

Corrigendum

05-01-2023

Specifications of the blood bags are as under:

Blood Bags Top & Bottom (Quadruple- 350 ml & 450 ml)

1. Blood Bag made up of DEHP plasticized PVC/Non PVC collapsible non-vented sterile containers complete with collection tube for completely closed system to avoid the chances of contamination.
2. Sterile pyrogen free transparent leak proof PVC/non PVC bags.
3. Dual packaging (Individual and aluminium) eliminating microbial contamination on surface maintaining the contents of the bag.
4. Primary bag having- 450 ml capacity with 63 ml CPD/350 ml capacity with 49 ml CPD. Open from top for transfer of plasma and open from bottom for red cells. Red cell bag with additive solution for extending life of red cells.
5. The thickness of mother bag should be such as to prevent breakage during centrifugation. The inner diameter of the transfer tube from mother bag to SAGM bag should be such as to provide easy flow of components.
6. Platelet storage bag should be properly labelled for 5 days of storage life.
7. Leukoreduction of PRBCs and platelet concentrate should be upto Log 1.
8. Ultra thin walled 16 G venipuncture needle as per ISO standard with authentication certificate.
9. Rectangular hard hub with marking to know the exact direction of venipuncture.
10. Soft twist off needle cover along with needle injury protector.
11. Highly flexible and kink resistant blood collecting tube. Blood bags should have marking in all tubes of the transfer bags. Tubes of plasma, platelet and red cell should have marking numbers to ensure traceability.
12. Safe and easy to open temper evident outlet port.
13. Highly transparent virgin grade PVC/Non PVC material.
14. High quality peel resistant label.
15. Should be able to resist temperature -70 degree centigrade to + 37 degree centigrade.
16. Blood bags and the boxes should be properly labelled with Mfg. date, Date of Expiry and Batch no.
17. Test reports should be provided as per USP standards.
18. Sample collection pouch should be present with the bag. Should be provided with Leur adapter for online withdrawal of Blood samples without contamination.
19. Automated Component Extractor of latest model should be provided by the firm free of cost of processing.
20. Satisfactory user certificates from three reputed government organizations.
21. Satisfactory company market standing for more than 10 years.

Transfer Blood Bags with spike

1. Manufacturer must comply with ISO 9002 quality system certification and provide proof of same.
2. Blood Bags must confirm to ISO 3826 for container, design, plastic (physical, chemical, biological) anticoagulant, label, Proof of compliance with ISO 3826 and ISO 1135-3 should be submitted by company.
3. External sterility of the blood bag must be assured.
4. RBC- Values for ATP%, 2,3 DGP, DEHP, leaching, % hemolysis, and pH must be furnished for 28/35 days.
5. Platelet Bag- Storage conditions of platelets for 5 days pH, pCO₂, pO₂, hypotonic shock recovery, collagen adhesion and pH should be submitted.
6. Satisfactory user certificates from three reputed government organizations.
7. Satisfactory company market standing for more than 10 years.