CrNi/rubber	5000- 10'000 prints+ labels/h	~ 4 kW	75'000-85'000	(1)	
452	Alternative = printing of ampoules and vials						
453	Blister packing machine for ampoules: HARRO HOEFLIGER(D) *) One unit may contain 1-10 ampoules/blisters. This machine is also used for packing sterile liquid ampoules	CrNi/brass/ plastic	up to 1800 units/h*)	3 kW	~ 60'000	1	
454	Small or semi automatic cartoning machine: BOSCH/HOEFLIGER+KARG(D), CAM(I), IWK(D), JONES(USA), 2 M di M. MARCHESINI(I), PETRI (D), UHLMANN(D). Alternative = conveyor belt working table. This equipment is also used for packing sterile liquid vials	CrNi/brass	up to 5000 folding cartons/h	1-5 kW	50'000-100'000	1	
455	Conveyor belt working table for up to 10 packers, 5 m long: MASCHIMPEX(D), ROTZINGER(CH), STOECKLING(CH), etc.	plastic, rubber	0.1-0.5 m/ sec. belt velocity	0.3-0.5 kW	6'000-12'000	1	
456	Check weigher: BOSCH/HOEFLIGER+KARG(D), COLLISCHAN(D), IWK(D), OPTIMA(D), TECNO- EUROPA-ELETTROMECCANICA(I), UHLMANN(D)	plastic, rubber	up to 30'000 cartons/h	0.3-0.6 kW	14'000-20'000	1	
457	Bundling machine (if need be): AUCOUTURIER(F), CAM(I), GM(I), SOLLAS(NL), PESTER(D), UHLMANN(D)	CrNi/brass	900-2000 bundles/h	1-4 kW	15'000-40'000	(1)	
458	Case packer-"boxing" (if need be): CAM(I), LINGENFELDER(D). Alternative = by hand	CrNi/brass	600-700 cases/h	0.3-0.5 kW	13'000-25'000	(1)	

1	2	3	4	5	6	7	8
	459	Strapping by hand: CYCLOP(USA), SIGNODE(D)	-	up to 300 cases/h	-	600	1
A-4	460	Floor balance: AVERY(GB), BIZERBA(D), BUSCH(CH), TOLEDO(USA). *) Alternative = movable	CrNi	100-200 kg*) (+ pre load)	(light)	1'500-5'000	1
	461	Table balance: AVERY(GB), BIZERBA(D), BUSCH(CH), TOLEDO(USA)	CrNi	3-50 kg (+pre load)	(light)	1'000-4'000	1
	462	Optical precision balance: GIBERTINI(I), METTLER(CH), SAUTER(D)	CrNi	0-2 kg	(light)	900-1'300	1
A	463	Pallet hand truck: AB-FYGG(S), JUNGHEINRICH(D), LANSING(GB), OM(I), STOECKLIN(CH), TOYOTA(J)	(Nylon wheels because of floor load)	2000 kg	-	500	1
A-5		Semifinished products store with shelves					
I-7, etc.		General: furniture, 1 telephone, 1 typewriter, wash basins, warm and cold water, steam 3-8 bar, compressed air 6 bar, vacuum.					
A-6/7		Sterile locker room, passage room for goods, sterile clothes					
A-5	464/5	Pass through box: GETINGE(S), DE LAMA(I), LEQUEUX(F), SCHAERER(CH), STERIL(I)	aluminium/ CrNi	50-100 l	(2.5-4 kW) (+ steam = 3 bar)	2'000-30'000	2
	466-8	Laminar flow cabin: GLATT(D), LUWA(CH), MEISSNER+WURST(D), SKAN(CH)		10 cu.m	3.5-4 kW	10'000-20'000	3
		<u>Freeze drying - additional equipment:</u>					
A-5	470	Freeze drying apparatus: BASI(I), LEYBOLD(D), USIFROID(F)	CrNi	50-100 l	~ 10kW	100'000	1

1	2	3	4	5	6	7	8
<u>Preparation of sterile liquid for injection:</u>							
A-1/5 A-2	481/2/3 442	Compact unit for washing, sterilizing and filling of ampoules or vials. Plugs and cap washing and sterilizing in equipment for preparation of parenterals.	CrNi(Mo)	up to 4000 A, V/h	20-32 kW	120'000-175'000	1
A-5	484	Collection tank for distilled water, movable	CrNiMo	100 l	-	5'000-10'000	1
P-8/10	485	Labelling machine on paper-glue basis: BOSCH/STRUNCK(D), GNUDI(I), KING(GB), NERI(I), JOHANN WEISS(D)	CrNi/brass	up to 7000 labels/h	0.5-1.5 kW	15'000-30'000	(1)
	486	Labelling machine for adhesive label bands: HERMANN(D), GUHL+SCHEIBLER(CH), STE. PILOT (F), JOHANN WEISS(D)	CrNi/brass	up to 7000 labels/h	1.0-2.5 kW	3'000-7'000	1
	487	Labelling machine with printing equipment: PRONTOPHOT-HAPA(CH)	CrNi/rubber	5000-10'000 prints+ labels/h	~ 4 kW	75'000-85'000	(1)
		Alternative = printing of ampoules and vials					
	453	Blister packing machine for ampoules: See machine for parenterals.					
	454	Small or semi automatic cartoning machine for blisters and vials: See machine for parenterals.					
	456-9	Check weigher, bundling machine, case packer, strapping, etc.: See corresponding equipment for parenterals.					
A-6/7		Sterile locker rooms, sterile clothes					

1	2	3	4	5	6	7	8
		<u>Intravenous infusions:</u>					
I-1	501/2	Mixing vessel, jacketed, closed, inside and outside surface ground, with stirrers: suppliers - see below	CrNiMo	1000 l	~ 5 kW	~ 25'000	2
	503	Auxiliary vessel, jacketed, closed, inside and outside surface ground, with stirrer: suppliers - see below	CrNiMo	500 l	~ 4 kW	~ 20'000	1
	504/5	Storage vessel for collection of sterile solution, jacketed, closed, inside and outside surface ground, with stirrer: DIESSEL (D), ANGELO PILOTA(I), PRESS INDUSTRIA(I), SEITZ(D), STOECKLIN (CH)	CrNiMo	1000 l	~ 5 kW	~ 25'000	2
	506	Prefiltration: AMF-CUNO(USA), FILTROX(CH), GELMAN(USA), MILLIPORE(USA), PALL(USA), SARTORIUS(D), DOMNICK-HUNTER(GB), SCHLEICHER+ SCHUELL(D), SEITZ(D)	CrNiMo/ cellulose with asbestos or kieselguhr, cellulose- nitrate or -triacetate, glass-fiber, mixture of cellulose ester	up to 1200 l/h	-	3'000-6'000	1
	506	Sterilization by filtration: GELMAN(USA), DOMNICK-HUNTER(GB), MILLIPORE(USA), PALL(USA), SARTORIUS(D), SCHLEICHER+SCHUELL(D)	CrNiMo/poly- sulfonate, cellulose- nitrate or -triacetate, PTFE, mixture of cellulose ester, nylon, teflon	up to 700 l/h	-	3'000-6'000	2

1	2	3	4	5	6	7	8
I-1/5	508-11	Transfer pump with rotary piston system: ALBIN(S), FRYMA(CH), JOHNSON(S), MAAG(CH), SEITZ(D), STAMP(D)	CrNi(Mo)	up to 5 cu.m/h	1.5-2 kW	3'000-5'000	4
I-5	512	Granulate sterilization, bag/bottle forming	CrNiMo	up to 950 bags/ bottles/h	~ 50 kW	~ 600'000	1
	513	bag/bottle filling under laminar flow bag/bottle printing or labelling: ROMMEL AG-BOTTLEPACK system (CH/D)					
P-10/ 11	514	Cartoning/boxing: CAM(I), JONES(USA) PETRI(D)	CrNi	up to 3000 cartons/ boxes/h	1-5 kW	50'000-70'000	1
	515	Alternative = conveyor belt working table for up to 10 packers, 5-6 m long: MASCHIMPEX(D), ROTZINGER(CH), STOECKLIN(CH), etc.	plastic/rubber	0.1-0.5 m/ sec. belt velocity	0.3-0.5 kW	6'000-12'000	1
	516	Check weigher: BOSCH/HOEFLIGER+KARG(D), COLLISCHAN(D), IWK(D), OPTIMA(D), TECNO- EUROPA-ELETTROMECCANICA(I), UHLMANN(D)	plastic, rubber	up to 30'000 cartons/h	0.3-0.6 kW	14'000-20'000	1
	517	Case packer-"boxing": CAM(I), LINGENFELDER(D)	CrNi/brass	600-700 cases/h	0.3-0.5 kW	13'000-25'000	1
	518	Strapping: CYCLOP(USA), SIGNODE(D) All other equipment together with prepara- tion of parenterals	-	600/h	0.6-1 kW	8'000	1
I-8		Reserve					

1	2	3	4	5	6	7	8
A-3	490/1	Distilled water preparation: PONZINI(I), SANTASALO-SOHLBERG(SF), STILMAS(I)	CrNiMo	220-420 l/h	1.5-13 kW steam = 3 bar, de- mineralized water = 5-10 bar	50'000-60'000	2
	492	Stainless steel CrNiMo(CrNi) or glass piping					
	493	Storage tank for distilled water, insulated, with heating coil	CrNiMo	1000 1	steam=3 bar	10'000-20'000	1
		<u>Antibiotics:</u>					
B-3/4	601/2	Hot air, double door sterilizer: COLUSSI(I) GETINGE(S), LEQUEUX(F), SCHAERER(CH), STIEFENHOFER(D), STERIL(I), VISMARA(I)	CrNi	400 1	~ 15 kW	~ 40'000	2
	603	Steam, double door sterilizer: GETINGE(S), DE LAMA(I), LEQUEUX(F), SCHAERER(CH), STIEFENHOFER(D)	CrNi	400 1	3-12 kW steam=3 bar	40'000-55'000	1
B-4	604	Sifting machine: ALLGAIER(D), RONCHI(I), RUSSEL-FINEX(B), VIANI(I), VIBROWEST(I)	CrNi	up to 900 kg/h	~ 1.5 kW	4'000-6'000	1
	605	Blender/mixer: EACHOFEN(CH), ENGELSMANN(D), ANGELO PILOTA(I). Alternative = drum mixer or turbo mixer: BACHOFEN(CH)	CrNi	60-120 1	0.4-2.2 kW	2'500-26'000	1
	606						

