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.	

Platelet Rich Plasma (PRP)

Platelet Rich Plasma (PRP) is a platelet component derived from single unit of fresh whole blood donation subjected to a light spin from which Platelets suspended in plasma (200 ml ± 50 ml) is separated from red cells into a satellite bag.

Preparation

A unit of freshly donated whole blood where the bleed time remains within 10 minutes is suitable for platelet production. Blood unit is stored at temperature between 22 ± 2° and platelets are prepared within 6 hours of phlebotomy.

Blood unit is centrifuged at a light spin so that an optimal number of platelets remain suspended in the supernatant plasma and the number of leucocytes and red cells are reduced to a defined level.

60 - 80 per cent of the supernatant plasma containing the platelets is separated into a satellite bag.

Quality Control Parameters

Parameter	Specification	Frequency of test
Visual Inspection	Swirling, gel formation, clots, and discoloration	All units
Volume	200 ml ± 50 ml	All Units
Platelet count	3.0 - 4.5 × 10^8 per ml	1 per cent of all units or 4 units/month (whichever is more)
Platelet content per unit	≥ Should be 3.5 × 10^{10} (for 350 ml bag) ≥ Should be 4.5 × 10^{10} (for 450 ml bag)	1 per cent of all units or 4 units/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/month (whichever is more)
Leucocyte count per unit	< 0.2 × 10^8 per unit	1 per cent of all units or 4 units/month (whichever is more)
Red cell contamination	Trace to 0.5 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.

Random donor Platelet concentrate, PRP

Platelet concentrate, PRP

Platelet concentrates or Random Donor Platelets (RDP) is a platelet component derived from a single unit of fresh Whole Blood donation. It contains the majority of the original whole blood platelet content, suspended in plasma.

Preparation

A unit of fresh Whole Blood, stored at temperature between 22 ± 2°, is centrifuged so that an optimal number of platelets remain in the plasma and the number of leucocytes and red cells are reduced to a defined level. Platelets are than derived from the PRP by sedimentation through hard-spin centrifugation.

Supernatant platelet-poor plasma is removed, leaving 60 ml ± 10 ml of it with the platelets. The platelets are allowed to disaggregate and are then re-suspended in the remnant plasma, and given resting period of 1 hour before storage.

Quality Control Parameters

Parameter	Specification	Frequency of test
Visual Inspection	Swirling, gel formation, clots, and discoloration	All units
Volume	60 ± 10 ml	All units
Platelet count	≥3.5/4.5 x 10^{10} platelets per unit from a unit of 350 ml and 450 ml blood, respectively	1 per cent of all units or 4 units/month (whichever is more)
Platelet content per unit	Should be 3.5 x 10^{10} (for 350 ml bag)	1 per cent of all units or 4 units/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/month (whichever is more)
Leucocyte count per unit	< 5.5 x 10^{7} to 5.5 x 10^{8}	1 per cent of all units or 4 units/month (whichever is more)
Red cell contamination	trace to 0.5 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.

Random donor Platelet concentrate, Buffy coat

Platelet concentrate, Buffy coat

Platelet concentrates or RDP is a platelet component derived from a single unit of fresh whole blood donation. It contains the majority of the original whole blood platelet content, suspended in plasma.

Preparation

A unit of fresh Whole Blood, stored at temperature 22 ± 2°, is centrifuged so that platelets are primarily sedimented to the buffy coat layer together with the leucocytes. The buffy coat is separated and processed further to obtain a platelet concentrate. Single buffy coats diluted with plasma are centrifuged so that the platelets remain in the supernatant plasma, but red cells and leucocytes are sedimented to the bottom of the bag. The final volume of the platelet concentrate is 60 ml ± 10 ml.

