Red Cell Components

1. Packed Red Blood Cells

Red Cells are obtained by removal of a major portion of the plasma from Whole Blood. Red Cells also contain the greater part of the Whole Blood leucocytes (about 2.5 to 3.0 × 10^9 cells) and a variable content of platelets, depending on the method of centrifugation.

Preparation

Packed Red blood -Cells is prepared by removing 200 ml ± 50 ml of supernatant plasma from Whole Blood unit by centrifugation. The entire red blood cell content is then suspended in the remaining 100 ml ± 50 ml of plasma depending on the type of blood bag (350ml / 450ml capacity) in which whole blood was collected.

Quality Control Parameters

Parameter	Specification	Frequency of testing
Appearance	No haemolysis, No turbidity, No Visible clots, no frothing, discoloration	All units
Volume	250 ml ± 10 per cent (for initial 450 ml blood in bag) 150 ml ± 10 per cent (for initial 350 ml blood in bag) (including anticoagulant-preservative solution)	1 per cent of all units or 4 units /month whichever is higher
Hematocrit	65 per cent -70 per cent when stored in in CPDA	1 per cent of all units or 4 units/month whichever is higher
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 higher
Sterility (2.2.11)	Complies with the tests for sterility.	1 per cent of all units or 4 units/month whichever is higher

Packed RBCs may be warmed using a designated/approved blood warmer if indicated.

Packed red blood cells resuspended in ABO compatible thawed Fresh frozen plasma (final Hematocrit - 0.5-0.6) are recommended for Exchange transfusion.

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

2. Red Cells, in Additive Solution

Red Cells, in Additive Solution (AS) is a red cell component prepared by the removal of the plasma from Whole Blood with subsequent addition of an appropriate additive solution.

Preparation

Whole Blood is collected, using CPD as the anticoagulant-preservative solution. After high-spin centrifugation of Whole Blood, almost entire plasma is removed and the additive solution is added immediately to red cells and mixed carefully.

Quality Control Parameters

Parameter	Specification	Frequency of test
Volume	350 ml± 10 per cent (for 450 ml Bags) 250± per cent (for 350 ml Bags) (including additive solution)	1 per cent of all units or 4 units/month whichever is higher
Hematocrit	50 – 60 per cent	1 per cent of all units or 4 units/month whichever is higher
Hemolysis at the end of storage period	< 0.8 per cent	1 per cent of all units or 4 units/month whichever is higher
Sterility (2.2.11)	Complies with the tests for sterility.	1 per cent of all units or 4 units/month whichever is higher

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

3. Red Cells, Buffy Coat Removed, in Additive Solution

Red Cells, Buffy Coat Removed (BCR), in additive solution is a red cell component prepared by the removal of a major part of the plasma and the buffy coat layer from Whole Blood.

Red Cells, BCR contains a minimum hemoglobin content of 40 g and hematocrit of 50 per cent to 60 per cent. Red Cells, BCR shall contain less than 5×10^8 leucocytes and a variable content of platelets, depending on the method of centrifugation.

Preparation

Red Cells, BCR is derived from Whole Blood by centrifugation. The supernatant plasma and 20 to 60 ml of the buffy coat layer are removed from Whole Blood after centrifugation, resulting in the loss of 10 to 30 ml of the red cells from the donated Whole Blood unit. Viscosity of the Red Cells is maintained by adding additive solution to maintain a hematocrit of 50 per cent - 60 per cent.

Quality Control Parameters

Parameter	Specification	Frequency of test

Volume	250 ml ± 50 ml 350 ml ± 10% (for 450 ml Bags) 150± 10% (+100ml additive solution) (for 350 ml Bags) (including additive solution (AS)	1 per cent of all units or 4 units/month whichever is higher
Hematocrit	50 per cent - 60 per cent	1 per cent of all units or 4 units/month whichever is higher
Hemolysis at the end of storage period	less than 0.8 per cent	1 per cent of all units or 4 units/month whichever is higher
Sterility (2.2.11)	Complies with the tests for sterility.	1 per cent of all units or 4 units/month whichever is higher
Leucocyte content	less than or equal to 5×10^8	1 per cent of all units or 4 units/month whichever is higher

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

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4. Leucodepleted red cells

Red Cells, Leucocyte depleted; Red Cells, leucoreduced using filter

Red Cells, Leucocyte-Depleted is a red cell component containing less than 5.0×10^8 leucocytes per unit when intended to prevent febrile reactions and containing 5.0×10^6 leucocytes per unit when required to prevent alloimmunisation or cytomegalovirus infection.

After leucocyte reduction by filtration of RBCs, the red cell component should contain at least 85% of the original red cell content.

Preparation

Generally, a filtration technique is used to produce Red Cells, Leucocyte depleted.

Leucocyte depletion should be completed within 48 hours of blood donation.

Red Cells, Leucocyte depleted can be produced:

• By leucocyte filtration of Whole Blood, with subsequent centrifugation and removal of the plasma

• By leucocyte filtration of a red cell component.

Quality Control Parameters

Red cells in Additive solution, Leucocyte Depleted (Prepared from 450 ml Whole blood)

Parameter	Specification	Frequency of test
Volume	250 ml ± 10 per cent (100 ml additive solution)	1 per cent of all units or 4 units/month whichever is higher
Leucocyte content	$<5.0 \times 10^6$ per unit	1 per cent of all units or 4 units/month whichever is higher

Hematocrit	50 per cent -60 per cent	1% of all units or 4 units/month whichever is more
Sterility (2.2.11)	Complies with the tests for sterility.	1 per cent of all units or 4 units/month whichever is higher

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

5. Red Cells, Irradiated

Red Cells, irradiated is prepared by exposing the blood unit to gamma or X-ray radiation with minimum dose of irradiation of 25 Gray delivered to the centre of the red cell bag and no part of the red cell component should receive less than 15 Gray.

Preparation

A unit of any red cell component is subjected to irradiation process in a designated gamma or X-ray irradiator and must ensure that no part of the component receives a dose less than 15 Gray or more than 25 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.

Red Cells 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 whichever is earlier.

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

All quality control parameters shall comply as per QC criteria of the original RBC component.

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