1	2	3	4	5	6	7	8
B-3	607	Vial washing and sterilizing machine: BAUSCH+STROEBEL(D), BOSCH/STRUNCK(D), NERI(I), PROT(I), ZANASI(I)	CrNiMo	up to 4000 v/h	~ 29 kW	70'000-80'000	(1)
E-4	608	Vial filling and plugging machine: BAUSCH+STROEBEL(D), BOSCH/HOEFLIGER+KARG(D), FARMOMAC(I), PERRY(USA), ZANASI(I)	CrNiMo	up to 4000 v/h	3-4 kW	40'000-70'000	(1)
B-3/4	609	Alternative = Combined vial washing, sterilizing, filling and plugging machine: BAUSCH+STROEBEL(D), BOSCH/HOEFLIGER+KARG(D), BOSCH/STRUNCK(D), ZANASI(I)	CrNiMo	up to 4000 v/h	25-32 kW	120'000-170'000	1
B-3	610	Plugs and cap washing and sterilizing machine: COLUSSI(I), NERI(I), SMEJA(D), ZANASI(I)	CrNiMo	40-80 l sterilizing volume	3-9 kW	10'000-90'000	1
B-4	611	Capping machine: BOSCH/HOEFLIGER+KARG(D), FARMOMAC(I), KING(GB), MACOFAR(I), ZANASI(I)	CrNi	up to 4000 caps/h	0.4-0.6 kW	6'000-12'000	1
	612	Vials surface washing machine: BAUSCH+STROEBEL(D), BOSCH/STRUNCK(D), NERI(I), PROT(I), ZANASI(I)	CrNi	up to 4000 v/h	3-4 kW	35'000-60'000	1
P-11/12	613/4/5	Labelling machine on paper-glue basis: BOSCH/STRUNCK(D), GNUDI(I), KING(GB), NERI(I)	CrNi/brass	up to 7000 labels/h	0.5-1.5 kW	15'000-30'000	1
	613/4/5	JOHANN WEISS(D). Alternative=adhesive labels or printing					
	616	Small or semi automatic cartoning machine: BOSCH/HOEFLIGER+KARG(D), CAM(I), IWK(D), JONES(USA), 2 M di M. MARCHESINI(I), PETRI(D), UHLMANN(D)	CrNi/brass	up to 5000 folding cartons/h	1-5 kW	50'000-100'000	1
	617	Check weigher: BOSCH/HOEFLIGER+KARG(D), COLLISCHAN(D), IWK(D), OPTIMA(D), TECNO-EUROPA-ELETTROMECCANICA(I), UHLMANN(D)	plastic, rubber	up to 30'000 cartons/h	0.3-0.6 kW	14'000-20'000	1

1	2	3	4	5	6	7	8
	618	Bundling machine (if need be): AUC OUTURIER(F), CAM(I), GM(I), SOLIAS(NL), PESTER(D), UHLMANN(D)	CrNi/brass	900-2000 bundles/h	1-4 kW	15'000-25'000	(1)
	619	Case packer-"boxing" (if need be): CAM(I), LINGENFELDER(D). Alternative = by hand	CrNi/brass	600-700 cases/h	0.3-0.5 kW	13'000-25'000	(1)
	620	Strapping equipment - hand/machine: CYCLOP (USA), SIGNODE(D)	-	hand operated/ 300-600/h	-/0.6-1 kW	600/8'000	1
B	621	Pallet hand truck: AB-BYGG(S), JUNGHEINRICH (D), LANSING(GB), OM(I), STOECKLIN (CH), TOYOTA(J), etc.	(Nylon wheels because of floor load)	2000 kg	-	500	1
B-6	622	Floor balance: AVERY(GB), BIZERBA(D), BUSCH (CH), TOLEDO(USA),. *) Alternative=movable	CrNi	100-250 kg*) (+pre load)	(light)	1'500-5'000	1
	623	Table balance: AVERY(GB), BIZERBA(D), BUSCH (CH), TOLEDO(USA)	CrNi	30-50 kg (+ pre load)	(light)	1'000-4'000	1
B-4	624	Optical precision balance: GIBERTINI(I), METTLER(CH), SAUTER(D)	CrNi	0-2 kg	(light)	900-1'300	1
B-7 etc.		General: furniture, 1 telephone, wash basins, warm and cold water, steam 3-8 bar, compressed air 6 bar, type writer					
B-1/2 B-5/6		Sterile locker room, passage room for goods, sterile clothes					
B-4	625/6	Pass through box: GETINGE(S), DE LAMA(I), LEQUEUX(F), SCHAEERER(CH), STERIL(I)	aluminium/ CrNi	50-100 l	(2.5-4 kW) (+ steam = 3 bar)	2'000-30'000	1-2
	627	Laminar flow cabin: GLATT(D), LUWA(CH), MEISSNER+WURST(D), SKAN(CH)		~ 10 cu.m	3.5-4 kW	10'000-20'000	1

Packaging:

- P-4 Office: furniture, 1 telephone, 1 typewriter
- P-5/12 Packaging machines and equipment as outlined above
- P-13 Reserve

Rest rooms:

- P-1 Furniture, preparation of coffee and tea
- L-1
- P-6

Toilets:

- P-2 For: females = installation
- P-3 males - " -
- L-4 males - " -
- L-5 females - " -
- P-14 males - " -
- P-15 females - " -

Corridors:

- C-0/1 Free circulation from and to the service building and warehouse. Optically operated sliding doors
- C-1/2 Passage to the sterile areas with floor contamination control screen and air lock. Optically operated sliding doors

1	2	3	4	5	6	7	8
C-3/4 C-5/6		Passage to the antibiotics area with floor contamination control screen and air lock. Optically operated sliding doors					
C-6/P-12		Intermediate passage					
C-7/8		Passage to sanitary/social facilities and to the warehouse. Optically operated sliding doors					
		<u>Warehouse</u>					
W-2		<u>Dispensing/weighing room:</u>					
001		Mechanical sifter, fixed, single desk, variable mesh sizes 12-120: ALLGAIER(D), RUSSEL-FINEX(B), VIBROWEST(I)	CrNi	300-1000 kg/h	0.4-1.5 kW	4'000-6'000	1
002		Milling of solid material: ENGELSMANN(D), MANESTY(GB), BACHOFEN(CH)	CrNi or porcelain for ball mill	50-200	0.4-2.2 kW	3'000-30'000	1
003		Floor balance (with spot ventilation): AVERY (GB), BIZERBA(D), BUSCH(CH), TOLEDO(USA)	mild steel or CrNi	200-600 kg (+pre load)		1'500-5'000	1
004		Table balance (with spot ventilation): AVERY (GB), BIZERBA(D), TOLEDO(USA), BUSCH(CH)	CrNi	30-50 kg (+ pre load)		1'000-4'000	1
005		Optical precision balance: GIBERTINI(I), METTLER(CH), SAUTER(D)	CrNi	0-2 kg	light	900-1'300	1

1	2	3	4	5	6	7	8
W-5/6	<u>Warehouse- and shipping-office:</u>						
	Furniture, telephone, typewriter (telex)						
W-8/9	<u>Store:</u>						
	Racks and shelves for equivalent 4000 pallet places						
006	Reach fork lift truck (center of gravity 0.6 m, pay-load height = 5.0-5.3 m): JUNGHEINRICH(D), LANSING(GB), TOYOTA(J), YALE(USA).	(castor/drive wheel+fork wheel = Nylon because of floor load)	1000-1500 kg	battery		20'000-35'000	1
007	Battery charging station			light		2'000-3'000	1
008-10	Pallet hand truck: AB-BYGG(S), JUNGHEINRICH(D), LANSING(GB), OM(I), STOECKLIN (CH), TOYOTA(J), etc.	(Nylon wheels because of floor load)	2000 kg	-		500	3
011	Electro-hydraulic hand fork lift truck: AB-BYGG(S), JUNGHEINRICH(D), STOECKLIN (CH)	(castor+fork wheels = Nylon because of floor load)	800 kg	battery or 2 kW		5'000-17'000	1
012/3	Strapping equipment-hand/machine: CYCLOP(USA), SIGNODE(D)	-	hand operated/300-600/h	-/0.6-1 kW		600/8'000	1-2
014	Marking equipment:						
015	Box/case roller conveyor: MASCHIMPEX(D) or standard	metal or plastic	-	-		3'000-5'000	1

1	2	3	4	5	6	7	8	
W-3	016/7	Cool room (15 ^o + 2 ^o C) or standardized container with racks or shelves and refrigerator(s) for cold storage (4 ^o + 1 ^o C) *) depending on volume to be stored. Cool room containers: ROSENMUND(CH), P. SCHALLER(CH), VISMARA(I)			5-50 cu.m 0.5-2cu.m	0.5-2.1 kW 0.5-1 kW	5'000-30'000 500-2'000	1-...*) 1-...*)
W-8		<u>Packaging material preparation:</u>						
	018	Printing machine: MOSER(CH), PRONTOFOT-HAPA (CH), SCHNELLPRESSEN FABRIK HEIDELBERG(D)	metal, rubber	3000- 6000 prints/h	1-15 kW	15'000-75'000	1	
	019	Leaflet folding machine: BAEUERLE(D), GUK(D)	metal, rubber	up to 18'000 folds/h	0.5-1.6 kW	6'000-10'000	1	
		<u>Safety:</u>						
W-8/9		Fire wall						
	020	Fire/smoke detectors						
	021	Fire fighting equipment						
		<u>Service building - ground floor:</u>						
1/8		Toilets for males = installation						
3/20		Toilets for females = installation						
2		Personnel manager: furniture, telephone						
4		Personnel office: furniture, telephone, 1 typewriter, 1 calculator						
5/7/9/11		Reserve						
6		Cashier: furniture, 1 telephone, 1 typewriter (alarm system, if need be)						
3		Secretary: furniture, 1 telephone, 1 typewriter						
10		Production manager: furniture, 1 telephone						
12		Production planning: furniture, 1-2 telephones, 1-2 typewriters, 2-3 calculators						
14		Purchasing, dispatch (and sales): furniture, 2 telephones, 2 calculators						
16		General administration (gate house, security, social services, external transport, telephone operator, paging, clocks, cleaning): furniture, 2 telephones, 1 calculator						

1	2	3	4	5	6	7	8
13/22		Canteen: 147(+ spare) covers (forks, knives, spoons, plates for soup, meat and cake - if need be), 24 tables, 147 chairs, 180 trays, 7 trolleys					
15		Kitchen: equipment for the preparation of complete meals *) (soup kettles, multipurpose stove, baking oven, tables for preparation of vegetables, washing throughs; spot ventilation over stove, servery, etc.					
17		Pantry: shelves					
17-A		Cold-store room : shelves					
19		Cooks office: furniture, 1 telephone					
21		Cloak room, for guests					
23		Room for cleaning utensils: washing machine, etc.					
25		Laundry: 2 washing and drying machines					
27		Canteen for higher office staff (if need be) or guests					
24/34		Cloak rooms for 99 males, divided into compartments which may be furnished according to need: lockers					
31/43		Cloak rooms for 110 females, divided into compartments which may be furnished according to need: lockers					
29		Toilets, wash-basis, showers					
40		Toilets, wash-basins, showers, room for cleaning utensils					
E-1		Entrance to cloak rooms					
E-2		Main entrance; reception (and telephone operator); seating garniture for guests					
E-3		Entrance to the service building					
E-4		Emergency exit					

*) beginning with one shift, later for two shifts

- E-5/7 Entrance to cloak rooms
- E-6 Entrance to the office wing (and laboratories)
- E-8 Corridor to manufacturing, packaging and warehouse
- E-9 Ramp for food supply and waste disposal
- Elevator: 2x1.9 m, capacity = 1500-2000 kg