Quality Control Parameters

Parameter	Specification	Frequency of test
Visual Inspection	Swirling, gel formation, clots, and discoloration	All units
Volume	70 ± 20 ml	1 per cent of all units or 4 units per month (whichever is more)
Platelet count	$> 6.0 \times 10^{10}$	1 per cent of all units or 4 units/month (whichever is more)
Platelet content per unit	Should be 3.5×10^{10} (for 350 ml bag)	1 per cent of all units or 4 units/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/month (whichever is more)
Leucocyte count per unit	$< 5.5 \times 10^{7}$	1 per cent of all units or 4 units/month (whichever is more)
Red cell contamination	trace to 0.5 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.

Pooled Platelets –Buffy Coat

Platelets pooled, Buffy Coat
Random donor platelet, Buffy Coat

Random Donor Platelets, Pooled (RDP-Pooled) is a platelet component derived from 4 to 6 fresh whole blood donations, which contains the majority of the original platelet content in a therapeutically effective dose, suspended in plasma.
RDP-Pooled contain a minimum content of 2×10^{11} platelets and a maximum of 5×10^{9} leucocytes.

Preparation

A Whole Blood unit, stored in at a temperature between 22 ± 2°, for up to 6 - 8 hours, is centrifuged so that the platelets are primarily sedimented to the buffy coat layer, together with the leucocytes.
The buffy coat is separated and further processed so that, usually, 4 to 6 ABO and Rh group-identical buffy coats are pooled in a sterile manner and re-suspended in plasma/additive solution. After careful mixing, the buffy coat pool is centrifuged (light- spin) so that the platelets remain in the supernatant, but the red cells and leucocytes are effectively sedimented to the bottom of the bag. The platelet-containing supernatant is immediately transferred into a suitable platelet storage bag in a sterile manner.

Quality Control Parameters

Parameter	Specification	Frequency of test
Visual Inspection	Swirling, gel formation, clots, and discoloration	All units
Volume	> 200 ml	All Units
Platelet count	3- 4.5 × 10^{8} per ml	1 per cent of all units or 4 units/month (whichever is more)
Platelet content per unit	Should be > 2×10^{11}	1 per cent of all units or 4 units/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/month (whichever is more)
Leucocyte count per unit	< 0.05×10^{9} per unit	1 per cent of all units or 4 units/month (whichever is more)
Red cell contamination	Trace	Visual inspection of all Units
Clumps, Leakages, Contamination	Absent	Visual inspection of all Units

If the pooling is done in an open system (using spikes for pooling), the shelf life of the pooled platelets will be 6 hours (use as soon as possible), while for closed system (using sterile connecting device) the expiry date will be that of the platelet unit having the shortest expiry date.
General requirements shall be referred regarding labelling, storage, and transportation requirements

Pooled Platelets -PRP

Platelets pooled, PRP

Random donor platelet, PRP

Random Donor Platelets, Pooled (RDP-Pooled) is a platelet component derived from 4 to 6 fresh whole blood donations, which contains the majority of the original platelet content in a therapeutically effective dose, suspended in plasma. RDP-Pooled contain a minimum content of 2×10^{11} platelets and a maximum of 5×10^{9} leucocytes.

Preparation

Four to six units of RDP prepared by the PRP method are connected and pooled.

If the pooling is done in an open system (using spikes for pooling), the shelf life of the pooled platelets will be 6 hours (use as soon as possible), while for closed system (using sterile connecting device) the expiry date will be that of the platelet unit having the shortest expiry date.

Quality Control Parameters

Parameter	Specification	Frequency of test
Visual Inspection	Swirling, gel formation, clots, and discoloration	All units
Volume	> 200 ml	All Units
Platelet count	3- 4.5 × 10^{8} per ml	1 per cent of all units or 4 units/month (whichever is more)
Platelet content per unit	Should be > 2×10^{11}	1 per cent of all units or 4 units/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/month (whichever is more)
Leucocyte count per unit	< 0.2×10^{9} per unit	1 per cent of all units or 4 units/month (whichever is more)
Red cell contamination	Trace	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