

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 |
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| Last Date for Comments | 25 November 2023 |
| Monograph Revision proposed for Inclusion in | IP 2026 |
| Tentative effective date of monograph | January, 2026 |
| Draft revision published on IPC website for public comments | NA |
| Further follow-up action as required. | |

1. **Morphine Sulphate Injection. Vol II, Page 2967**

Bacterial Endotoxins (2.2.3)

Change From: Not more than 17.0 Endotoxins Units per mg of morphine; if labelled for intrathecal use it contains not more than 14.29 Endotoxins Units per mg of morphine.

To: Not more than 17.0 Endotoxins Units per mg of **morphine sulphate**; if labelled for intrathecal use it contains not more than 14.29 Endotoxins Units per mg of **morphine sulphate**.

2. **Ceftriaxone Sodium. Vol II, Page No. 1800**

Bacterial Endotoxins (2.2.3)

Change From: Not more than 0.20 Endotoxins Units per mg of ceftriaxone sodium.

To: Not more than **0.08 Endotoxins Units per mg of ceftriaxone sodium**.

3. **Ceftriaxone Injection. Vol II, Page 1801**

Bacterial Endotoxins (2.2.3)

Change From: Not more than 0.20 Endotoxins Units per mg of ceftriaxone.

To: Not more than **0.08 Endotoxins Units per mg of ceftriaxone**.

Draft Revisions for Comments (Unofficial Text)