Service building - first floor:

- 101/117 Toilets for females = installation
- 103/119 Toilets for males = installation
- 102 Laboratories' manager (and assistant or guest): furniture
- 800 1 telephone, literature, manufacturing procedures
- 105 Secretary: furniture, 1 telephone, 1 typewriter
- 104 Packaging material control room:
Equipment to measure and define:
 - 801 - glass container dimensions and quality
 - 802 - aluminium/plastic foil dimensions, quality and moisture-vapour permeability
 - 803 - metal/plastic/rubber closures tolerances, quality and tightness
 - 804 - tube inner layer quality and closure tightness
 - 805 - paper and carton quality, weight per sq.m, grain direction, surface treatment, etc.
 - 806 - carton box and drum stability for internal and external transport
 - 807 - drawing equipment
 - - etc.
- Place for visual control
- Laboratory benches, wash basin (hood)

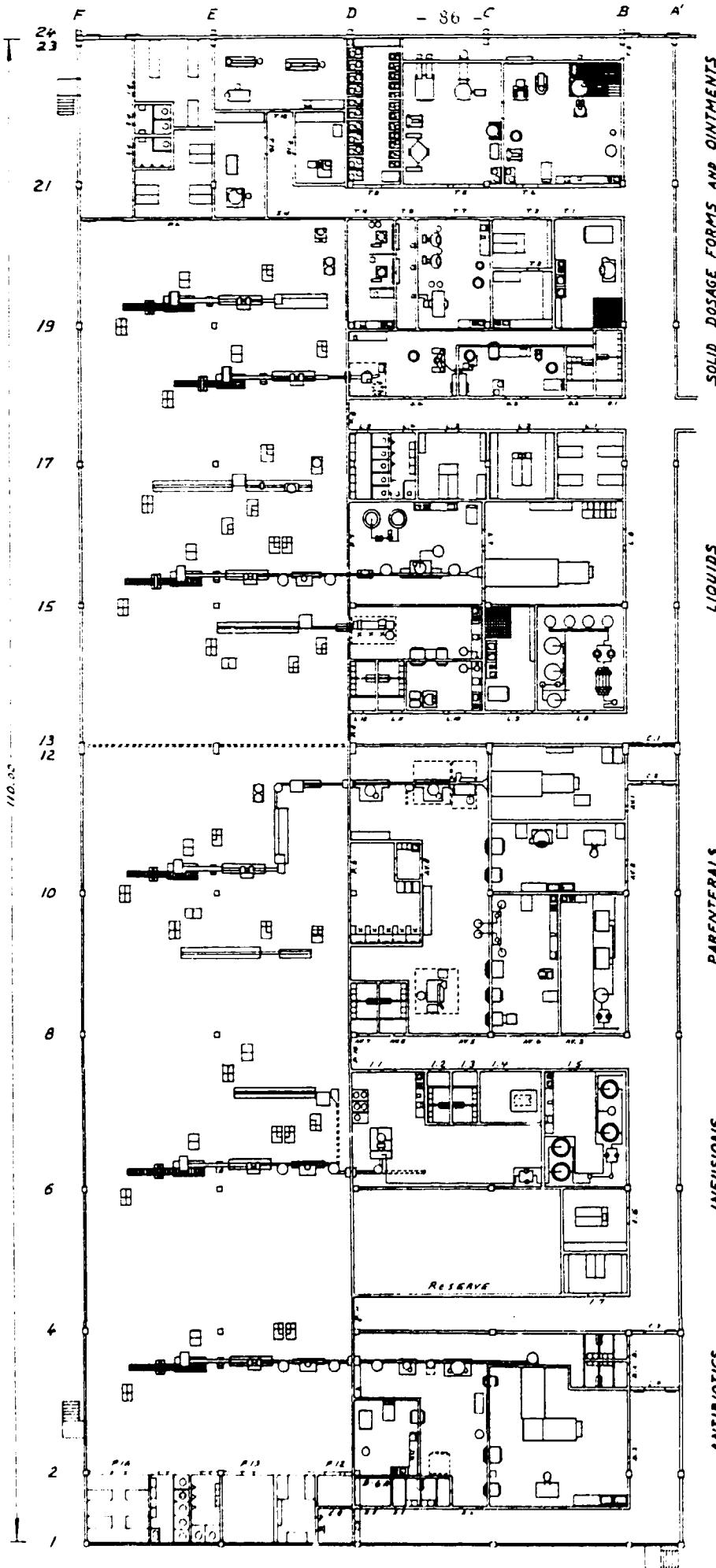
1	2	3	4	5	6	7	8
106		Instrument room:					
	811	UV spectro-photometer (with recorder): Beckmann					1
	812	Polarimeter					1
	813	Refractometer					1
	814	Flame, photometer					1
	815	Thin layer chromatograph					
		Laboratory benches, wash basin					
108		Chemical-physical laboratory:					
	821	p-H meter: METTLER(CH)					1
	822	Melting point apparatus: BUECHI(CH), METTLER(CH)					1
	823	Moisture tester: BRABENDER(D)					1
	824	Drying oven					1
	825	Vacuum oven					1
	826	Muffle furnace					1
	827,8	Analytical balance					2
	829	Karl Fischer apparatus					1
	830	Nitrogen determination apparatus *)					1
	831	Ammonia distillation unit					1
	832	Non-aqueous filtration unit					1
	833	Potentiometer - complete assemblies *)					1
	834	Magnetic stirrer					1
	835	Blender					1
	836	Ultrasonic bath					1
	837	Centrifuge (with refrigeration) *)					1
	838	Distillation apparatus					1
	839	Water distillation unit *) : BUECHI(CH)					1
	840	Water bath: HAAKE(D), SALVIS(CH)					
		Laboratory benches, wash basin, hood(s)					

*) Depending on grade of installation desirable and product mix to be tested

1	2	3	4	5	6	7	8
110		Micro biological laboratory:					
	851	Colony counter					1
	852	Turbidometer					1
	853	Microscope: LETIZ(D)					1
	854/5	Membrane filter					2
	856	Centrifuge					1
	857	Top loading balance: GIBERTINI(I),METTLER(CH),SAUTER(D)					1
	S58/9	Refrigerator					2
	860	Incubator *)					1
	861	Autoclave					1
	862	Anderson sampler					
	S63	Laminar flow, hoods, wash basin, laboratory benches					2
114		Store for chemicals, culture media, buffers and reagents: shelves, table					
107/9/15		Reserve					
111		Glassware and equipment store: shelves					
113		Wash-room: 2 sinks - 80x50 x30 cm 1 drying cabinet 1 table for dirty, 1 table for clean glass-ware					
116		Accounting: furniture, filing cabinets, 1 telephone, calculators					
113		Plant manager's office: furniture, 1 telephone					
120		Conference room/library: furniture, shelves. The room may be divided into two parts by means of a flexible wall.					
121		Office for a guest: furniture (1 telephone)					
123		Secretary's office: furniture, 1 telephone, typewriter					
E-101/2		Entrance to laboratory wing					
E-103		Exit to roof/future extension, respectively					

*) Depending on grade of installation desirable and product mix to be tested.

