REQUIREMENTS OF PLANT AND EQUIPMENT
[Schedule M]

1. *External Preparations*. -

The following equipments are recommended for the manufacture of .External preparations. i.e. **Ointments, Emulsion, Lotions, Solutions, Pastes, Creams, Dusting powders** and such identical products used for external applications whichever is applicable, namely :-

(1) Mixing and storage tanks (stainless steel),
(2) Jacketted Kettle (steam, gas or electrically heated),
(3) Mixer (electrically operated)
(4) Planetary mixer
(5) A colloid mill or a suitable emulsifier.
(6) A triple roller mill or an ointment mill.
(7) Liquid filling equipment (electrically operated).
(8) Jar or tube filling equipment (electrically operated)

Area. - (1) A minimum area of thirty square meters for basic installation and ten square meters for Ancillary area is recommended.

(2) Areas for formulations meant for external use and internal use shall be separately provided to avoid mix-up.

2. *Oral Liquid Preparations*. -

The following equipments are commended for the manufacture of oral/internal use preparations i.e. Syrups, Elixirs, Emulsions and suspensions, whichever is applicable, namely: -

(1) Mixing and storage tanks (stainless steel),
(2) Jacketted Kettle / Stainless steel tank (steam, gas or electrically heated).
(3) Portable stirrer (electrically operated)
(4) A colloid mill or suitable emulsifier (electrically operated)
(5) Suitable filtration equipment (electrically operated)
(6) Semi-automatic/automatic bottle filling machine
(7) Pilfer proof cap sealing machine.
(8) Water distillation unit or deioniser
(9) Clarity testing inspection units.

Area. - A minimum area of thirty square meters for basic installation and ten square meters for Ancillary area is recommended.

3. Tablets

The Tableting section shall be free from dust and floating particles and may be air-conditioned. For this purpose, each tablet machine shall be isolated into cubicles and connected to a vacuum dust collector or an exhaust system. For effective operations, the tablet production department shall be divided into four distinct and separate sections as follows: -

(a) Mixing, Granulation and Drying section.
(b) Tablet compression section.
(c) Packaging section (strip/blister machine wherever required).
(d) Coating section (wherever required).

3.1. The following electrically operated equipments are recommended for the manufacture of **compressed tablets** and **hypodermic tablets**, in each of the above sections, namely: -

(a) Granulation-cum-Drying section

(1) Disintegrator and sifter
(2) Powder mixer
(3) Mass mixer/Planetary mixer/Rapid mixer granulator.
(4) Granulator
(5) Thermostatically controlled hot air oven with trays (preferably mounted on a trolley)/Fluid bed dryer.
(6) Weighing machines.

(b) Compression section.

(1) Tablet compression machine, single/multi punch/rotatory.
(2) Punch and dies storage cabinets.
(3) Tablet de-duster
(4) Tablet Inspection unit/belt.
(5) Dissolution test apparatus
(6) In-process testing equipment like single pan electronic balance, hardness tester, friability and disintegration test apparatus.
(7) Air-conditioning and dehumidification arrangement (wherever necessary)

(c) Packaging section.

(1) Strip/blister packaging machine.
(2) Leak test apparatus (vacuum system)
(3) Tablet counters (wherever applicable)
(4) Air-conditioning and dehumidification arrangement (whereever applicable).

Area. - A minimum area of sixty square meters for basic installation and twenty square meters for Ancillary area is recommended for un-coated tablets.

(d) Coating section,

(1) Jacketted kettle (steam, gas or electrically heated for preparing coating suspension).
(2) Coating pan (stainless steel)
(3) Polishing pan (where applicable)
(4) Exhaust system (including vacuum dust collector)
(5) Air-conditioning and dehumidification arrangement.
(6) Weighing balance.

3.2. The Coating section shall be made dust free with suitable exhaust system to remove excess powder and fumes resulting from solvent evaporation. It shall be airconditioned and dehumidified wherever considered necessary.

Area. - A minimum additional area of thirty square meters for coating section for basic installation and ten square meters for Ancillary area is recommended.

Separate area and equipment for mixing, granulation, drying, tablet compression, coating and packing shall be provided for Penicillin group of drugs on the lines indicated above. In case of operations involving dust and floating particles, care shall be exercised to avoid cross-contamination.

3.3. The manufacture of Hypodermic tablets shall be conducted under aseptic conditions in a separate air-conditioned room, the walls of which shall be smooth and washable. The granulation, tableting and packing shall be done in this room.

3.4. The manufacture of effervescent and soluble/dispersible tablets shall be carried out in air-conditioned and dehumidified areas.

(4) Powders

The following equipment is recommended for the manufacture of powders, namely:-

(1) Disintegrator
(2) Mixer (electrically operated)
(3) Sifter.
(4) Stainless steel vessels and scoops of suitable sizes.
(5) Filling equipment (electrically operated).
(6) Weighing balance.

In the case of operation involving floating particles of fine powder, suitable exhaust system shall be provided. Workers should be provided with suitable masks during operation.

