

डॉ.राजीव सिंह रघुवंशी
सचिव-सह-वैज्ञानिक निदेशक

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Secretary-cum-Scientific Director

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

Date: August 1, 2023

NOTICE

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

This is in continuation of IPC's Notice No. T.11015/01/2020-AR&D dated October 27, 2022 wherein clarification was issued on the subject mentioned above. This is once again brought to the notice of all concerned that:

1. IPC has introduced a new General Chapter on 'Elemental Impurities' in the IP 2022 for information of the stakeholders which is not yet referred in the individual monographs and; therefore, it remains a non-mandatory requirement. However, stakeholders are encouraged to adopt and implement this general chapter as an alternative to the test on heavy metals as per the provisions of the IP General Notices.
2. Meanwhile, IPC has 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 will discuss such changes with the Expert Working Group(s) along with publishing the same on IPC website prior to their adoption in the IP 2026.
3. Accordingly, the general chapter on elemental impurities (5.10) shall be referred in the General Requirements of Active Pharmaceutical Ingredients and in individual monographs of drug products in the IP 2026 so as to make it a mandatory requirement.

In view of the above, all concerned are requested to start working on required necessary changes in their quality systems for the 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 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