

### **Triple blood bags Specification**

Blood collection bag Made up of DEHP (Di-2-ethylhexyl 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 embolism(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
7. The bag should have sample pouch.

### **Tubing of bag:**

1. Flexible 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 multiple printed ID/Segment number. The number should be legible and clear
7. A clamp should be provided for closed system

### **Needle:**

1. 16 gage ultra thin walled and straight with needle protector.
2. Sharp, regular and smooth margins and beveled tip
3. Rust proof
4. Tightly fixed with hub covered with sterile guard
5. Hermetically sealed
6. The needle should not separate from the tube at any point of time, especially while removing 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

**Resistance to distortion:**

Filled to normal capacity and a acceleration of 5000g for 30 min at temperature 4°C to 24°C

- Bag shall withstand a acceleration of 5000g for 30 min at temperature 4°C to 24°C 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 anticoagulant quality 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 manufacturing, 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  $\frac{3}{4}$ th of the total shelf life
  - **Resistance to distortion:**
  - Filled to normal capacity
  - Bag shall withstand a acceleration of 5000g for 30 min at temperature 4°C to 24°C

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