# **Technical Specifications of Blood Bags**

## **Single blood bags:**

Blood collection bag Made up of DEHP (Di-2-ethyhexyl phthalate) plasticized PVC(polyvinylchloride), collapsible non- vented sterile containers complete with collecting tube for completely closed system to avoid the chances of contamination.

Capacity: single blood bag 450 ml

## Design and shape:

- 1. Flexible pre sterilized
- 2. Pyrogen free
- 3. Non toxic, non haemolytic, biocompatible material
- 4. No risk of contamination and air embloism(close system) with leaks proof seals
- 5. Slit on both sides of the bags should be enough to accommodate
- 5-10 ml test tubes.
- 6. The capacity of the bag should be enough to prevent any ballooning/rupture of the bag from seam when it is filled up with the requisite volume of blood

## **Tubing of bag:**

- 1. Flixible non kinking
- 2. Non sticking
- 3. Transparent
- 4. Leak proof
- 5. The minimum length of tubing from primary bag to the needle should be 80 cm.
- 6. The tube should have mulitple printed ID/Segment number. The number should be legible and clear
- 7. A clamp should be provided for closed system

#### **Needle:**

- 1. 16 guge ultra thin walled and straight
- 2. Sharp, regular and smooth margins and beveled tip
- 3. Rust proof
- 4. Tightly fixed with hub coverd with sterile guard
- 5. Hermetically sealed
- 6. The needle should not separate from the tube at any point of time, especially while rempving it from the vein for the donor safety

## **External port:**

- 1. Tamper proof and should not be re-capped
- 2. Easily accessible

# Package:

- 1. Protective dual packaging (individual & Aluminium) eliminating microbial contamination on surface maintaining the contents of the bag
- 2. Easy to handle

# Anticoagulant and preservative solution:

- 1. CPDA-1 The quantity of anticoagulant/(63 ml)
- 2. Clear & colorless
- 3. No discoloration on storage at room temperature
- 4. Manufacturer to supply anticoagualnt qaulity check certificate

#### Label:

- 1. Non peel- off
- 2. Heat sealed/ pressure embossed labels
- 3. Remain attached between room temperature to 4 °C with a transparent adhesive
- 4. Date of manufaturing, date of expiry and lot number must mentioned on each bag
- 5. The expiry date should be at least 2 years from the date of manufacturing of blood bags and residual shelf life at the time of supply should be at least 3/4th of the total shelf life

# **Triple blood bags:**

Blood collection bag Made up of DEHP (Di-2-ethyhexyl phthalate) plasticized PVC(polyvinylchloride), collapsible non- vented sterile containers complete with collecting tube for completely closed system to avoid the chances of contamination.

# **Capacity:** Triple blood bag:

Primary bag(450 ml)

First satellite bag(of 300 ml capacity)

Second satellite bag(of 300 ml capacity) for platelet storage for 5 Days

## **Design and shape:**

- 1. Flexible pre sterilized
- 2. Pyrogen free
- 3. Non toxic, non haemolytic, biocompatible material
- 4. No risk of contamination and air embloism(close system) with leaks proof seals
- 5. Slit on both sides of the bags should be enough to accommodate
- 5-10 ml test tubes.
- 6. The capacity of the bag should be enough to prevent any ballooning/rupture of the bag from seam when it is filled up with the requisite volume of blood

## **Tubing of bag:**

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- 4. Tightly fixed with hub coverd with sterile guard
- 5. Hermetically sealed
- 6. The needle should not separate from the tube at any point of time, especially while rempving it from the vein for the donor safety

## **External port:**

- 1. Tamper proof and should not be re-capped
- 2. Easily accessible

# Package:

- 1. Protective dual packaging (individual & Aluminium) eliminating microbial contamination on surface maintaining the contents of the bag
- 2. Easy to handle

# Anticoagulant and preservative solution:

- 1. CPDA-1 The quantity of anticoagulant/(49 ml/63 ml)
- 2. Clear & colorless
- 3. No discoloration on storage at room temperature
- 4. Manufacturer to supply anticoagualnt qaulity check certificate

#### Label:

- 1. Non peel- off
- 2. Heat sealed/ pressure embossed labels
- 3. Remain attached between room temperature to 4 °C with a transparent adhesive
- 4. Date of manufaturing, date of expiry and lot number must

mentioned on each bag

5. The expiry date should be at least 2 years from the date of manufacturing of blood bags and residual shelf life at the time of supply should be at least 3/4th of the total shelf life

# **Resistance to distortion:**

Filled to normal capacity

 $^{\circ}$  Bag shall with stand a acceleration of 5000g for 30 min at temperature 4°C to 24°C

Bag should be able to withstand temerature upto -80°C without breakage