ANNEX RIVa



ANTIBIOTICS

INFUSIONS

PARENTERALS

LIQUIDS

SOLID DOSAGE FORMS AND OINTMENTS

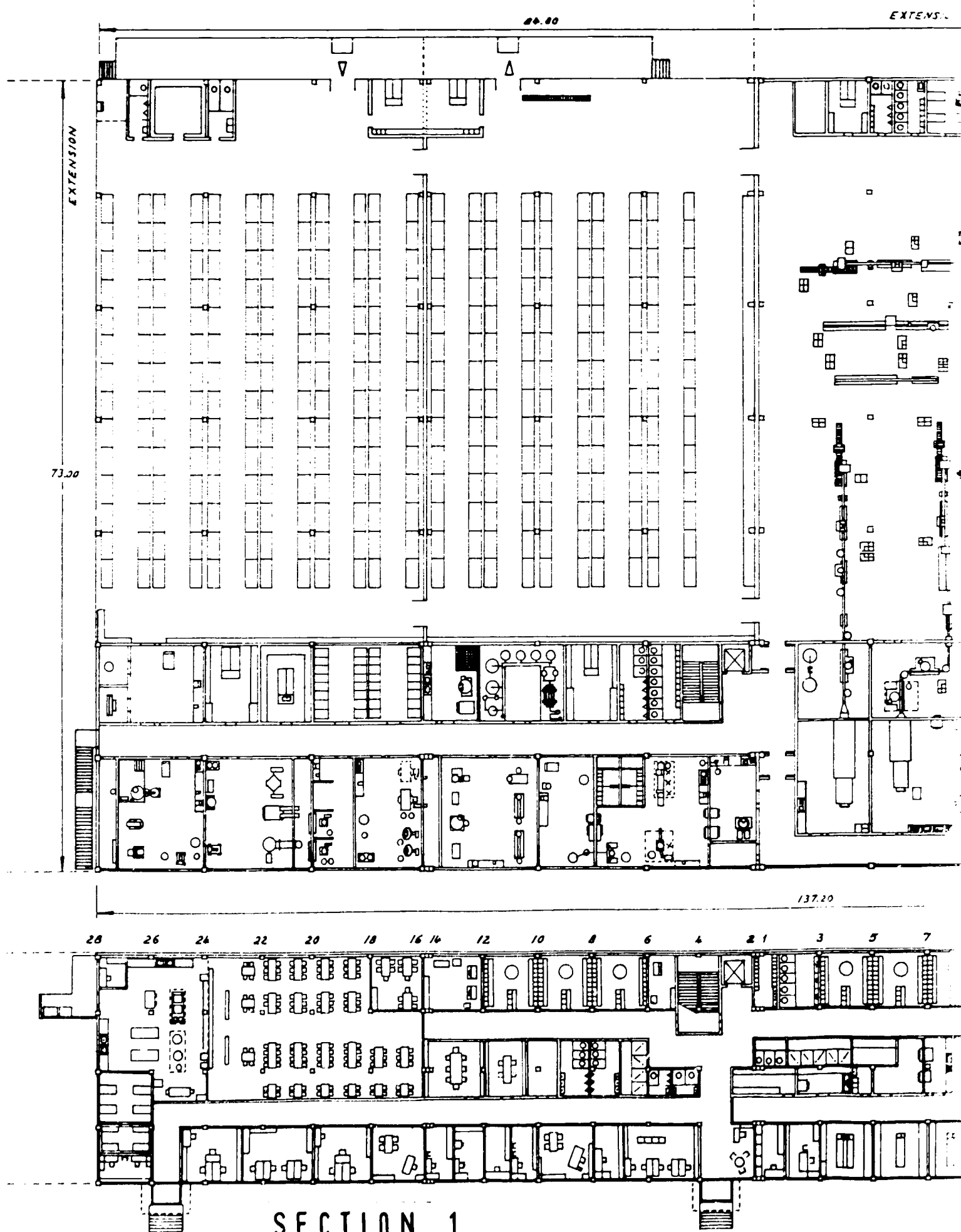
MANUFACTURING AND PACKAGING

LAYOUT

FOR MORE DETAILS SEE INDIVIDUAL LAYOUTS IN SCALE = 1:200

SCALE = 1:400

UNIDO 85.4.009



SECTION 1

EXTENSION

PHARMACEUTICAL PRODUCTION PLANT

ALTERNATIVE LAYOUT

SCALE = 1:400

UNIDO 85.3.001

I FOR MORE DETAILS SEE INDIVIDUAL LAYOUTS IN SCALE = 1:200

GROUND FLOOR

MANUFACTURING
PACKAGING
WAREHOUSE

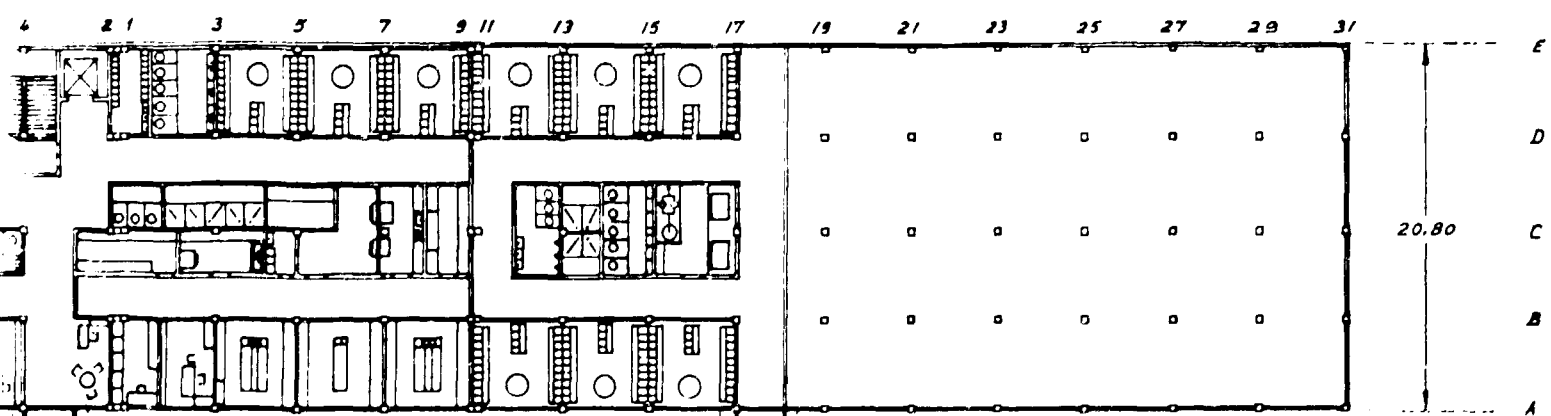
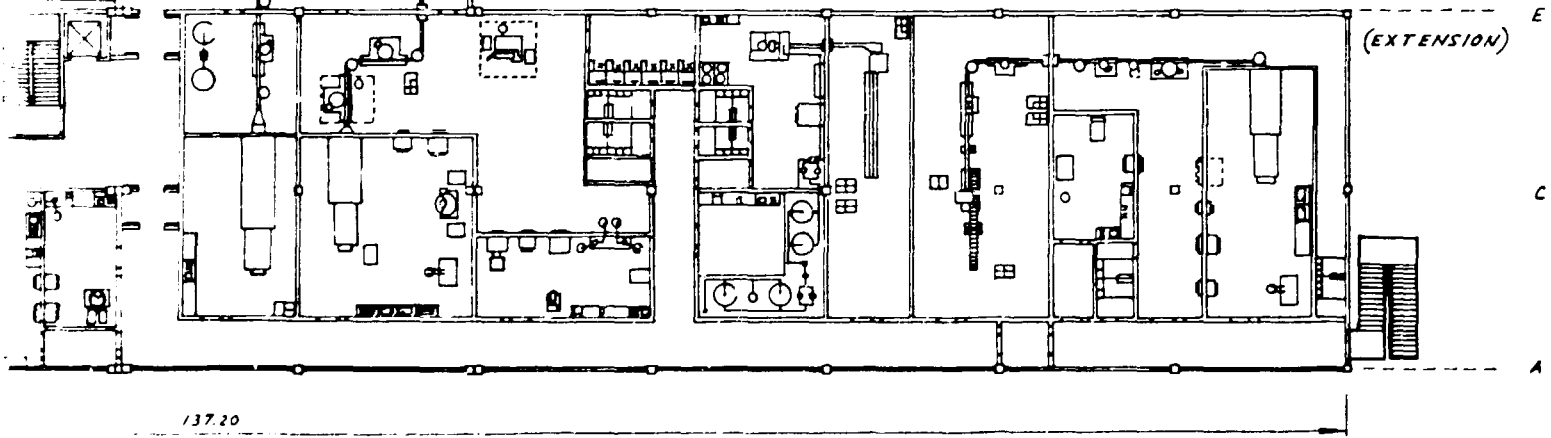
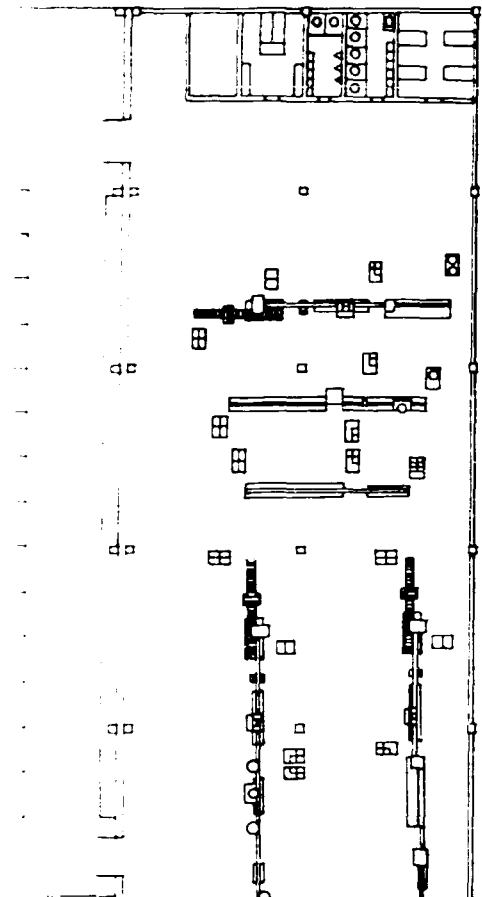
LOWER GROUND FLOOR

ADMINISTRATION
QUALITY CONTROL LABORATORIES
PRODUCTION OFFICES
SOCIAL SERVICES
CLOAK ROOMS (CAPACITY TO NEED)
RESERVE

FIRST PHASE

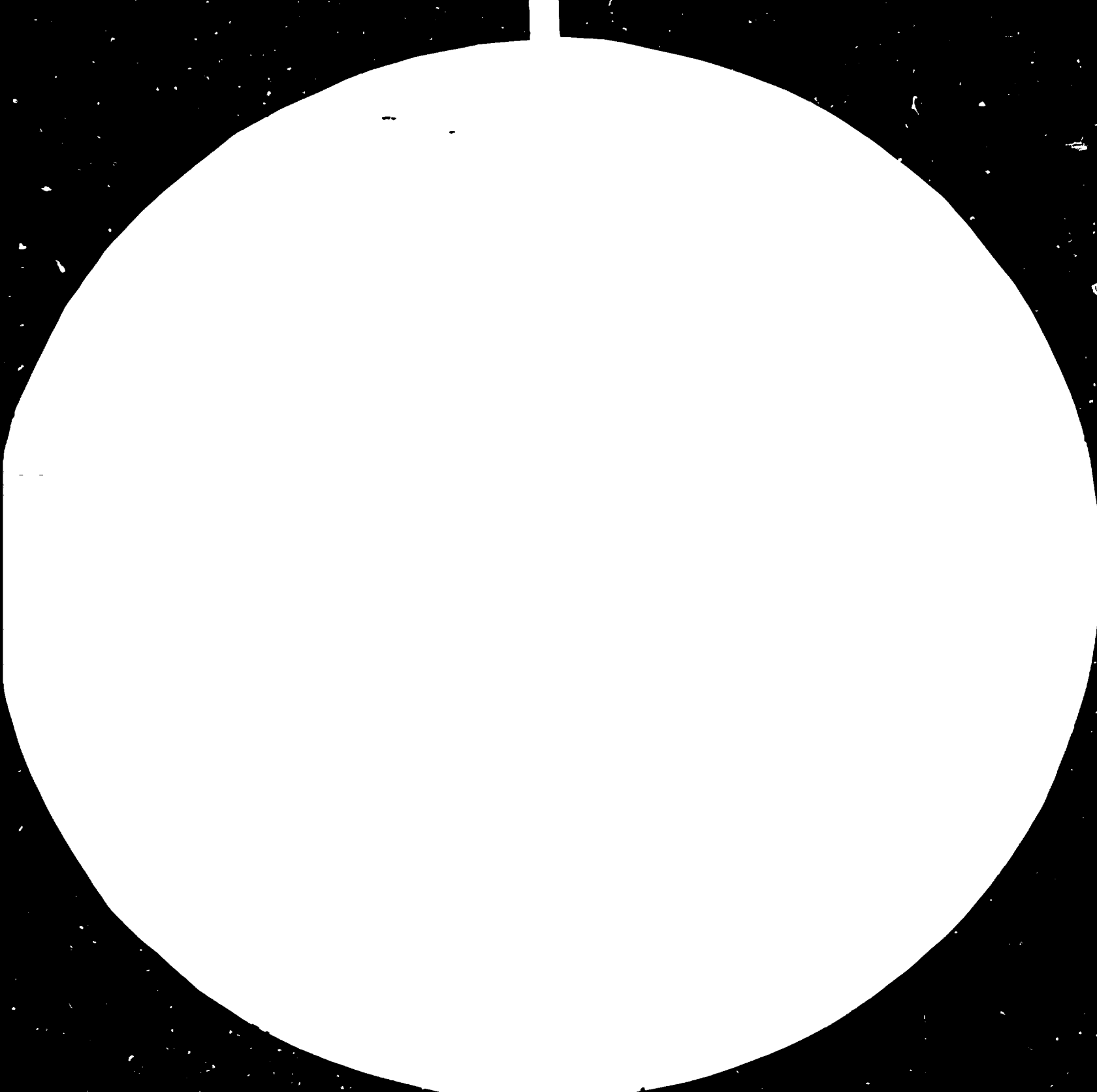
SOLID DOSAGE FORMS
CREAMS, OINTMENTS
LIQUIDS
(SMALL STERILE PRODUCTION)

