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INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Government of India
Sector 23, Raj Nagar
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डा. राजीव सिंह रघुवंशी
सचिव-सह-वैज्ञानिक निदेशक

Dr. Rajeev Singh Raghuvanshi
Secretary-cum-Scientific Director

F. No. T.11015/01/2020-AR&D

Date: May 19, 2025

NOTICE

Subject: Ensuring Use of Authentic Indian Pharmacopoeia (IP), IP Reference Standards, and Impurity Standards for Quality Testing of Drugs-reg.

In order to fulfil the requirements of the Drugs and Cosmetics (D&C) Act, 1940 and Rules 1945 there under, the Indian Pharmacopoeia Commission (IPC) publishes the Indian Pharmacopoeia (IP) at regular intervals along with the certification and distribution of IP Reference Standards (IPRS) and Impurity Standards. As per the Schedule M of the D&C Act, Part I, Quality Control System (16.14)- "Pharmacopoeia reference standards, working standards, references, spectra, other reference materials and technical books, as required, shall be available in the Quality Control Laboratory of the licensee".

IP is a legal book of standards for drugs in the country. Moreover, IPRSs are specifically required to establish conformance to IP standards. An IPRS, being an integral and essential component of the IP standard, is an official standard that alone is authoritative in assessing the quality of drugs, and the use of any unauthorized Reference Standard is a noncompliance with the IP standards.

IPC has been making efforts to promote the use of authentic IP, IPRS, and Impurity Standards by the manufacturers and testing laboratories, and steps are being taken to stop the use of unauthorized standards in quality control testing. However, despite all these efforts, the current trends of the sale of IP, IPRS, and Impurity Standards from IPC do not match the number of pharmaceutical manufacturers and testing laboratories in India. Moreover, it has been observed that there is a tendency among the stakeholders to procure unauthorised copies of the IP and Reference Standards from dubious sources and to use them in routine drug analysis.

Using unauthorised copies of IP, IPRS, and Impurity Standards is an illegal act in accordance with the provisions of the Drugs and Cosmetics Act 1940. Also, such malpractices could be the cause of the manufacture and marketing of counterfeit/spurious drugs in India, which may have serious effect on the health of its citizens.

In view of the above, stakeholders are once again requested to purchase authentic copies of the IP, IPRS, and Impurity Standards from the IPC by visiting its website www.ipc.gov.in. All concerned are requested to bring it to the notice of all authorities under their control for its compliance.

(Dr. Rajeev Singh Raghuvanshi)

To,

1. The Drugs Controller General (India)
2. All State Drug Controllers
3. CDSCO Zonal Offices
4. Directors of the Drugs Testing Laboratories
5. IDMA/OPPI/BDMA/FOPE/FSSAI/Small Scale Industry Associations