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.	

Granulocyte concentrates prepared by apheresis

Granulocytes, Apheresis

Granulocyte, Apheresis or Single Donor Granulocytes is a component prepared from a single donor using a suitable apheresis machine where the blood is withdrawn and anticoagulated, which is separated into components with retention of granulocytes as the major cellular product, suspended in a portion of the plasma. The remaining elements may be returned to the donor.

An adult therapeutic dose of Granulocytes, Apheresis should contain between 1.5×10^8 to 3.0×10^8 granulocytes/kg body weight of the designated recipient.

Granulocytes, Apheresis has a significant content of red blood cells, lymphocytes and platelets.

Granulocytes, Apheresis must be irradiated and not to be agitated during storage.

Preparation

Donors of Granulocytes, apheresis require pre-treatment with corticosteroids and/or growth factors. Granulocytes, apheresis are collected from a single donor by apheresis. Optimal collection yields require the use of a sedimenting agent, such as hydroxyethyl starch (HES), low molecular weight dextran or modified fluid gelatine.

Quality Control Parameters

In addition to the mandatory and other tests required for blood donations described, all components tested for the parameters shown in Table below shall meet the specified values.

Parameter	Specification	Frequency of test
Volume	< 500 ml	All Units
Granulocyte content	$1.5 - 3 \times 10^8$ granulocytes per kg body weight or Adult patient of 60 kg $\geq 1 \times 10^{10}$ granulocytes per unit	All Units
HLA typing	As per requirement	Only for designated units

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

Granulocytes, Pooled, Buffy Coat Derived

Granulocyte concentrates prepared by pooling multiple units of buffy coat

Pooled granulocytes are derived from buffy coats of 5 - 10 fresh whole blood donation with retention of neutrophils as the major cellular product, suspended either in plasma or in a mixture of the plasma (30 - 40 per cent) and platelet additive solution (60 -70 per cent).

Preparation

Pool Granulocytes in AS is prepared from whole blood-derived buffy coats.

A Whole Blood unit, stored in conditions validated to maintain a temperature between 22 ± 2° is centrifuged so that the leucocytes are primarily sedimented to the buffy coat layer, together with the platelets.

The buffy coat is separated and further processed so that, usually, 5 -10 blood group compatible buffy coats are pooled in a sterile manner and suspended either in the plasma or additive solution added to the final mixture containing plasma.

Further, if required to reduce the volume of the mixture, the buffy coat pool after careful mixing, is centrifuged (hard-spin) so that the leucocytes with red cells sediments to the bottom of the bag. Requisite quantity of the supernatant is removed to make the final volume to 200 ± 50 ml.

Quality Control Parameters

In addition to the mandatory and other tests required for blood donations described, all components tested for the parameters shown in Table below shall meet the specified values.

Parameter	Specification	Frequency of test
Volume	200 $\pm$ 50 ml	All Units
Granulocyte content	$>5 \times 10^{10}$ per unit (prepared from 10 units)	All Units
HLA typing	As per requirement	Only for designated units

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