ALTERNATIVE TO LOWER GROUND FLOOR = SEPARATE SERVE BUILDING



SECTION 2

86.04.28
AD.87.04
1115541





28



32



36

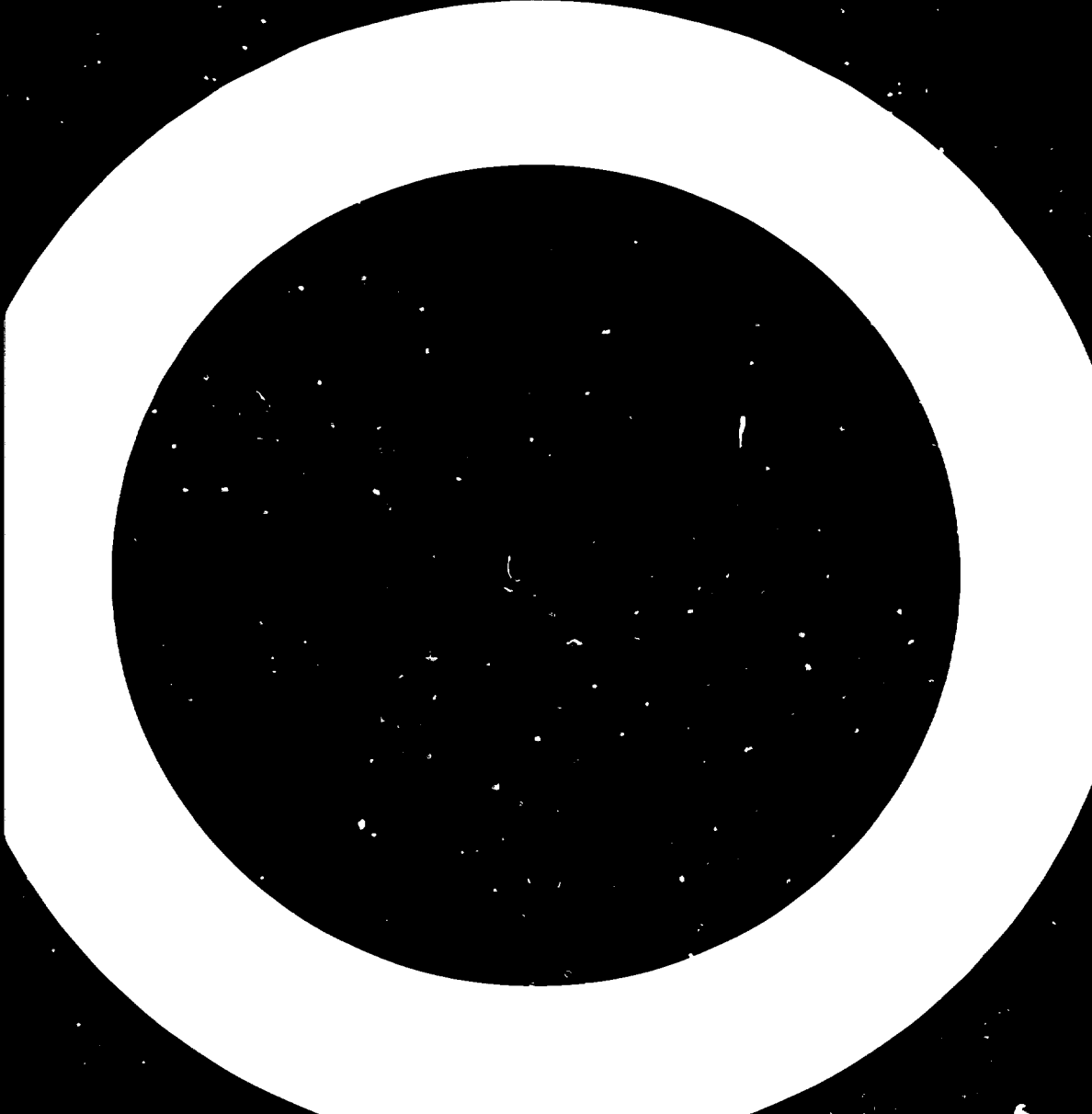


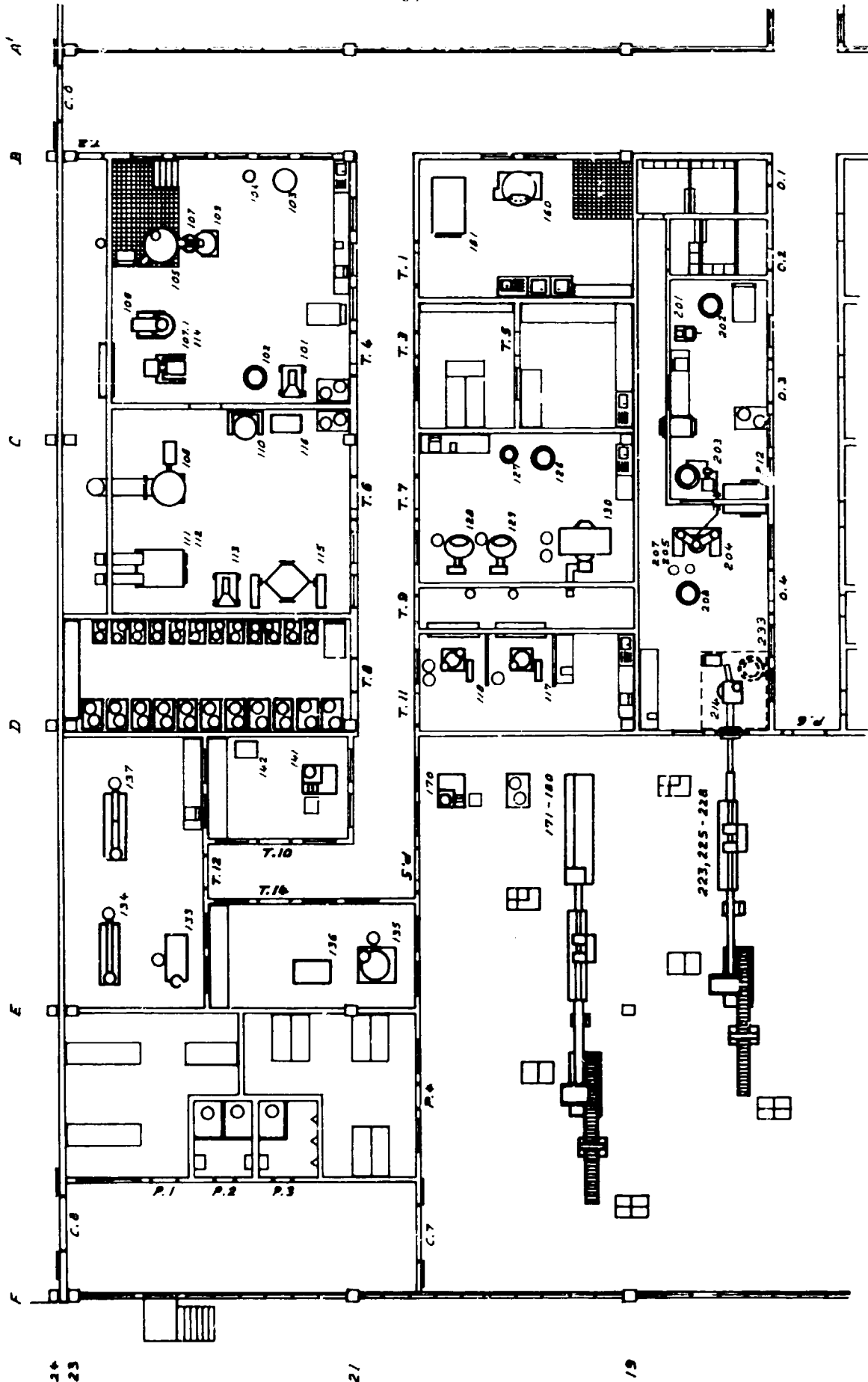
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MICROSCOPY RESOLUTION TEST CHART

