

# Draft Revision for Comments and Inclusion in The Indian Pharmacopoeia

## DRAFT REVISIONS FOR COMMENTS

This draft revisions 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](mailto: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	20 January 2023
Last Date for Comments	28 February 2023
Monograph Revision proposed for Inclusion in	IP Addendum 2024
Tentative effective date of monograph	April, 2024
Draft revision published on IPC website for public comments	NA
Further follow-up action as required.	

1. **Ergotamine Injection.** Vol II, Page 2258

**Bacterial Endotoxin (2.2.3)**

Change **from:** Not more than 357.0 Endotoxins Units per mg of ergotamine.

**to:** Not more than 357.0 Endotoxins Units per mg of **ergotamine tartrate.**

2. **Hydralazine Injection.** Vol II, Page 2526

**Bacterial Endotoxin (2.2.3)**

Change **from:** Not more than 1.45 Endotoxins Units per mg of hydralazine.

**to:** Not more than 1.45 Endotoxins Units per mg of **hydralazine hydrochloride.**

DRAFT FOR COMMENTS