

Draft for Comments and Inclusion in The Indian Pharmacopoeia

DRAFT MONOGRAPHS FOR COMMENTS

This contains draft new monograph 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	7 th February 2025
Last Date for Comments	25 th March 2025
Monograph proposed for Inclusion in	IP 2026
Tentative effective date of monograph	January, 2026
Draft published on IPC website for public comments	NA
Further follow-up action as required.	

Single Donor Platelets (SDP)/ Plateletpheresis

Apheresis Platelets

Platelets Apheresis or Single Donor Platelets (SDP) is a component obtained by platelet apheresis of a single donor using automated cell separation equipment, which contains platelets in a therapeutically effective dose suspended in plasma.

SDP should contain a minimum content of 3×10^{11} platelets and a residual leucocyte count less than 5×10^6 cells.

Preparation

For preparation of Apheresis Platelets / SDP, Whole Blood is removed from the donor by the apheresis machine, anti-coagulated with a citrate solution and then the platelets are harvested.

For use in neonates and infants, SDP can be divided into satellite units under sterile conditions.

Quality Control Parameters

Parameter	Specification	Frequency of test
Visual Inspection	Swirling, gel formation, clots, and discoloration	All units
Volume	>200 ml	All Units
Platelet content per unit	$\geq 3 \times 10^{11}$ /unit	1 per cent of all units or 4 units per month (whichever is more)
pH at end of shelf life	> 6.0 (at the end of permissible storage period)	1 per cent of all units or 4 units per month (whichever is more)
Leucocyte count per unit	$<5 \times 10^6$ /unit	1 per cent of all units or 4 units per month (whichever is more)
Red cell contamination	Traces to 5 ml	Visual inspection of all Units
Clumps, Leakages, Contamination	Absent	Visual inspection of all Units

General requirements shall be referred regarding labelling, storage, and transportation requirements.