NATIONAL BUREAU OF STANDARDS
GAITHERSBURG, MARYLAND 20899
ASTM designation: E 2878-10

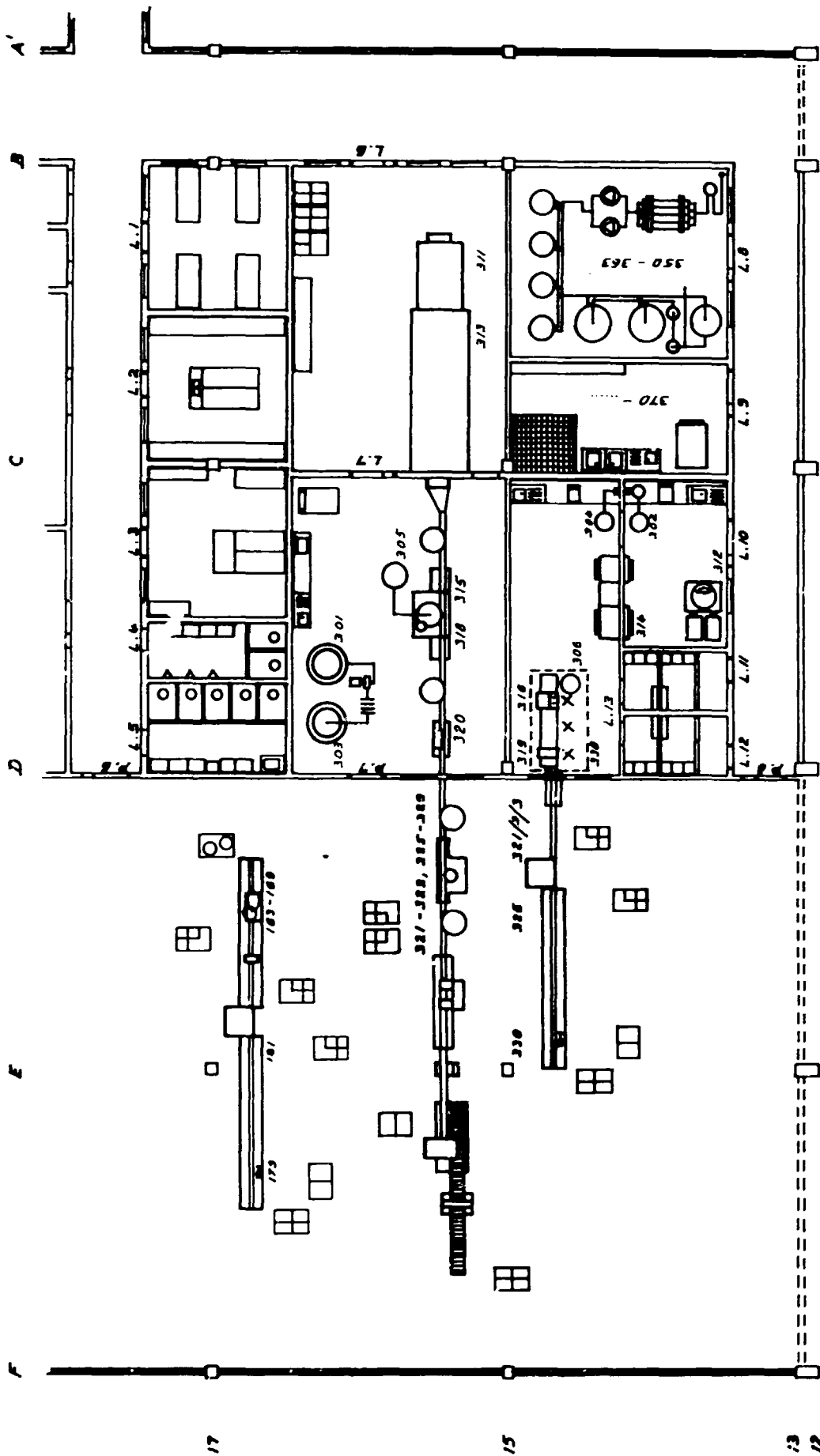




SOLID DOSAGE FORMS AND OINTMENTS

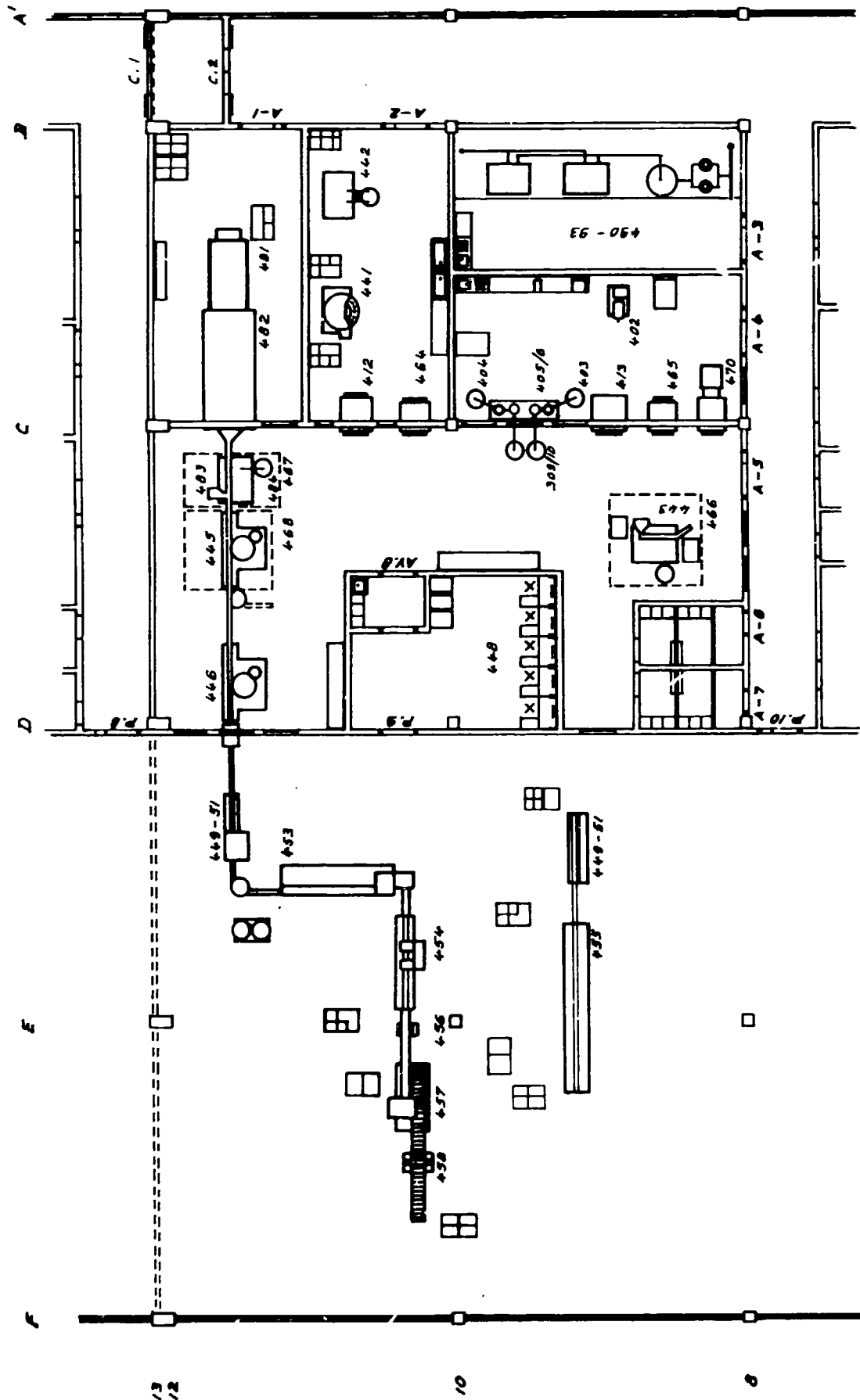
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UNIDO 85.4.004



