

Draft Revision for Comments and Inclusion in The Indian Pharmacopoeia

DRAFT REVISIONS FOR COMMENTS

This draft revision contains revised monograph text for inclusion in the Indian Pharmacopoeia (IP). The content of this draft document is not final, and the text may be subject to further revisions prior to publication in the IP. This draft does not necessarily represent the decisions or the stated policy of the IP or Indian Pharmacopoeia Commission (IPC).

Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Comments received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to lab.ipc@gov.in before the last date for comments.

Document History and Schedule for the Adoption Process

Description	Details
Document version	1.0
First Draft published on IPC website for public comments	17 August 2026
Last Date for Comments	01 October 2026
Monograph Revision proposed for Inclusion in	IP Addendum 2028
Tentative effective date of monograph	NA
Draft revision published on IPC website for public comments	NA
Further follow-up action as required.	

1. Pantoprazole for Injection. IP 2026; Vol III; Page No. 3610

Add before Assay

Bacterial Endotoxins (2.2.3). Not more than 6.25 Endotoxins Units per mg of pantoprazole.

2. Artesunate. IP 2026; Vol II; Page No.1676

Add after Assay

Artesunate intended for use in the manufacturer of parenteral preparations without a further appropriate procedure for the removal of bacterial endotoxins as well as further appropriate sterilization procedure, comply with the following additional requirement.

Bacterial endotoxins (2.2.3). Not more than 2.5 Endotoxins Units per mg of artesunate.

Sterility (2.2.11). Complies with the test for sterility.

3. Amifostine. IP 2026; Vol II; Page No.1579

Add after Assay

Amifostine intended for use in the manufacturer of parenteral preparations without a further sterilization procedure comply with the following additional requirement.

Sterility (2.2.11). Complies with the test for sterility.

4. Heavy Kaolin. IP 2026; Vol II; Page No.3013

Add after Loss on Ignition

Microbial Contamination (2.2.9). Total aerobic viable count is not more than 10^3 cfu per g and total combined yeast and molds is not more than 10^2 cfu per g.

5. Diclofenac Injection. IP 2026; Vol II; Page No. 2370

Add before Assay

Bacterial Endotoxins (2.2.3). Not more than 9.34 Endotoxins Units per mg of diclofenac sodium.