

Red Cells, Apheresis

Erythrocytapheresis/ Erythropheresis

Red Cells, Apheresis is a red cell component obtained by apheresis of a single donor using automated cell-separation equipment.

Preparation

For preparation of Red Cells, Apheresis, Whole Blood is removed by an appropriate apheresis machine from the blood donor and anti-coagulated with a citrate-containing solution. The red cell is retained at a pre-determined quantity/volume, while the plasma and other cellular content is returned back to the donor.

Two units of Red Cells, Apheresis can be collected during a single procedure.

Red Cells, Apheresis can be used either unmodified or can undergo further processing, e.g. leucocyte depletion or addition of an additive solution.

Quality Control Parameters

Parameter	Specification	Frequency of test
Volume	Each unit of 200 ml \pm 20 ml	All units
Hematocrit	0.65 -0.75	1 per cent of all units or 4 units per month (whichever is more)
Hemolysis at the end of storage period	Not more than 0.8 per cent	1 per cent of all units or 4 units per month (whichever is more)
Leucocyte count in leucodepleted units	Not more than 5.0×10^6 per unit	1 per cent of all units or 4 units per month (whichever is more)
Sterility (2.2.11)	Complies with the tests for sterility.	1 per cent of all units or 4 units per month (whichever is more)

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