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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

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Secretary-cum-Scientific Director

F. No. T.11015/01/2023-AR&D

Date: May 30, 2025

NOTICE

Subject: Clarification on impurity limits published in the Indian Pharmacopoeia (IP)-reg.

The IPC is in receipt of enquiries from various stakeholders regarding impurity limits prescribed in the IP and their applicability in the development and regulatory approval of new drugs. In order to address these issues, following clarifications are issued:

2. The IPC is an autonomous institution under the Ministry of Health & Family Welfare that is solely responsible for setting official drug standards of the IP. The IPC does not have any role in the regulatory review and approval of drugs in India. As per provisions of the Drugs and Cosmetics Act 1940, the Central Drugs Standards Control Organization (CDSCO) and/or State Licensing Authorities are competent to take regulatory decisions.

3. Impurity limits for the drug substances (DS) and drug products (DP) are specified in the individual IP monographs that are based on the batch data submitted by the stakeholders or in harmonization with global pharmacopoeial standards. Additionally, IP has also included impurity limits in the general chapter {5.5} 'Impurities' which aligns with the ICH Q3A and Q3B that serves as a guideline for controlling impurities in new DS and DP.

4. Moreover, compliance with general chapter {5.5} 'Impurities' may be desired by the concerned regulatory authority from manufacturers seeking regulatory approval of new DS and/or DP. Any deviation or modification to the established impurity limits of the general chapter {5.5} 'Impurities' may be considered by the regulatory authority, provided it is supported with valid scientific justification and relevant data.

5. Further, impurity limits specified in individual IP monographs may also serve as a reference for establishing impurity specifications in new DP, including fixed-dose combinations (FDCs) that are not part of the IP. However, approval of impurity specifications for new DP or FDCs falls exclusively under the jurisdiction of the competent regulatory authority. Stakeholders are advised to undertake thorough risk assessments while formulating new DP using the IP monograph specifications.

6. It is clarified that, in any case, the IPC does not have a mandate to approve or endorse impurity specifications for DS and/or DP. Moreover, the IPC, being a standard setting organization, is also not responsible to express opinion or recommendation in such regulatory matters.

7. Stakeholders are also encouraged to engage with the IPC by submitting scientific evidence to support monograph revisions, wherever required, to promote harmonization with global standards.

All concerned are requested to bring this clarification to the notice of all authorities under their control.

(Dr. Rajeev Singh Raghuvanshi)

To,

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