SCALE = 1:200

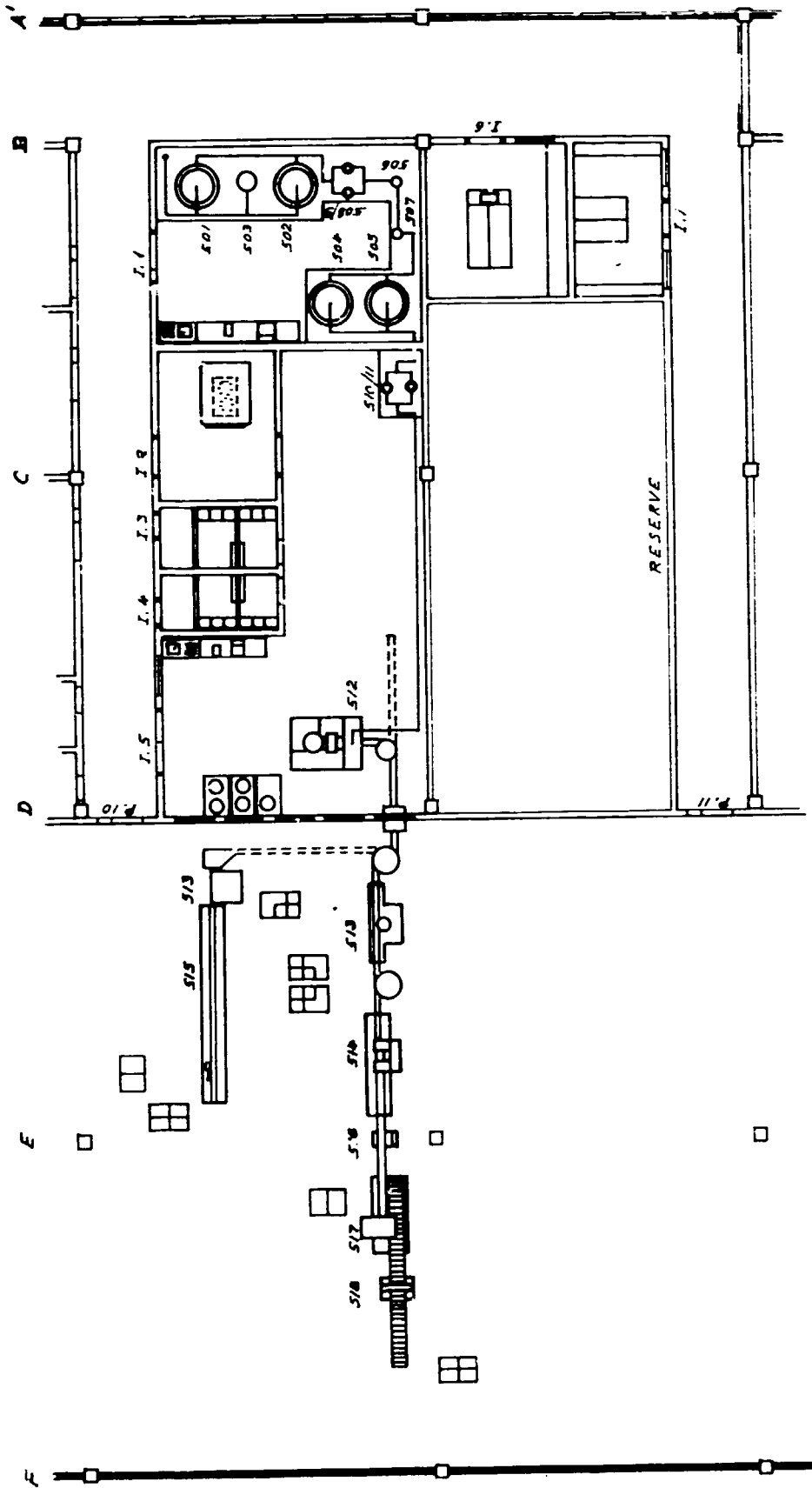
LIQUIDS
UNIDO 85.4.005



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PARENTERALS

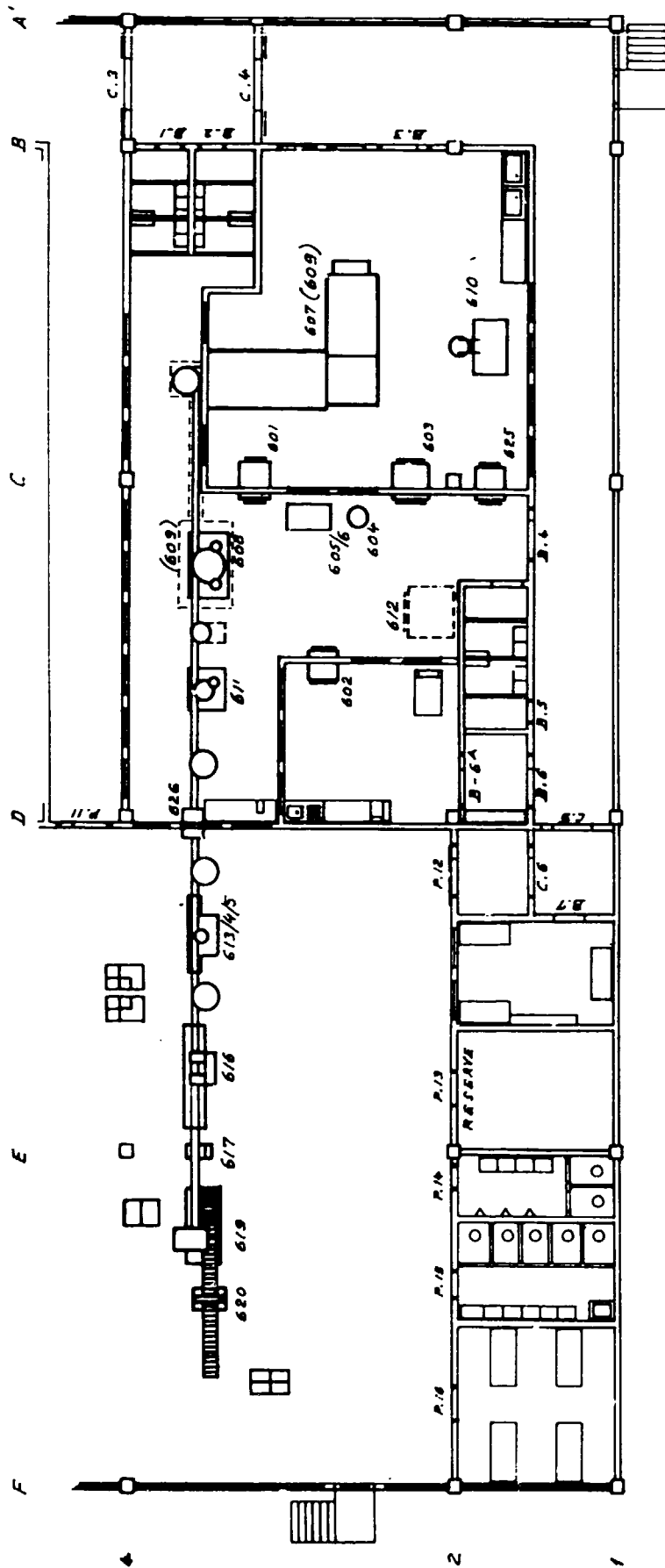
UNIDO 85.4.006



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INFUSIONS

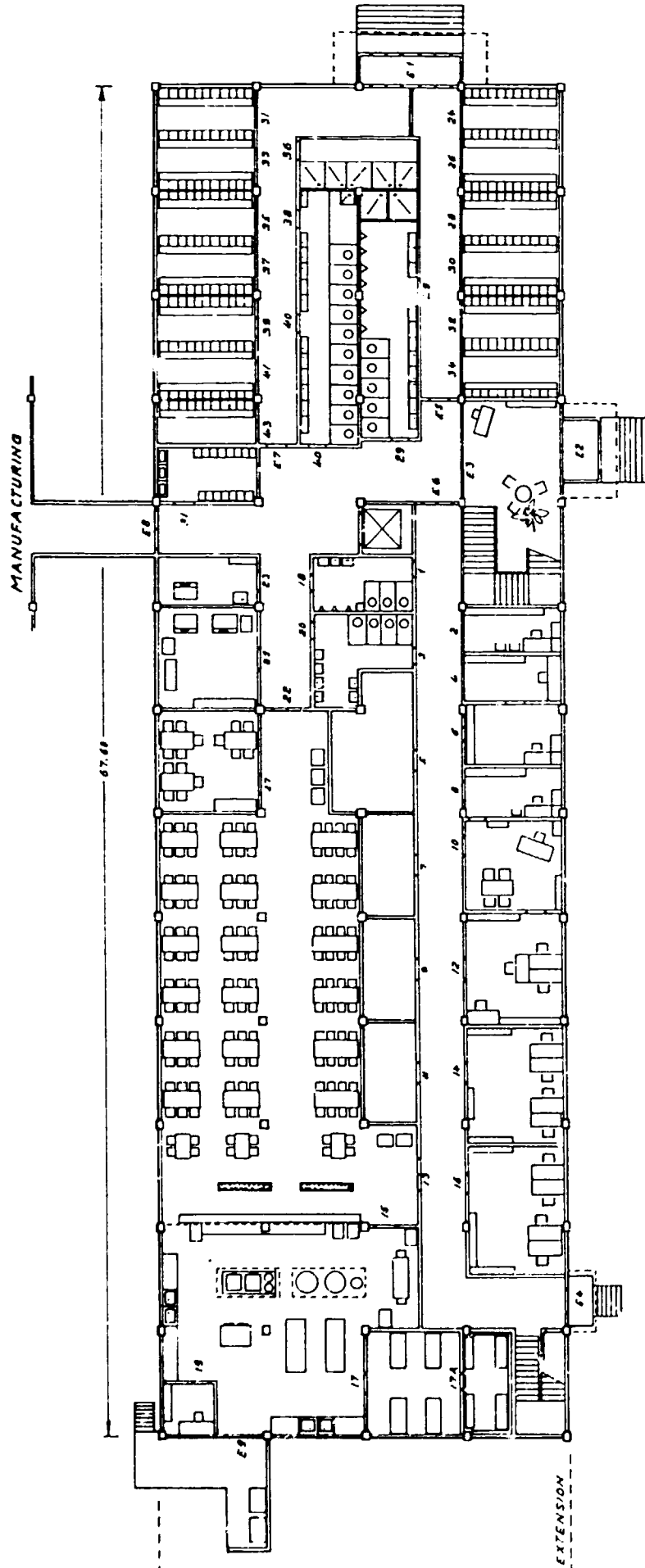
UNIDO 85.4.007



ANTIBIOTICS

SCALE = 1:200

UNIDO 85.4.008



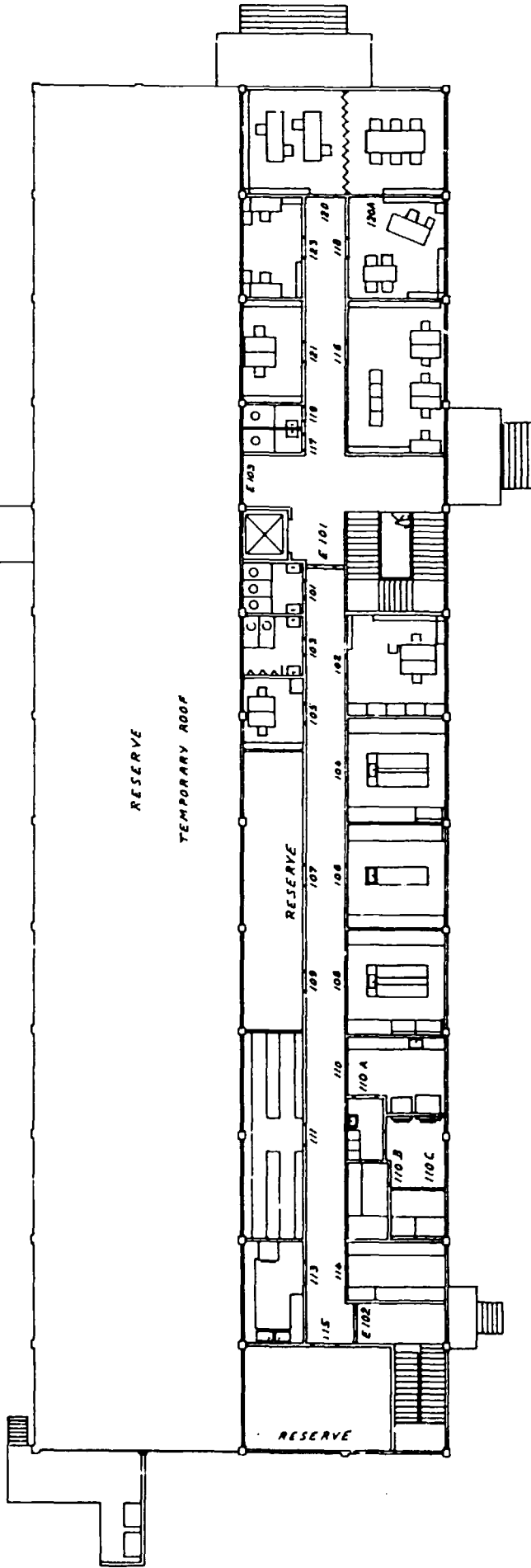
SERVICE BUILDING

GROUND FLOOR

UNIDO 05.4.012

SCALE - 1 : 300

MANUFACTURING



SERVICE BUILDING

FIRST FLOOR

UNIDO 85.4.013

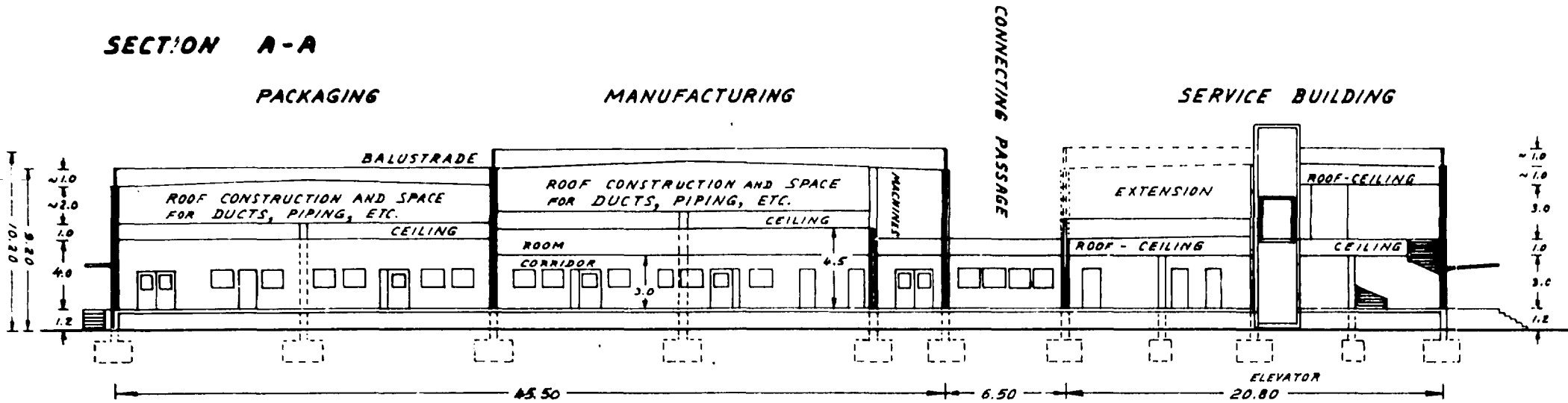
SCALE = 1 : 300

SECTION A-A

PACKAGING

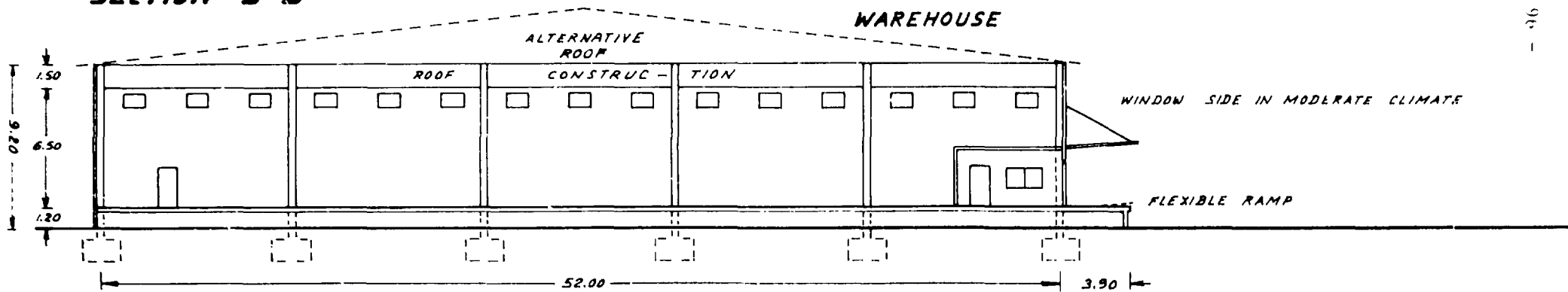
MANUFACTURING

SERVICE BUILDING



SECTION B-B

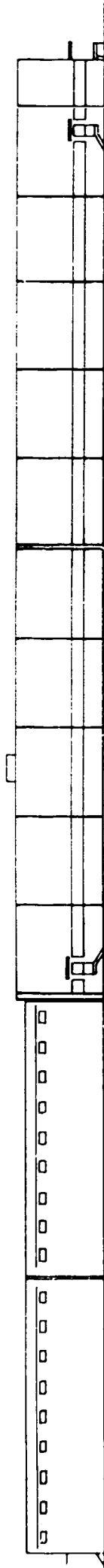
WAREHOUSE



SCALE = 1:300

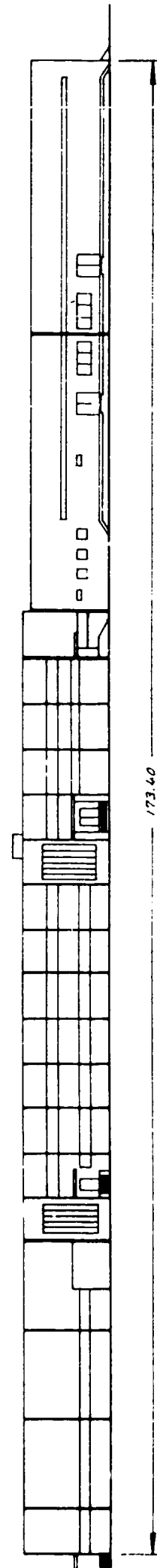
SECTIONS
UNIDO 85.4.014

REAR VIEW



WAREHOUSE WINDOW SIDE IN TROPICAL CLIMATE

FRONT VIEW



FAÇADES
 UNIDO 85.4.015

SCALE = 1:640

STANDARD WORKSHOP
FOR A PHARMACEUTICAL PRODUCTION PLANT

Equipment list for major items in the mechanical section:

