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.	

Double Single Donor Platelets

(Double SDP)

Double Single Donor Platelets is a component obtained by platelet apheresis of a single donor using automated cell separation equipment, which contains therapeutic dose of platelets suspended in plasma.

Double Single Donor Platelets should contain atleast 6×10^{11} platelets. Residual leucocyte count in leucoreduced Double Single Donor Platelets shall not be more than 8.0×10^{6} per collection.

Donor Selection Criteria for Double SDP

In addition to meeting the general eligibility criteria for plateletpheresis, donors for Double SDP shall have:

Weight above 60 kg

Hemoglobin (Hb) $\geq$ 12.5 g/dL,

Platelet count $\geq 2.5 \times 10^{11}$ /L,

Interval between two Double SDPs- 7 days (limited to 2 procedures per month; not more than 12 pheresis collections in a rolling 12-month period years)

The total plasma volume (excluding anticoagulant) per collection of Platelets, apheresis should not exceed 500 ml vol (maximum of 1 litre per month)

Quality Control Parameters

Parameter	Specification	Frequency of test
Visual Inspection	Swirling present No gel formation, clots, discoloration, leakages and contamination	All units
Volume	Not less than or equal to $\leq$ 500 ml	All Units
Platelet content per unit	Not less than 6×10^{11} platelets /unit If platelet count is less than this, unit shall be labelled with actual platelet count	1 per cent of all units or 4 units per month (whichever is more)
pH at end of shelf life	Not less than 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 in leucoreduced Double SDP	Not more than 8.0×10^{6} per collection	1 per cent of all units or 4 units per month (whichever is more)
Sterility (2.2.11)	Complies with the test for sterility.	1 per cent of all units
Red cell contamination	Traces to 0.5 ml	Visual inspection of all Units

General requirements shall be referred regarding labeling, storage, and transportation requirements