Enclosure

TOP AND BOTTOM QUADRUPLE BLOOD BAG CPD-SAGM 350 ML

1. Quadruple top and bottom bag to collect blood and prepare blood component through buffy method.
2. Mother bag of the Top and bottom Quadruple blood bag should have 350ml capacity with 49 ml CPD solution and is connected to two satellite transfer bags of 350ml capacity and to a bottom bag of 350 ml capacity with 80 ml SAGM/SAGM-2solution. The platelet bag should be suitable for 5 days storage. Transfer bags are designed for freezing at -80^{0}C for preparing cryoprecipitate with improved yield and quality.
3. Mother bag should be with 0.39 mm (-0.01mm +0.02 mm) thickness to prevent breakage during centrifugation and the inner diameter of the transfer tube from mother bag to SAGM/ SAGM-2_bag should be with 3.8 mm ID to provide easy flow of the component.
4. Needle should be 16G with triple bevel design to reduce penetration force and enable painless vein puncture.
5. Blood bags should have hot markings in all tubes of the transfer bags. Tubes of plasma, platelet and red cell should have hot marking numbers to ensure traceability.
6. Sampling features
    a. Donor tubes should be provided with Luer adapter for online withdrawal of blood samples without contamination. **Needle Injury protectors, Pre-donation bag** should also be provided to ensure more safety. The needle guard should be such that the needle can be drawn from the venipuncture site smoothly in a single step directly into the needle guard. The engagement of the needle guard should require minimal force and have an audible click or tick indication.
    b. The Break off Valve should be present in the donor line to avoid contamination of the donor line with the first volume of contaminated blood and to avoid mixing of the anticoagulant solution with the first volume of collected blood.
7. Different color-coded clamps should be provided on donor tube and sampling line for easy identification and to avoid confusion for blood collection staff.
8. 3 units of bags should be packed in an outer cover with sufficient barrier properties to prevent moisture loss during storage.
9. Blood Bags and corrugated boxes should be properly labelled with Batch. No., Date of Mfg., and Date of Expiry. Platelet storage bag should be properly labelled for the days of storage of platelet.
10. Should be compatible with Automatic Component Extractor (Archimede NG).
11. **Product labels should be barcoded as per ISBT-128.Secondary packing and shipping cartons should be barcoded as per GS1-128.**
12. **Complies to ISO 3826-(2019) and quality of blood components stored as per EU Guidelines.**
13. **Sample bags to be provided for technical evaluation by the bidder (6 each size).**
14. **Mandatory for Manufacturer or its authorized distributors to provide 5 satisfactory end user certificates of last 5 years from Institute of National Importance (like AIIMS Delhi, JIPMER).**

Enclosure

TOP AND BOTTOM QUADRUPLE BLOOD BAG CPD-SAGM 450 ML

1. Quadruple top and bottom bag to collect blood and prepare blood component through buffy method.
2. Mother bag of the Top and bottom Quadruple blood bag should have 450ml capacity with 63 ml CPD solution and is connected to two satellite transfer bags of 450ml capacity and to a bottom bag of 450 ml capacity with 100 ml SAGM/SAGM-2 solution. The platelet bag should be suitable for 5 days storage. Transfer bags are designed for freezing at -80^{0}C for preparing cryoprecipitate with improved yield and quality.
3. Mother bag should be with 0.39 mm (-0.01mm +0.02 mm) thickness to prevent breakage during centrifugation and the inner diameter of the transfer tube from mother bag to SAGM /SAGM-2 bag should be with 3.8 mm ID to provide easy flow of the component.
4. Needle should be 16G with triple bevel design to reduce penetration force and enable painless vein puncture.
5. Blood bags should have hot markings in all tubes of the transfer bags. Tubes of plasma, platelet and red cell should have hot marking numbers to ensure traceability.
6. Sampling features
    - Donor tubes should be provided with Luer adapter for online withdrawal of blood samples without contamination. **Needle Injury protectors, Pre-donation bag** should also be provided to ensure more safety. The needle guard should be such that the needle can be drawn from the venipuncture site smoothly in a single step directly into the needle guard. The engagement of the needle guard should require minimal force and have an audible click or tick indication.
    - The Break off Valve should be present in the donor line to avoid contamination of the donor line with the first volume of contaminated blood and to avoid mixing of the anticoagulant solution with the first volume of collected blood.
7. Different color-coded clamps should be provided on donor tube and sampling line for easy identification and to avoid confusion for blood collection staff.
8. 3 units of bags should be packed in an outer cover with sufficient barrier properties to prevent moisture loss during storage.
9. Blood Bags and corrugated boxes should be properly labelled with Batch. No., Date of Mfg., and Date of Expiry. Platelet storage bag should be properly labelled for the days of storage of platelet.
10. Should be compatible with Automatic Component Extractor (Archimede NG).
11. **Product labels should be barcoded as per ISBT-128.Secondary packing and shipping cartons should be barcoded as per GS1-128.**
12. **Complies to ISO 3826 (2019) and quality of blood components stored as per EU Guidelines.**
13. **Sample bags to be provided for technical evaluation by the bidder (6 each size).**
14. **Mandatory for Manufacturer or its authorized distributors to provide 5 satisfactory end user certificates of last 5 years from Institute of National Importance (like AIIMS Delhi, JIPMER).**