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Secretary-cum-Scientific Director

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NOTICE

Subject: Clarification on General Chapters of the Indian Pharmacopoeia (IP) 2022-regarding.

Indian Pharmacopoeia Commission (IPC) has published the Indian Pharmacopoeia (IP) 2022 and Hon'ble Union Health Minister released the 9th edition of IP 2022 on 1st July, 2022 in Vigyan Bhawan, New Delhi. In IP 2022, several new monographs and general chapters have been introduced while several others are revised to meet the current analytical and regulatory requirements.

After the release of IP 2022, IPC has received several enquiries from the stakeholders on implementation and compliance of new and/or revised pharmacopoeial text. In order to address the enquiries of the stakeholders, clarification on following general chapters of the IP 2022 is compiled and issued:

S. No.	General Chapter in IP 2022	IPC's Clarification
1.	General Chapter 2.5.4 (i) Uniformity of Dosage Units	IPC has introduced a general chapter on 'Uniformity of Dosage Units' in harmonization with other pharmacopoeias under section 2.5.4 (i) on page 361, Volume I of IP 2022. This chapter is presently introduced in IP 2022 for information and awareness of the stakeholders and is not referred in the individual monographs and, therefore, remains non-mandatory requirement. However, stakeholders may adopt this chater before its implementation is made mandatory by IPC.
2.	General Chapter 5.10 Elemental Impurities	IPC has introduced new general chapter on 'Elemental Impurities' on page 1204, Volume I of IP 2022 for information and awareness of the stakeholders and is not referred in the individual monographs. Therefore, it remains non-mandatory requirement. However, stakeholders may adopt and implement this general chapter as an alternative to test on heavy metals as per the provisions of the IP General Notices. IPC will gradually replace test on heavy metals in the individual monographs to make elemental impurities mandatory from the next edition of IP (i.e. IP 2026).
3.	General Chapter 5.11 Nitrosamine Impurities	IPC has introduced new general chapter on 'Nitrosamine Impurities' on page 1210, Volume I of IP 2022 for guidance of the stakeholders which is also referred in sartan API monographs of the IP. However, it is expected that stakeholders adopt this general chapter for determining the nitrosamine impurities in other drugs as well, wherever deemed appropriate and necessary.

Yours sincerely,

(Dr. Rajeev Singh Raghuvanshi)