

Red Cells, Washed

Red Cells, washed is derived from secondary processing of a red cell component or Whole Blood involving sequential washing and resuspension of red cells in an additive solution.

Most of the plasma, leucocytes and platelets are removed by washing of the red cells. The amount of residual plasma depends upon the washing protocol. Hematocrit can be varied according to clinical need.

Preparation

Firstly, most of the plasma or additive solution should be removed from red cells/ whole blood by high-speed centrifugation. Then, this red cell component is washed by sequential addition and removal of 0.9 per cent w/v sodium chloride for injection. Washing should be repeated till the supernatant fluid is clear in color. Centrifugation must be performed at a controlled temperature. Washing can be performed by interrupted or continuous flow centrifugation.

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 Red Cells, washed, may then be suspended in Normal saline or in an approved additive solution.

If the washing process results in the transfer of the final component into a pack that was not part of the original pack assembly, a secure system must be in place to ensure the correct donation identification number is put on the component pack.

The shelf life of washed red cells prepared in

- Open system: 24 hours
- Closed system: 14 days / original expiration date, whichever is earlier.

Quality Control Parameters

Parameter	Specification	Frequency of test
Volume	200 ± 20ml (from 350ml bag) 250 ± 25 ml (from 450ml bag)	All Units
Hematocrit	50 - 60 per cent	All Units
Hemolysis at the end of process	Less than 0.8 per cent	All Units
Protein content of final product	Less than 0.5 g 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)

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