

**Seventh Schedule****[See rules 23(4), 26(b)]****Good manufacturing practices and requirements of premises, plants and equipment for manufacture of cosmetics****I. General requirements**

(A) Location and surroundings.— The factory shall be located in a sanitary place any hygienic conditions shall be maintained in the premises. Premises shall not be used for residence or be interconnected with residential areas. It shall be well ventilated and clean.

In the manufacture of cosmetic products overall control and monitoring is essential to ensure that the consumer receives products of specified quality.

(B) Buildings.— The buildings used for the factory shall be constructed so as to permit production under hygienic conditions and not to permit entry of insects, rodents, flies, etc.

Effective measures should be taken to avoid any contamination from the surrounding environment.

The walls and floors of the room in which manufacturing operations are carried out, be free from cracks and open joints to avoid accumulation of dust. These shall be smooth, washable, coved and shall permit easy and effective cleaning and disinfection.

Buildings should be adequately lit and properly ventilated appropriate to the operations.

Testing laboratories should preferably be physically separated from the production areas.

Storage areas should be of adequate space provided with suitable lighting, arranged and equipped to allow dry, clean and orderly placement of stored materials and products.

The walls of the room in which manufacturing operations are carried out, shall be up to a height of above six feet from the floor.

(C) Personnel.— There should be an adequate number of personnel having, experience and capabilities relevant to their assigned function.

(D) Water supply.— The water used in manufacture shall be of potable quality.

(E) Disposal of waste.— The disposal of sewage and effluents (solid, liquid and gas) from the manufacturing premises shall be in conformity with the requirements of Environment Pollution Control Board.

(F) Health, clothing and sanitary requirements of the staff.— All workers shall be free from contagious or infectious diseases. They shall be provided with clean uniforms, masks, headgears and gloves wherever required. Washing facilities shall also be provided.

(G) Medical services.— Adequate facilities for first-aid shall be provided.

(H) Maintenance.— All equipment should be serviced and calibrated regularly, wherever required records should be maintained.

(I) Testing and release of raw materials & finished cosmetic products.— Quality control of raw materials & finished cosmetic products is an essential part of Good Manufacturing Practices. It provides assurance that cosmetic products will be of consistent quality appropriate to their intended use.

A quality control system should be established to ensure that products contain the correct materials of specified quality and quantity and are manufactured under proper conditions according to standard operating procedures.

Quality control involves sampling, inspecting and testing of raw or packaging materials, in process, intermediate, bulk, and finished products.

Parametric release of raw material can be adopted provided vendors of raw materials are approved and such procedures are robust, validated, based on the trend of earlier testing experience for such purposes.

Parametric release for finished product can also be adopted, provided such procedures are robust, validated, based on the trend of earlier testing experience for such purposes, except for the cosmetics in the category of eye products, lipstick, and dental products.

Note: Each batch of raw material, finished product or in-process parameters need not required to be tested however it needs to be approved and released by quality control on the basis of standard operating procedure for parametric release.

(J) Working benches shall be provided for carrying out operations such as filling, labelling, packing, etc. Such benches shall be fitted with smooth, impervious tops capable of being washed.

(K) Adequate facilities shall be provided for washing and drying of glass containers if the same are to be used for packing the product.

## II. Requirements of plant and equipment

List of categories of cosmetics for the purpose of grant of licence to manufacture for sale of cosmetic in the country

Category
(A) Powders
(B) Skin Powder for Infants
(C) Creams, lotions, emulsions, pastes, cleansing milks, shampoos, pomade, brilliantine, shaving-creams and hair-oils, etc.
(D) Nail Polishes and Nail Lacquers.
(E) Lipsticks and Lipgloss.
(F) Depilatories
(G) Preparations used for Eyes 1. Eyebrows, Eyelashes, Eyeliners. 2. Kajal and surma.
(H) Aerosol
(I) Alcoholic Fragrance solutions
(J) Hair Dyes
(K) Tooth-powders and toothpastes, etc. 1. Tooth-powder in General. 2. Tooth pastes. 3. Tooth — Powder (Black).
(L) Toilet Soaps

The following equipment, area and other requirements are recommended for the manufacture of.—

A. Powders.— Face-powder, cake make-up, compacts, face-packs, masks and rouges etc.

Equipments:

- (a) Powder mixer of suitable type provided with a dust collector.
- (b) Perfume and colour blender.