Area. - A minimum area of thirty square meters is recommended to allow for the basic installations. Where the actual blending is to be done on the premises, an additional room shall be provided for the purpose.

(*5*) *Capsules*

For the manufacture of capsules, separate enclosed area suitably air-conditioned and dehumidified with an airlock arrangement shall be provided. The following equipment is recommended for filling Hard Gelatin Capsules, namely: -

(1) Mixing and blending equipment (electrically or power driven).
(2) Capsules filling units (preferably semi automatic or automatic filling machines).
(3) Capsules counters (wherever applicable)
(4) Weighing balance.
(5) Disintegration test apparatus.
(6) Capsule polishing equipment.

Separate equipment and, filling and packaging area shall be provided in penicillin and non-penicillin sections. In case of operations involving floating particles of fine powder, a suitable exhaust system shall be provided. Manufacture and filling shall be carried out in air-conditioned area. The room shall be dehumidified.

Area. - A minimum area of twenty-five square meters for basic installation and ten square meters for Ancillary area each for penicillin and non-penicillin sections is recommended.

(6) *Surgical Dressing*

The following equipment is recommended for the manufacture of Surgical Dressings other than Absorbent Cotton Wool, namely:-

(1) Rolling machine
(2) Trimming machine
(3) Cutting equipment.
(4) Folding and pressing machine for gauze.
(5) Mixing tanks for processing medicated dressing.
(6) Hot air dry oven.
(7) Steam sterilizer or dry heat sterilizer or other suitable equipment.
(8) Work tables/benches for different operations.

Area. - A minimum area of thirty square meters is recommended to allow for the basic installations. In case medicated dressings are to be manufactured, another room with a minimum area of thirty square meters shall be provided.

(7) *Ophthalmic Preparations.*

For the manufacture of Ophthalmic preparations, separate enclosed areas with airlock arrangement shall be provided. The following equipment is recommended for the manufacture under aseptic conditions of Eye-Ointment, Eye-Lotions and other preparations for external use, namely

(1) Thermostatically controlled hot air ovens (preferably double ended).
(2) Jacketted kettle/stainless steel tanks (steam, gas or electrically heated).
(3) Mixing and storage tanks of stainless steel/Planetary mixer.
(4) Colloid mill or ointment mill.
(5) Tube filling and crimping equipment (semi-automatic or automatic filling machines).
(6) Tube cleaning equipment (air jet type),
(7) Tube washing and drying equipment, if required
(8) Automatic vial washing machine.
(9) Vial drying oven.
(10) Rubber bung washing machine.
(11) Sintered glass funnel, Seitz filter and filter candle (preferably cartridge and membrane filters).
(12) Liquid filling equipment (semi-automatic or automatic filling machines).
(13) Autoclave (preferably ventilator autoclave).
(14) Air conditioning and dehumidification arrangement (preferably centrally airconditioned and dehumidification system).
(15) Laminar airflow units.

Area. - (1) A minimum area of twenty-five square meters for basic installation and ten square meters for Ancillary area is recommended. Manufacture and filling shall be carried out in air-conditioned areas under aseptic conditions. The rooms shall be further dehumidified as considered necessary if preparations containing antibiotics are manufactured.

(2) Areas for formulations meant for external use and internal use shall be separately provided to avoid mix up.

(8) *Pessaries and Suppositories*

(i) The following equipment is recommended for manufacture of Pessaries and Suppositories, namely: -
(1) Mixing and pouring equipment
(2) Moulding equipment.
(3) Weighing devices.

Area. - A minimum area of twenty square meters is recommended to allow for the basic installation.

(ii) In the case of Pessaries manufactured by granulation and compression, the requirements as indicated under .Item 3 of Tablet., shall be provided.

9. *Inhalers and Vitralle*

The following equipment is recommended for manufacture of inhalers and vitrallae, namely: -

(1) Mixing equipment.
(2) Graduated delivery equipment for measurement of the medicament during filling.
(3) Sealing equipment.

Area. - An area of minimum twenty square meters is recommended for the basic installations.

10. *Repacking of Drugs and Pharmaceutical Chemicals.*

The following equipment is recommended for repacking of drugs and pharmaceuticals chemicals, namely:-

(1) Powder disintegrator
(2) Powder sifter (electrically operated)
(3) Stainless steel scoops and vessels of suitable sizes
(4) Weighing and measuring equipment.
(5) Filling equipment (semi-automatic / automatic machines).
(6) Electric sealing machine.

Area- An area of minimum thirty square meters is recommended for the basic installation. In case of operations involving floating particles of fine powder, a suitable exhaust system shall be provided.

