

Technical Specifications of Blood Bags

Minutes of the Meeting of the Technical Committee to Review Specifications of Blood Bags for use in Blood Banks

15th February 2017

A Meeting of the Technical Committee to Review Specifications of Blood Bags for use in Blood Banks was held on 15th Feb 2017 at 11:00 AM in Room No. 439 (A Wing), Nirman Bhawan, MoHFW, New Delhi under the chairmanship of Dr. B.D. Athani, Special DGHS.

The following members attended the meeting:

1. Dr. Kiran Chaudhary, HOD, Dept. of Transfusion Medicine, Dr.RML Hospital, New Delhi
2. Dr. Ravi Kant Sharma, Asst. Drugs Controller, CDSCO, New Delhi
3. Dr. Manjula Singh, Scientist D, ICMR HQ, New Delhi
4. Dr. Reba Chhabra, Dy. Director QC Incharge, Diagnostics, NIB Noida
5. Dr. Manjubala, Consultant & Professor, Safdarjung Hospital
6. Dr. Bharat Singh, Director SBTC, New Delhi
7. Dr. Vanshree Singh, Director (Blood Bank), IRCS, New Delhi
8. Dr. Abhijit Kadam, Scientist B, NARI
9. Dr. Meenu Bajpai, Addl. Professor, Transfusion Medicine, ILBS
10. Dr. Shobini Rajan, Director (NBTC)/ ADG (BTS), NACO
11. Dr. Shanoo Mishra, PO (QC), NBTC/NACO

Point wise Meeting Agenda:-

- 1.) Review of General Specifications of all Blood Bags.
- 2.) Review of Technical Specifications of Single Blood Bags (350ml.)
- 3.) Review of Technical Specifications of Double Blood Bags (350ml / 450 ml.)
- 4.) Review of Technical Specifications of Triple Blood Bags (350ml / 450 ml.)
- 5.) Review of Technical Specifications of Quadruple Blood Bags (350ml / 450 ml.)
- 6.) Review of Technical Specifications of Transfer Bags (300ml/600 ml/1000 ml capacity)
- 7.) View of Technical Committee on Use of SAGM as additive in Triple (450ml.) Blood Bags.
- 8.) View of Technical Committee Use of Blood Bags with higher specifications like needle protector, diversion pouches, leukoreduction filters etc.

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Technical Specifications of Blood Bags

Agenda Item No.1: Review of General specifications of all Blood Bags:

The following general specifications were approved by the Committee:

- (a) Plastic Blood Bags should meet all the standards as laid down in ISO 3826, for the manufacturers have to produce documentary evidence from the laboratories approved by Government of India.
- (b) Bio-compatibility of the material of the plastics blood bags must be certified by the manufacturer and must be supported by the test reports of the following.
 1. Cell culture cyto-toxicity
 2. Hemolysis
 3. Systemic infections (acute toxicity)
 4. Sensitization
 5. Intra-cutaneous injection (irritation)
 6. Pyrogen test
 7. Sterility
- (c) To assess quality of stored blood, manufacturer should provide documented evidence of following Bio-chemical parameters of blood stored in CPDA/CPDA-1/CPD-SAGM containing DEHP plasticized PVC blood bags manufactured by the company on 28th/35th/42nd day of storage. The parameters are:
 1. Plasma pH
 2. ATP (% of initial volume)
 3. 2,3-DPG (% of initial volume)
 4. Plasma K⁺ (mEq/L)
 5. % of viable red cells (24 hours post transfusion)
 6. DEHP leaching (mg/100ml).
 7. DEHP should not be more than 0.01% w/v in the PVC.
- (d) The plastic blood bag should have a shelf-life of minimum 2 years. Stability reports from a recognized laboratory must be produced.
- (e) Slit present at the bottom of the bag should be "adequate to hang the blood bag during transfusion".
- (f) Packing size of goods: Individual plastic blood bags should be packed in a plastic pack, 1-10 bags should be packed in aluminium foil pack. The label of the aluminium foil pack should read as 'Aluminium foil pack once opened, the bags should be used within ten days. Ten such aluminium foiled packs should be packed in the corrugated boxes which

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should indicate clearly and legibly the name of the manufacturer, name of the product, batch number, quantity, date of manufacturing, date of expiry, gross and net weight and consignee's name and address and other particulars as required. It should also mention "storage temperature not to exceed 30⁰C". It should be the responsibility of the manufacturer to ensure proper transportation of the consignment of blood bags in temperature controlled conditions.

