भारतीय भेषज संहिता आयोग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
सैक्टर २३, राज नगर
गाज़ियाबाद २०१००२ (उ. प्र.), भारत

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

Dr. Rajeev Singh Raghuvanshi
Secretary-cum-Scientific Director

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

Date: July 24, 2024

NOTICE

Subject: Ensuring Compliance with the Indian Pharmacopoeia (IP) General Chapter 5.10 on Elemental Impurities-regarding

This is in continuation of IPC's Notice No. T.11015/01/2023-AR&D dated August 1, 2023 wherein clarification was issued on the subject mentioned above. This is once again brought to the notice of all concerned that:

1. IPC is in process to adopt elemental impurity requirements in-line with other global pharmacopoeia. Recently, ICH Q3D (R2) has been revised with respect to limits of some elementals. Hence, IPC is also revising the current IP General Chapter 5.10 on Elemental Impurities in-line with revised ICH Q3D guideline.
2. IPC has also started working on gradually replacing test on heavy metals in the individual monographs to make elemental impurities mandatory from the next edition of the IP (i.e. IP 2026). IPC has also started discussions within the Expert Working Group constituted for this subject beside publishing the proposed revisions on the IPC website for inviting public comments prior to their adoption in the IP 2026.
3. Accordingly, the General Chapter 5.10 on Elemental Impurities shall be referred in the General Requirements of Active Pharmaceutical Ingredients and in individual monographs of drug products in the IP 2026 thereby making it a mandatory requirement.

In view of the above, all concerned are once again requested to start working on required necessary changes in the quality systems for their readiness and ensuring compliance with the revised elemental impurities standards of the IP 2026. For further information, please keep on visiting IPC website (www.ipc.gov.in).

(Dr. Rajeev Singh Raghuvanshi)

To,

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