- (c) Sifter with sieves of suitable mesh size.
- (d) Ball mill of suitable grinder.
- (e) Trays and scoops (stainless steel).
- (f) Filling and sealing equipment provided with dust extractor.
- (g) For compacts:-
  - (i) a separate mixer
  - (ii) Compact pressing machine.
- (h) Weighing and measuring devices.
- (i) Storage tanks.

An area of 15 square metres is recommended. The section is to be provided with adequate exhaust fans.

(B) Skin Powder for Infants.-

Equipments:

- (a) Powder mixer of suitable type provided with a dust collector.
- (b) Perfume and colour blender.
- (c) Sifter with sieves of suitable mesh size.
- (d) Ball mill of suitable grinder.
- (e) Trays and scoops (stainless steel). Filling and sealing equipment provided with dust extractor.
- (f) Weighing and measuring devices.

An area of 15 square metres is recommended. The section is to be provided with adequate exhaust fans.

(C) Creams, lotions, emulsions, pastes, cleansing milks, shampoos, pomade, brilliantine, shaving-creams and hair-oils, etc.-

Equipments:

- (a) Mixing and storage tanks of suitable materials.
- (b) Heating kettle — steam, gas or electrically heated.
- (c) Suitable agitator.
- (d) Colloidal mill or homogeniser (wherever necessary).
- (e) Triple roller mill (wherever necessary).
- (f) Filling and sealing equipment.
- (g) Weighing and measuring devices.

An area of 25 square metres is recommended.

(D) Nail Polishes and Nail Lacquers.-

1. Equipments:

- (a) A suitable mixer.
- (b) Storage tanks.
- (c) Filling machine - hand operated or power driven.
- (d) Weighing and measuring devices.

An area of 15 square metres is recommended. The section shall be provided with flame proof exhaust system.

2. Premises.— The following are the special requirements related to Nail Polishes and Nail Lacquers :
- (a) It shall be situated in an industrial area.
  - (b) It shall be separate from other cosmetic-manufacturing area by metal/brick partition up to ceiling.
  - (c) Floors, walls, ceilings and doors shall be fireproof.
  - (d) Smoking, cooking and dwelling shall not be permitted and no naked flame shall be brought in the premises.
  - (e) All electrical wiring and connections shall be concealed and main electric switch shall be outside the manufacturing area.
  - (f) All equipment, furniture and light fittings in the section shall be flameproof.
  - (g) Fire extinguisher like foam and dry powder and sufficient number of buckets containing sand shall be provided.
  - (h) All doors of the section shall open outwards.
3. Storage.— All explosive solvents and ingredients shall be stored in metal cupboards or in a separate enclosed area.
4. Manufacture.—
- (a) Manufacture of lacquer shall not be undertaken unless the above conditions are complied with.
  - (b) Workers shall be asked to wear shoes with rubber soles in the section.
5. Other requirements.— No objection certificate from local Fire Brigade Authorities shall be furnished.
- (E) Lipsticks and Lipgloss.-

Equipments:

- (a) Vertical mixer.
- (b) Jacketted kettle — steam, gas or electrically heated.
- (c) Mixing vessels (stainless steel).
- (d) Triple roller mill/Ball mill.
- (e) Moulds with refrigeration facility.
- (f) Weighing and measuring devices.

An area of 15 square meters is recommended

(F) Depilatories.—

Equipments:

- (a) Mixing tanks.
- (b) Mixer.
- (c) Triple roller mill or homogeniser (where necessary).
- (d) Filling and sealing equipment.
- (e) Weighing and measuring devices.
- (f) Moulds (where necessary).

An area of 10 square meters is recommended.

(G) Preparations used for Eyes.— Such preparations shall be manufactured under strict hygienic conditions to ensure that these are safe for use.

1. Eyebrows, Eyelashes, Eyeliners.—

Equipments:

- (a) Mixing tanks.
- (b) A suitable mixer.
- (c) Homogeniser (where necessary).
- (d) Filling and sealing equipment.
- (e) Weighing and measuring devices.

An area of 10 square metres is recommended.

2. Kajal and surma.—

Equipments:

- (a) Base steriliser.
- (b) Powder steriliser (dry heat oven).
- (c) Stainless steel tanks.
- (d) A suitable Mixer.
- (e) Stainless steel sieves.
- (f) Filling and sealing arrangements.
- (g) Weighing and measuring devices.
- (h) Homogeniser (where necessary).
- (i) Pestle and Mortar (for Surma).

An area of 10 square metres with a separate area of 5 square metres for base sterilization is recommended.

