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

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Further follow-up action as required.	

Single Donor Platelets (SDP) in Additive Solution (SDP-PAS)

/ Plateletpheresis in Additive Solution (SDP-PAS)

Apheresis Platelets in Additive Solution (SDP-PAS)

Platelets, Apheresis, in Additive Solution (SDP-PAS) 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 a mixture of plasma (30 - 40 per cent) and an additive solution (60 - 70 per cent).

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

Preparation

To prepare SDP - PAS, Whole Blood is removed from the donor by the apheresis machine, anti-coagulated with a citrate solution and then the platelets are harvested. Platelets are stored in a combination of plasma and an appropriate additive solution.

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

Quality Control Parameters

Parameter	Specification	Frequency of test
Volume	> 200 ml	All Units
Platelet content per Unit	$\geq 3 \times 10^{11}$/ unit (Standard Adult Units) $\geq 0.5 \times 10^{11}$/unit (For use in Neonates and Infants)	1 per cent of all units or 4 units per month
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
Leucocyte count per unit	5.5×10^{6}	1 per cent of all units or 4 units per month
HLA and/or HPA	As per requirement	Only for designated units
Red cell contamination	Should trace to 0.5 ml	Visual inspection of all Units
Clumps, Leakages, contamination	Should be absent	Visual inspection of all Units

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