REQUIREMENTS OF PLANT AND EQUIPMENT

11. *Parenteral Preparations*

The whole operation of manufacture of parenteral preparations (small volume injectables and large volume parenterals) in glass and plastic containers may be divided into the following separate areas/rooms, namely: -

11.1 ***Parenteral preparations in glass containers-***

(1) Water management area: this includes water treatment and storage
(2) Containers and closures preparation area: This includes washing and drying of ampoules, vials, bottles and closures.
(3) Solution preparation area: This includes preparation and filtration of solution.
(4) Filling, capping and sealing area: This includes filling and sealing of ampoules and/or filling, capping and sealing of vials and bottles.
(5) Sterilization area
(6) Quarantine area
(7) Visual inspection area
(8) Packaging area

The following equipment is recommended for different above-mentioned areas, namely: -

(a) Water management area, -

(1) De-ionised water treatment unit
(2) Distillation (multi-column with heat exchangers) unit.
(3) Thermostatically controlled water storage tank.
(4) Transfer pumps.
(5) Stainless steel service lines for carrying water into user areas.

(b) Containers and closures preparation area, -

(1) Automatic rotary ampoule/vial/bottle washing machine having separate air, water distilled water jets.
(2) Automatic closures washing machine,
(3) Storage equipment for ampoules, vials, bottles and closures.
(4) Dryer/sterilizer (double ended)
(5) Dust proof storage cabinets.
(6) Stainless steel benches/stools.

(c) Solution preparation area. .

(1) Solution preparation and mixing stainless steel tanks and other containers.
(2) Portable stirrer.

(3) Filtration equipment with cartridge and membrane filters/bacteriological filters.
(4) Transfer pumps.
(5) Stainless steel benches/stools

(d) Filling, capping and sealing area, -

(1) Automatic ampoule/vial/bottle filling, sealing and capping machine under laminar air flow workstation.
(2) Gas line (Nitrogen, Oxygen, Carbon dioxide) wherever required.
(3) Stainless steel benches / stools

(d) Sterilization area, -

(1) Steam sterilizer preferably with computer control for sterilization cycle along with trolley sets for loading/unloading containers before and after sterilization).
(2) Hot air sterilizer (preferably double ended).

(3) Pressure leak test apparatus.

(e) Quarantine area. .

(1) Storage cabinets.
(2) Raised platforms/steel racks.

(g) Visual inspection area, -

(1) Visual inspection units (preferably conveyor belt type and composite white and black assembly supported with illumination).
(2) Stainless steel benches/stools.

(h) Packaging area. -

(1) Batch coding machine (preferably automatic)
(2) Labelling unit (preferably conveyor belt type)
(3) Benches/stools

Area. - (1) A minimum area of one hundred and fifty square meters for the basic installation and an Ancillary area of one hundred square meters for Small Volume Injectables are recommended. For Large Volume Parenterals, an area of one hundred and fifty square meters each for the basic installation and for Ancillary area is recommended.
These areas shall be partitioned into suitable enclosures with airlock arrangements.

(2) Areas for formulations meant for external use and internal use shall be separately provided to avoid mix up.
(3) Packaging materials for large volume parenteral shall have a minimum area of 100 square meters.

11.2 ***Parenteral preparations in plastic containers by Form-Fill-Seal/Blow, Fill-Seal Technology. –***

The whole operation of manufacture of large volume parenteral preparations in plastic containers including plastic pouches by automatic (all operations in one station) Form-Fill-Seal machine or by semi-automatic blow moulding, filling-cumsealing machine may be divided into following separate areas/rooms, namely: -

(1) Water management area
(2) Solution preparation area
(3) Containers moulding-cum filling and sealing area
(4) Sterilization area
(5) Quarantine area
(6) Visual inspection area
(7) Packing area

The following equipment is recommended for different above mentioned areas namely: -

(a) Water management area, -

(1) De-ionised water treatment unit
(2) Distillation unit (multi column with heat exchangers)
(3) Thermostatically controlled water storage tank
(4) Transfer pumps
(5) Stainless steel service lines for carrying water into user areas.

(b) Solution preparation area, -

(1) Solution preparation and storage tanks.
(2) Transfer pumps
(3) Cartridge and membrane filters.

(c) Container moulding-cum-filling and sealing area, -

(1) Sterile Form-Fill-Seal machine (all operations in one station with built-in laminar air flow workstation having integrated container output conveyor belt through pass box).
(2) Arrangement for feeding plastic granules through feeding-cum-filling tank into the machine.

(d) Sterilization area, - Super heated steam sterilizer (with computer control for sterilization cycle along with trolley sets for loading/unloading containers for sterilization).

(e) Quarantine area, - Adequate number of platforms/racks with storage system.

(f) Visual inspection area, - Visual inspection unit (with conveyor belt and composite

(g) Packaging area, -

(1) Pressure leak test apparatus (pressure belt or rotating disc type)
(2) Batch coding machine (preferably automatic)
(3) Labelling unit (preferably conveyor belt type).

Area. - (1) A minimum area of two hundred and fifty square meters for the basic installation of an Ancillary area of one hundred and fifty square meters for large volume parenteral preparations in plastic containers by Form-Fill-Seal technology is recommended. These areas shall be partitioned into suitable enclosures with airlock arrangements.
(2) Areas for formulations meant for external use and internal use shall be separately provided to avoid mix up.
(3) Packaging materials for large volume parenteral shall have a minimum area of 100 square meters.]