- 1 Lathe - working length = 1000 mm. diameter ϕ = 300 mm; tools for turning, milling and grinding
- 2 Drilling machine - working height = 300 mm, working ϕ = 300 mm; variable speed, "precision" type; for borer ϕ = 1.0 - 16 mm
- 3 Folding press - working length = 1200 mm for metal thickness = up to 5-6 mm
- 4 Grinding machine with one fine and one coarse grinding stone
- 5 Grinding machine with one fine grinding stone and one brush
- 6 Sand - belt machine with different grades of grain belts
- 7 Mechanically operated metal saw with saw length = 350 mm
- 8 Manually operated press
- 9 Electric welding equipment with iron working table, suitable also for argon welding
- 10 Autogenous welding apparatus
- 11 4-6 vices with working table and tool cupboard
- 12 Working table with metal plate top for rectifying work
- 13 Tripod for pipe fitter's work
- 14 Anvil
- 15 Plate cutter
- 16 Pulley block with trestle; free height = 2.5-3 m, max. load = 2000 kg
- 17 Set of threading tools for ϕ = 2-16 mm and ϕ = 16-30 mm
- 18 Set of female screw threading tools for ϕ = 2-16 mm and ϕ = 16-30 mm
- 19 4-6 metal hand saws
- 20 4-6 slide-gauges, usable length = 140-150 mm
- 21 Precision instruments: e.g. micrometer for measuring outside and inside dimensions, apparatus to measure "Brinell" surface hardness of metals, etc.
- 22 4 movable working carts with tool kit
- 23 General tools - for each mechanic: e.g. special hammers, tongs, drivers, files, rule, etc.

Equipment list for major items
in the electro-mechanical and instrument section:

- 41 2 kits with electrician tools, 2 vices and 2 working tables with tool cupboards
- 42 Kit with tools for measuring and servicing instruments and automatic controls
- 43 Soldering equipment (80 and 90 Watt)
- 44 2 metal hand saws

- 45 Combined volt meter: V^{\sim} , V^{\equiv} , A, mA, Ω , μF
- 46 General tools for each electrician: hammer, tongs, drivers, files, rule; all insulated against current.

General:

- 51 Air compressor (if the workshop is not connected to the general compressed air grid)
 - 52 Spot ventilation at the welding- and grinding work-places
 - 53 Used oil recovery
 - 54 Equipment for servicing and repair of furniture (if not included in above items)
 - 55 Equipment for servicing and repair of buildings
 - 56 Painting facilities
 - 57 Furniture for offices, including one drawing stage, telephone and typewriter
 - 58 Planning board, card files, place of deposit for drawings and instructions of production machines
 - 59 Organization for preventive maintenance
 - 60 Cloak room, if not combined with boiler house
 - 61 Sanitary facilities if not combined with boiler house crew facilities
- PS. AC = window air conditioner

In case of plant location in an area with insufficient infrastructure, the workshop space would have to be enlarged up to a maximum of 600 sq.m and the following equipment may be required:

- 1 Lathe - working length = 2500 mm, diameter ϕ = 600 mm
- 1 Drilling machine - working height = 400 mm, working ϕ = 500 mm; borer up to ϕ = 30 mm
- 1 Milling machine - working length = 1200 mm; tools
- 1 Band-saw - working height = 400 mm
- 1 Hydraulically operated press
- 2 Vices, large type, swivel mounted, with working table and tool-cupboard
- 1 Anvil
- div. Additional hand tools as required, furthermore goniometer, metal rulers, circle, scribe, etc; tools which are necessary to service and repair larger machine parts in the own workshop.
- 1 Spin winder for electric motors
- 1 Furnace for electric motor rotors
- div. Equipment and furnace to temper and possibly chromium plate metal pieces such as punches and dies, transport arms on packaging machines, etc

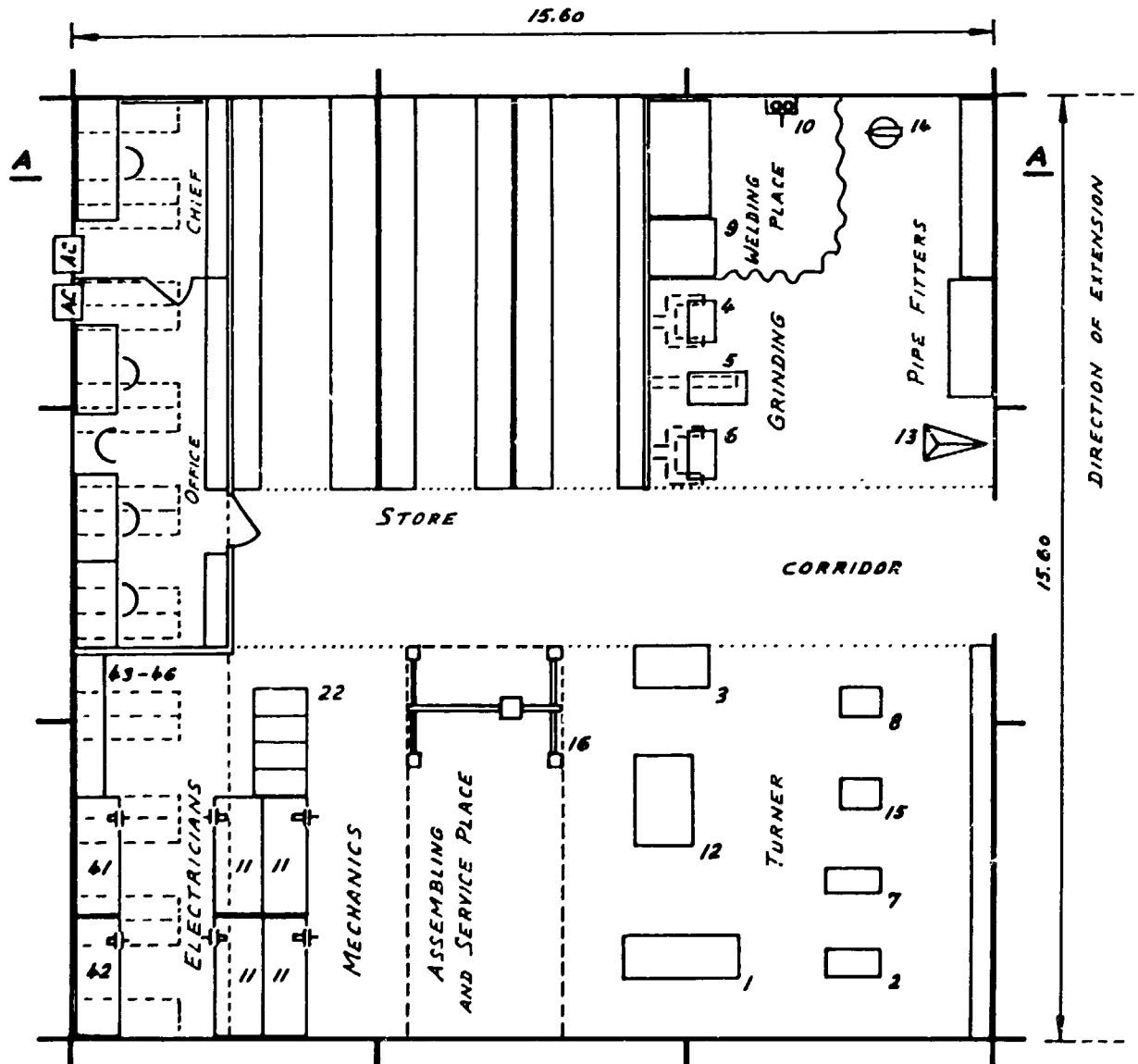
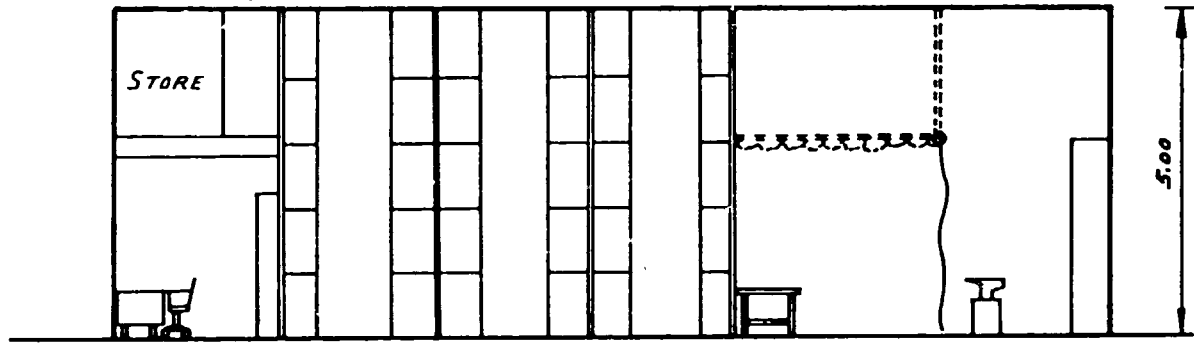
For the carpenter:

- 1 Band saw for wood
- 1 Combined saw for wood
- 1 Work table for cupboard joiner and carpenter
- 1 Set of planes
- Tools for maintenance, repair and manufacture of furniture

Furthermore, the following services could be required:

- Facilities to service internal and external transport vehicles
- Repair of vessels
- Repair of buildings and small extensions
- Manufacture of air ducts and filter frames
- etc.

SECTION A-A



PROPOSED STANDARD WORKSHOP

SURFACE = 243 sq.m
SCALE = 1:111

FOR REF. No's. SEE EQUIPMENT LIST
UNIDO 85.4.010