- (g) External sterility of the plastic blood bags should be ensured. The outer surface should be moisture free.
- (h) Each carton should contain:
 - ❖ A copy of test reports.
 - ❖ A certificate mentioning " Blood may be collected up to the expiry date marked on the label which will be compatible with shelf life of components prepared as per required standards"
- (i) Satisfactory Report from reputed Government users for last two years to be provided.
- (j) At least five bags should be provided for the technical evaluation at the time of quotation.
- (k) Preferably with a needle protection device.

Agenda Item No.2: Review of Technical Specifications of Single Blood Bags (350ml.):

The following technical specifications were approved by the Committee:

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: Single blood bag – 350 ml

Design and shapes:

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

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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 needle should be 80 cm.
6. The tube should have multiple printed ID/Segment numbers. The numbers should be legible and clear.
7. A clamp should be provided for closed system.

Needle:

1. 16 gauge ultra thin walled and straight
2. Sharp, regular and smooth margins and bevelled 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 donor safety.

External Port:

1. Tamper proof and shouldn't be re-capped
2. Easily accessible

Package:

1. Protective dual packaging (Individual & Aluminum) 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)
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

[Handwritten signatures and initials in blue ink]

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4. Date of manufacturing, date of expiry and lot number must be 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.

Agenda Item No.3: Review of Technical Specifications of Double Blood Bags (350ml./450ml.):

The following technical specifications were approved by the Committee:

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

Capacity:

- Double bag
 - Primary bag (350 ml /450 ml)
 - One Satellite bag (300 ml)

Design and shapes:

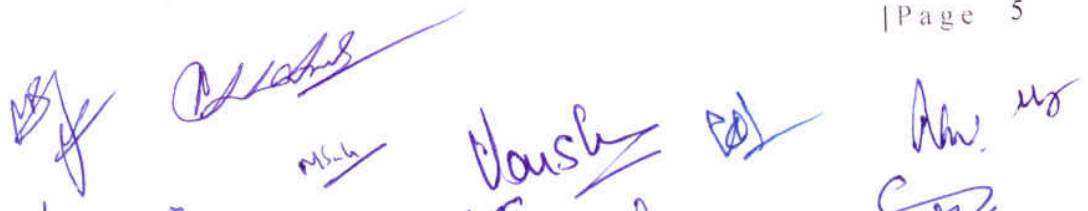
1. Flexible pre-sterilized
2. Pyrogen free
3. Non-toxic, non-haemolytic, biocompatible material
4. No risk of contamination and air embolism (closed system) with all leak proof seals (Disposable Bags).
5. Slits at both sides of the bags should be enough to accommodate 5 – 10 ml volume test tubes.
6.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

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 needle should be 80 cm.

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6. The tube should have multiple printed ID/Segment numbers. The numbers should be legible and clear.
7. A clamp should be provided for closed system.

Needle:

1. 16 gauge ultra thin walled and straight
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 donor safety.

External Port:

1. Tamper proof and shouldn't be re-capped
2. Easily accessible

Package:

1. Protective dual packaging (Individual & Aluminum) 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 anticoagulant quality check certificate

Labels:

1. Non-peel off
2. Heat sealed/ pressure embossed labels
3. Remain attached between room temperature to 4⁰C with a transparent adhesive
4. Date of manufacturing, date of expiry and lot number must be 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 ¾th of the total shelf life.

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Resistance to distortion:

Filled to normal capacity,

- Bag shall withstand an acceleration of 5000g for 30 min at temperature 4°C to 24°C without becoming permanently distorted
- Bag should be able to withstand temperature up to -80°C without breakage.

Agenda Item No.4: Review of Technical Specifications of Triple Blood Bags (350ml./450ml.):

The following technical specifications were approved by the Committee:

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 – 350 ml / 450 ml)

First Satellite bag (of 300 ml capacity)


Second Satellite bag (of 300 ml capacity) for platelet storage for 5 days

Design and shapes:

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

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 needle should be 80 cm.



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6. The tube should have multiple printed ID/Segment numbers. The numbers should be legible and clear.
7. A clamp should be provided for closed system.

Needle:

1. 16 gauge ultra thin walled and straight
2. Sharp regular and smooth margins and bevelled 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 donor safety.

