

¹[**SCHEDULE R1**
(See Rules 109A, 109, 109C and 125A)]

The medical devices shall conform to the Indian Standards laid down from time to time by the Bureau of Indian Standards. If there are no Bureau of Indian Standards then it shall conform to the International Standards, like International Organisation for Standardisation, or other International Pharmacopeia Standards and such other standards as may be specified for this purpose. In case national or international standards are not available, the device shall conform to the manufacturer's validated standards.]

²[**SCHEDULE S**
[See Rule 150-A]]

STANDARDS FOR COSMETICS

Standards for cosmetics in finished form – The following cosmetics in finished form shall conform to the Indian Standards specifications laid down from time to time by the ³[Bureau of Indian Standards (BIS)].

1. Skin Powders.
2. Skin Powder for infants.
3. Tooth Powder.
4. Toothpaste.
5. Skin Creams.
6. Hair Oils.
7. Shampoo, Soap-based.
8. Shampoo, Synthetic-Detergent based.
9. Hair Creams.
10. Oxidation hair dyes, Liquid.
11. Cologne.]
- ⁴[12. Nail Polish (Nail Enamel).
13. After Shave Lotion.
14. Pomades and Brilliantines.
15. Depilatories Chemical.
16. Shaving Creams.
17. Cosmetic Pencils.
18. Lipstick.]
- ⁵[19. Toilet Soap.
20. Liquid Toilet Soap.
21. Baby Toilet Soap.
22. Shaving Soap.
23. Transparent Toilet Soap.]

1. Subs. by G.S.R. 690(E), dt. 25.9.2014.
2. Ins. by G.S.R. 510(E), dt. 26.07.1982.
3. Subs. by G.S.R. 673(E), dt. 27.10.1993.
4. Ins. By G.S.R. 731(E) dated 23-08-1990
5. Ins. By G.S.R. 673(E) dated 27-10-1993

- ¹[24. Lipsalve IS:10284.
- 25. Powder Hair Dye IS: 10350.
- 26. Bindi (Liquid) IS: 10998.
- 27. Kum Kum Powder IS: 10999.
- 28. Henna Powder IS: 11142.]
- ²[29. Bathing Bars IS: 13498: 1997
- ³[30. Sindoor IS: 14649: 1999
- ⁴[31. Liquid Foundation makeup IS 14318
- ⁴[32. Cold Wax Hair remover IS 15152
- ⁴[33. Face pack IS 15153
- ⁴[34. Kajal IS 15154
- ⁴[35. Oxidation Hair Dyes (Emulson Type) IS 15205
- ⁴[36. Cream Bleach IS 15608

1. Ins. by G.S.R. 553(E), dt. 20.7.1995.

2. Ins. by G.S.R. 592(E), dt.13.8.2008.

3. Ins. by G.S.R. 724(E), dt. 07.11.2013.

4. Ins. by G.S.R. 203(E), dt.18.03.2015.

⁵[SCHEDULE T

(See rule 157)

GOOD MANUFACTURING PRACTICES FOR AYURVEDIC, SIDDHA AND UNANI MEDICINES

The Good Manufacturing Practices (GMP) are prescribed as follows in Part I and Part II to ensure that:

- (i) Raw materials used in the manufacture of drugs are authentic, of prescribed quality and are free from contamination.
- (ii) The manufacturing process is as has been prescribed to maintain the standards.
- (iii) Adequate quality control measures are adopted.
- (iv) The manufactured drug which is released for sale is of acceptable quality.
- (v) To achieve the objectives listed above, each licensee shall evolve methodology and procedures for following the prescribed process of manufacture of drugs which should be documented as a manual and kept for reference and inspection. However, under IMCC Act 1970 registered Vaidyas, Siddhas and Hakeems who prepare medicines on their own to dispense to their patients and not selling such drugs in the market are exempted from the purview of G.M.P.

5. Subs. by G.S.R. 560(E), dt. 07.3.2003.