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	4th November 2024
Last Date for Comments	19th December 2024
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.	

Whole Blood

A unit of blood collected from a suitable blood donor using a sterile and pyrogen-free approved container with anti-coagulant-preservative solution.

Whole Blood is a source material for component preparation, which is its major use.

Whole Blood for transfusion may also be used without further processing into blood components.

Whole Blood for transfusion should not contain irregular antibodies of clinical significance.

Preparation

A person fulfilling all the donor selection criteria, as per applicable regulatory requirements is selected for whole blood donation. The volume of blood collected shall be proportional to the volume of anticoagulant, with ± 10 per cent variation and shall not exceed 10 ml/kg body weight, limited to the volume of 450 ml through strict aseptic measures with a single clean, non traumatic venepuncture and constant agitation for proper mixing of blood with anti-coagulant preservative solution. A unit of whole blood consists of 450 ml ± 10 per cent of blood plus 63 ml of anticoagulant preservative solution, or 350 ml ± 10 per cent of blood plus 49 ml of anticoagulant-preservative solution, which is then stored in an approved storage conditions.

Quality Control Parameters

Parameter	Specification	Frequency of test
Visual Inspection	No hemolysis, no turbidity, no visible clots, no frothy appearance	All units
Volume	450 ml ± 10 per cent, or 350 ml ± 10 per cent (excluding anticoagulant-preservative solution)	1per cent of all units or 4 units/month (whichever is more)
PCV (HCT)	>30 per cent	1 per cent of all units or at least 4 units/month (whichever is more)
Sterility (2.2.11)	Complies with the tests for sterility	Periodically (1 per cent of all units)
Hemolysis at the end of storage period	<0.8 per cent	1 per cent of all units or 4 units/month (whichever is more)

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

Whole Blood, Irradiated

Whole Blood, Irradiated is a component derived from Whole Blood by exposing the blood unit to gamma or X-ray radiations with minimum expected dose of irradiation of 25 Gray and no part of the component should receive more than 50 Gray.

Preparation

A unit of whole blood is subjected to irradiation process in a designated gamma (Cs-137 or Co-60) or X-ray irradiator and must ensure that no part of the component receives a dose less than 25 Gray or more than 50 Gray. The exposure time must be set to ensure that blood unit receive the specified recommended minimum dose, with no part receiving more than the maximum recommended dose.

Regular dose mapping of equipment must be undertaken. Exposure time must be standardised for each irradiation source and revalidated at suitable intervals. Radiation indicators must be used as an aid to differentiating irradiated from non-irradiated blood.

Whole Blood unit may be irradiated up to 28 days after collection. Irradiated cells must be transfused as soon as possible, but no later than 14 days after irradiation and, in any case, no later than 28 days after collection.

Lymphocytes can be rendered non-viable by exposure to irradiation. Irradiation at doses specified in the Standards does not cause significant harm to other blood cells.

Quality Control Parameters

Parameter	Specification	Frequency of test
Visual Inspection	No hemolysis, no turbidity, no visible clots, no frothy appearance	All units
Volume	450 ml ± 35 ml, or 350 ml ± 35 ml (excluding anticoagulant-preservative solution)	1 per cent of all units or 4 units/month (whichever is more)
PCV (HCT)	>30 per cent	1 per cent of all units or atleast 4 units/month (whichever is more)
Hemolysis at the end of storage period	<0.8 per cent of red cell mass	1 per cent of all units or 4 units/month (whichever is more)

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