External Port:

1. Tamper proof and shouldn't be re-capped
2. Easily accessible

Package:

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

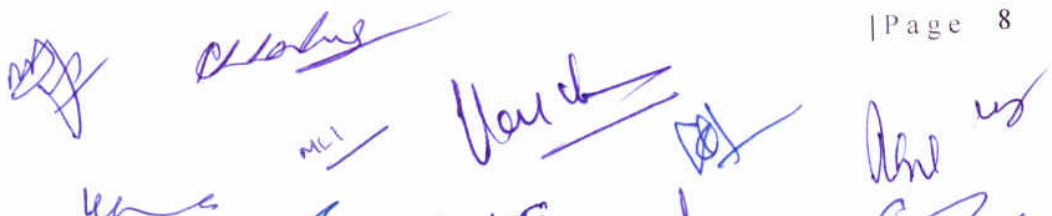
Anticoagulant and preservative solution:

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 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 be 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.

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Resistance to distortion:

Filled to normal capacity,

- Bag shall withstand an acceleration of 5000g for 30 min at temperature 4°C to 24°C without becoming permanently distorted
- Bag should be able to withstand temperature up to -80°C without breakage.

Agenda Item No.5: Review of Technical Specifications of Quadruple Blood Bags (350ml. / 450ml.):

The following technical specifications were approved by the Committee:

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:

Quadruple blood bag:

Primary bag – (350ml./ 450 ml) with top and top

First Satellite bag (of 300 ml. capacity containing 78ml/ 100 ml additive solution) – for 42 days red cell storage

Second Satellite bag (of 300 ml capacity) for platelet storage for 5 days

Third Satellite bag (of 300 ml capacity)

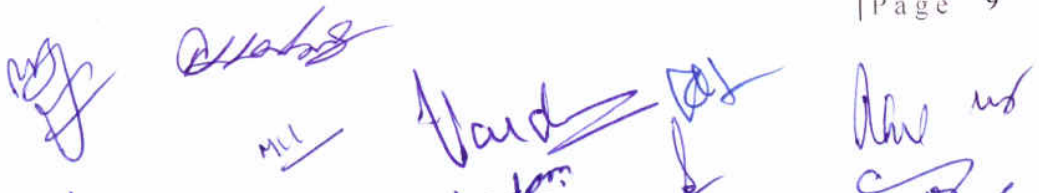
Design and shapes:

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

Tubing of bag:

1. Flexible non-kinking
2. Non-sticking
3. Transparent

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4. Leak-proof
5. The minimum length of tubing from primary bag to needle should be 80 cm.
6. The tube should have multiple printed ID/Segment numbers. The numbers should be legible and clear.
7. A clamp should be provided for closed system.

Needle:

1. 16 gauge ultra thin walled and straight
2. Sharp regular and smooth margins and bevelled 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 donor safety.

External Port:

1. Tamper proof and shouldn't be re-capped
2. Easily accessible

Package:

1. Protective dual packaging (Individual & Aluminum) 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/ pre (49 ml/ 63 ml.)
2. Additive Solution : ^{1st} First Satellite bag. (78ml for 350ml and 100ml for 450ml blood bag)-
3. Clear & colorless
4. No discoloration on storage at room temperature
5. 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



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4. Date of manufacturing, date of expiry and lot number must be 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 4⁰C to 24⁰C without becoming permanently distorted
- Bag should be able to withstand temperature up to -80⁰C without breakage.

Agenda Item No.6: Review of Technical Specifications of Transfer Bags (300ml capacity):

The following technical specifications were approved by the Committee:

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


Capacity: Single blood bag – 300 ml

Design and shapes:

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

Tubing of bag:

1. Flexible non-kinking
2. Non-sticking
3. Transparent
4. Leak-proof



Handwritten signatures and initials in blue ink, including names like 'Jacob' and 'M.L.C.', and some illegible scribbles.

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5. The minimum length of tubing from primary bag to needle should be 80 cm.
6. The tube should have multiple printed ID/Segment numbers. The numbers should be legible and clear.
7. A clamp should be provided for closed system.

Package:

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

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 be 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 ¾th of the total shelf life.

Resistance to distortion:

Filled to normal capacity

- Bag shall withstand an acceleration of 5000g for 30 min at temperature 4°C to 24°C without becoming permanently distorted.
- