DRAFT REVISIONS FOR COMMENTS

These draft amendment contains revised text of monographs 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/ biologics-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	2nd August 2024
Last Date for Comments	17th September 2024
Monograph Revision proposed for Inclusion in	IP 2026
Tentative effective date of proposed amendment	January, 2026
Draft revision published on IPC website for public comments	NA
Further follow-up action as required.	

Dried Human Antihaemophilic Fraction, (Pg. 4528)

Tests

Abnormal toxicity (2.2.1).

Insert following at the end
Note: "The abnormal toxicity test may be omitted for routine batch release testing. Manufacture should ensure the product safety for each lot/batch"

Human Albumin, (Pg. 4535)
Tests

Abnormal toxicity (2.2.1).

Insert following at the end
Note: "The abnormal toxicity test may be omitted for routine batch release testing. Manufacture should ensure the product safety for each lot/batch"

Human Normal Immunoglobulin, (Pg. 4541)
Tests

Change title
from: **Molecular Size**

to: **Molecular Size Distribution**

Abnormal toxicity (2.2.1).

Insert following at the end
Note: "The abnormal toxicity test may be omitted for routine batch release testing. Manufacture should ensure the product safety for each lot/batch"

Human Normal Immunoglobulin for Intravenous use, (Pg. 4544)
Tests

Change title
from: **Molecular Size**

to: **Molecular Size Distribution**

Human Plasma Protein Fraction, (Pg. 4551)

Tests

Abnormal toxicity (2.2.1).

Insert following at the end

Note: "The abnormal toxicity test may be omitted for routine batch release testing. Manufacture should ensure the product safety for each lot/batch"