

## Requirements of Equipment for manufacture of Homoeopathic preparations: (as per Schedule M- I )

### *1.1 Mother tinctures and mother solution section. –*

The following equipment shall be provided: -

- (i) Disintegrator
- (ii) Sieved Separator
- (iii) Balances, weights and fluid measures, all in metric system
- (iv) Chopping table/boards and knives.
- (v) Macerators with lids ( made of stainless steel of grade 304 or neutral glass)
- (vi) Percolators ( made of stainless steel of grade 304)
- (vii) Moisture determination apparatus
- (viii) Filtering press / sparkler filter ( all metal parts of stainless steel)
- (ix) Mixing vessels and storage vessels (stainless steel of grade 304).
- (x) Portable stirrers (rods, blades and screws of stainless steel).
- (xi) Water still / water purifier
- (xii) Macerators and percolators for preparing mother solutions of chemical origin.  
These shall be of material which will not react with chemicals used, and which do not bleach.
- (xiii) Filling and sealing machine.

The area for manufacture of mother tinctures and mother solutions shall not be less than 55 squaremetres for basic installations.

### *1.2 Potentisation section. –*

The section shall have following facilities:

- (i) Work benches with washable impervious tops.
- (ii) Facilities for orderly storage of different potencies and back potencies of various drugs
- (iii) Suitable devices for measuring and dispensing potencies / back potencies into the potentisation phials.
- (iv) Potentiser with counter

An area of 20 sq. meters shall be provided for basic installations.

*.Note:* - (1) The requirement of Potentiser is not mandatory. The process may be done manually also with proper SOPs.

(2) The manufacturer shall use back-potencies procured from licensed manufacturers and shall maintain proper records of purchase, or shall prepare own back-potencies. Container of potencies and back-potencies shall be properly labeled to avoid any mix-up.

### *1.3 Containers and Closures Section-*

Separate area for preparation of containers and closures shall be provided adjacent to potentiation section. This area shall have following facilities:

- (i) Washing tanks with suitable mechanical or hand operated brushes.
- (ii) Rinsing tanks. Purified water shall be used for rinsing.
- (iii) Closures washing/ macerating tanks.
- (iv) Driers

Note- a. Different droppers shall be used only for each different medicine and different potency.  
b. All measures shall be in metric system. Measures shall be of neutral glass or stainless steel. Metal droppers and plastic droppers shall not be used.  
c. Glass droppers shall be used only after proper cleaning and sterilization.  
d. Potentiation shall be done by the methods prescribed in Homoeopathic Pharmacopoeia of India.

### *1.4 Trituration, Tableting, Pills and Globules making section -*

The following basic equipment and facilities shall be provided, as per the requirements of manufacturing process:-

- (i) Triturating machine
- (ii) Disintegrator
- (iii) Mass Mixer
- (iv) Granulator
- (v) Electric Oven
- (vi) Tablet punching machine
- (vii) Kettle (Steam/electrically heated) for preparing solutions.
- (viii) Driers for drying granules and tablets.
- (ix) Sieved separator, (Stainless Steel)
- (x) Tablet counters
- (xi) Balances.
- (xii) Coating pan with spray gun
- (xiii) Multi-sifter
- (xiv) Mill with perforations

An area of 55sq. meters shall be provided for basis installations. The area shall be suitably divided into cubicles to minimize cross contamination, mix up, etc.

*Note:* - The section shall be free from insects, worms, rodents, dust and other floating particles and moisture.

### *1.5 Syrups and other liquids section: -*

The following basic equipment and facilities shall be provided:-

- (i) Mixing and storage tank (stainless steel of grade 304)
- (ii) Potable stirrer
- (iii) Filter press / sparkler filter ( all metal parts of stainless steel)
- (iv) Filling and sealing machine.
- (v) pH meter

An area of 20 sq. meters shall be provided for basic installations.

The section shall be free dust and other floating particles, cobwebs, flies, ants and other insects, birds, lizards and rodents.

1. Adequate number of workbenches shall be provided.
2. Visual inspection table shall be provided. This shall comprise of a colour contrast background with a lamp for providing diffused light, mounted on a suitable table.

### *1.6 Ointments and lotions section.*

The following basic equipment and facilities shall be provided as per the requirements of manufacturing process:-

- (i) Mixing tank (Stainless Steel)
- (ii) Kettle (Steam/electrically heated) for preparing solutions
- (iii) Suitable powder/ planetary mixer
- (iv) Ointment mill / Colloidal mill/ Emulsifier.
- (v) Filling and sealing machine / crimping machine.
- (vi) Filtering equipment.
- (vii) Balance and weights.

A minimum area of 20 sq. meters shall be provided for basis installations. An ancillary area for washing vessels and equipments shall be provided. An ancillary area for heating purposes shall also be provided.

### *1.7 Ophthalmic Preparations section:*

The following basic equipment and facilities shall be provided:-

- (i) Hot air oven, electrically heated, with thermostatic control.
- (ii) Laminar air flow bench.
- (iii) Air Handling Unit with HEPA filters, air locks.
- (iv) Colloidal mill or ointment mill.

- (v) Mixing and storage tanks ( stainless steel grade 304)
- (vi) Pressure vessels, as may be needed.
- (vii) Sintered glass funnel, Seitz filter or filter candle.
- (viii) Vacuum pump
- (ix) Filling machines for liquids ointments, etc.
- (x) Autoclaves with pressure and temp gauges.
- (xi) Necessary workbenches, visual inspection bench, etc.

Minimum area of 20 sq. meters shall be provided for basic installations.

Note-

1. The section shall have a clean room facility of class 100 specification.
2. The section shall be air-conditioned and humidity controlled.
3. Entry to the section shall be regulated through air locks with differential air pressures with the air lock adjacent to the section having higher pressure and the first one through which entry is made with the least pressure.
4. Materials shall be passed to the sections through suitable hatches.
5. The personnel shall wear sterile clothing including headgear, which shall not shed fibre.
6. Washing of phials shall be done in separate areas with proper equipment.
7. Separate area shall be provided for labeling and packing.

### *Equipment in Quality Control Division.*

The following equipment shall be provided:-

- (i) Microscope of suitable magnification and photographic device
- (ii) Compound microscope
- (iii) TLC apparatus
- (iv) UV lamp viewer
- (v) Monopan digital electronic balance
- (vi) Hot air oven
- (vii) Distillation apparatus
- (viii) Water bath
- (ix) Polarimeter
- (x) Refractometer
- (xi) Melting point apparatus
- (xii) PH meter
- (xiii) Magnetic stirrer
- (xiv) Table centrifuge
- (xv) Muffle furnace / electric Bunsen
- (xvi) Moisture determination apparatus
- (xvii) U V Spectrophotometer
- (xviii) Rotary microtome / Section cutting facilities
- (xix) Tablet disintegration machine.