

Red Cells, Cryopreserved

Definition

Red Cells, Cryopreserved is a red cell component derived by secondary processing of a red cell component or Whole Blood.

Red cells are frozen (preferably within 7 days of collection) using a cryoprotectant (glycerol) and stored at -60° to -80° or below, depending on the method of cryopreservation.

Preparation

Two methods are generally used for the preparation of Red Cells, Cryopreserved. One is a high glycerol, the other a low glycerol technique.

Both methods require thawing and washing/de-glycerolisation procedure before use. Red Cells, Thawed and Washed, Leucocyte Depleted may then be suspended in an approved additive solution.

The concentration and nature of the cryoprotectant must provide appropriate protection of the red cells at the intended storage temperature. The entire process of freezing, thawing and washing must be validated and documented.

The use of validated washing procedures that incorporate chilled saline, at least for the final wash and chilled approved additive solution for suspension, is recommended. This will minimize the risk of bacterial contamination and helps to produce a component that meets the transit temperature requirements.

The procedure should ensure adequate removal of cryoprotective agents, result in minimal free haemoglobin in the supernatant solution, and yield a mean recovery of greater than or equal to 80 per cent of pre glycerolization red cells following deglycerolization process.

Quality Control Parameters

Parameter	Specification	Frequency of test
Volume	Not less than 180 ml	All units
Supernatant Osmolality	1 per cent	All units
pH	Not less than 6	All units
Hemolysis	Not more than 1 per cent	All units
Post-wash Hemoglobin in supernatant	Not more than 0.2 g per unit	All units
Red cell Recovery	Not less than or equal to 80 per cent	All units
Leucocyte count	Not more than 5.0×10^6 per unit	All units
Sterility (2.2.11)	Complies with the tests for sterility.	1 per cent of all units or 4 units per month (whichever is more)

Since cryopreservation allows prolonged storage, serum and/or plasma samples obtained at collection must also be stored to enable future testing for newly discovered markers of transmissible diseases when components are thawed for use.

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

