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सचिव-सह-वैज्ञानिक निदेशक

Dr. Rajeev Singh Raghuvanshi
Secretary-cum-Scientific Director

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

Date: September 12, 2024

NOTICE

Subject: General Chapter 2.5.4 (i) on Uniformity of Dosage Units-regarding

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. General Chapter 2.5.4 (i) on 'Uniformity of Dosage Units' in the IP 2022 was introduced in harmonization with other international pharmacopoeias.

2. In the forthcoming edition of the IP (i.e. IP 2026), the General Chapters 2.5.3. Uniformity of Weight of Single-Dose Preparations and 2.5.4. Uniformity of Content of Single-Dose Preparations will be replaced with General Chapter 2.5.4 (i) on 'Uniformity of Dosage Units'.

3. Meanwhile, IPC has started working on adoption of General Chapter 2.5.4 on 'Uniformity of Dosage Units' test in the General Monographs and individual monographs to make 'Uniformity of Dosage Units' mandatory from the next edition of the IP 2026 so as to make it a mandatory requirement. 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.

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 'Uniformity of Dosage Units' 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