Other requirements for 1 and 2:

- (a) False ceiling shall be provided wherever required.
- (b) Manufacturing area shall be made fly proof. An airlock or an air curtain shall be provided.
- (c) Base used for Kajal shall be sterilised by heating the base at 150° C for required time in a separate enclosed area.
- (d) The vegetable carbon black powder shall be sterilised in a drying oven at 120° C for required time.
- (e) All utensils used for manufacture shall be of stainless steel and shall be washed with detergent water, antiseptic liquid and again with distilled water.
- (f) Containers employed for 'Kajal' shall be cleaned properly with bactericidal solution and dried.
- (g) Workers shall put on clean overalls and use hand gloves wherever necessary.

(H) Aerosol:

Equipments:

- (a) Air-compressor (wherever necessary).
- (b) Mixing tanks.
- (c) Suitable propellant filling and crimping equipments.
- (d) Liquid filling unit.
- (e) Leak testing equipment.

- (f) Fire extinguisher (wherever necessary).
- (g) Suitable filtration equipment.
- (h) Weighing and measuring devices.

An area of 15 square meters is recommended.

Other requirements.— No objection certificate from the Local Fire Brigade Authorities shall be furnished.

(I) Alcoholic Fragrance solutions.—

Equipments:

- (a) Mixing tanks with stirrer.
- (b) Filtering equipment.
- (c) Filling and sealing equipment.
- (d) Weighing and measuring devices.

An area of 15 square meters is recommended.

(J) Hair Dyes.-

Equipments:

- (a) Stainless steel tanks.
- (b) Mixer.
- (c) Filling unit
- (d) Weighing and measuring devices.
- (e) Masks, gloves and goggles.

An area of 15 square meters with proper exhaust is recommended.

(K) Tooth-powders and toothpastes, etc.-

1. Tooth-powder in General.

Equipments:

- (a) Weighing and measuring devices.
- (b) Dry mixer (powder blender).
- (c) Stainless steel sieves.
- (d) Powder filling and sealing equipments.

An area of 15 square meters with proper exhaust is recommended.

2. Tooth pastes.

Equipments:

- (a) Weighing and measuring devices.
- (b) Kettle—steam, gas or electrically heated (where necessary).
- (c) Planetary mixer with de-aerator system.
- (d) Stainless steel tanks.
- (e) Tube filling equipment.
- (f) Crimping machine.

An additional area of 15 square meters with proper exhaust is recommended.

## 3. Tooth — Powder (Black).

## Equipments:

- (a) Weighing and measuring devices.
- (b) Dry mixer powder blender.
- (c) Stainless steel sieves.
- (d) Powder filling arrangements.

An area of 15 square meters with proper exhaust is recommended. Areas for manufacturing “Black” and “White” tooth-powders should be separate.

## (L) Toilet Soaps.—

## Equipments:

- (a) Kettles or pans for saponification.
- (b) Boiler or any other suitable heating arrangement.
- (c) Suitable stirring arrangement.
- (d) Storage tanks or trays.
- (e) Driers.
- (f) Amalgamator or chipping machine.
- (g) Mixer.
- (h) Triple roller mill.
- (i) Granulator.
- (j) Plodder.
- (k) Cutter.
- (l) Pressing stamping and embossing machine.
- (m) Weighing and measuring devices.

A minimum area of 100 square meters is recommended for the small-scale manufacture of toilet soaps.

The areas recommended above are for basic manufacturing of different categories of cosmetics. In addition to that separate adequate space for storage of raw materials, finished products, packing materials shall be provided in factory premises.

Note I : The above requirements of the Schedule are made subject to the modification at the discretion of the Licensing Authority, if he is of the opinion that having regard to the nature and extent of the manufacturing operations it is necessary to relax or alter them in the circumstances of a particular case.

Note II : The above requirements do not include requirements of machinery, equipment and premises required for preparation of containers and closers of different categories of cosmetics. The Licensing Authority shall have the discretion to examine the suitability and adequacy of the machinery, equipment and premises for the purpose taking into consideration the requirements of the licensee.

Note III : This schedule specifies equipment and space required for certain categories of cosmetics only. There are other cosmetics items, viz. Attars, perfumes, etc., which are not covered in the above categories. The Licensing Authority shall, in respect of such items or categories of cosmetics, have the discretion to examine the adequacy of factory premises, space, plant and machinery and other requisites having regard to the nature and extent of the manufacturing operations involved and direct the licensee to carry on necessary modification in them.