

**Government of Maharashtra****Commissioner****Food and Drug Administration, Maharashtra State,**

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E-Office file no. 3453326 (Drug/DI11/2026)

(Email)

Date: 29/09/2026

CIRCULAR

SUBJECT: Procurement of Reference Standards (IPRS) from Indian Pharmacopoeia Commission (IPC) reg.

Ref: Revised Schedule M, Part – I, Point no. 15 — Reference Standards

As per the GSR 922 (E) dated 28 December 2023, it has been made mandatory for all allopathic drug manufacturers operating within the state to strictly comply with the Good Manufacturing Practices (GMP) and Requirements of Premises, Plant, and Equipment as outlined in the Revised Schedule M.

Attention is specifically drawn to Revised Schedule M, Part – I, Point no. 15 — Reference Standards. All licensed allopathic drug manufacturing units are hereby instructed to adhere to the following statutory directives with immediate effect:

- 1. Procurement of Official Reference Standards:** Whenever official reference standards exist, they shall be used. Specifically, all Indian Pharmacopoeia Reference Standards (IPRS) must be procured directly from the Indian Pharmacopoeia Commission (IPC).
- 2. Authorized Usage:** Official reference standards shall only be used for the specific purpose described in the appropriate monograph.
- 3. In-House Reference Standards:** Reference standards prepared by the manufacturer shall be tested, released, and stored in the same manner as official standards. They shall be maintained under the direct responsibility of a designated person in a secure area.
- 4. Secondary / Working Standards:** Secondary or working standards may be established by applying appropriate tests and checks at regular intervals to ensure standardization. All in-house working standards or secondary standards must be standardized against an official reference standard, when available, initially and at regular intervals thereafter.

5. **Labelling Requirements:** All reference standards must be properly labelled with at least the following information:

- Name of the material
- Batch or lot number and control number
- Date of preparation
- Shelf-life
- Potency
- Storage conditions

6. **Storage & Handling:** All reference standards shall be stored and used in a manner that will not adversely affect their quality.

This is therefore instructed to comply with the above directives as per the Schedule M of Drugs & Cosmetics Rules, 1945 with respect to the reference Standards used for quality checks of Pharmaceuticals.

(With approval of Hon'ble Commissioner, FDA Maharashtra)

Yours,

Digitally signed by
GANESH RAMCHANDRA ROKADE
Date: 29-09-2026 23:31:24

(Ganesh Rokade)
Joint Commissioner (Drug) (HQ)
&
Controlling Authority
Food & Drug Administration
Maharashtra State

TO:

All Licensed Allopathic Drug Manufacturing Units
Maharashtra State

COPY TO:

All Joint Commissioners (Drugs), Food and Drug Administration (State) — for strict implementation, enforcement, and verification during routine and risk-based inspections of Manufacturing Units within their respective jurisdictions.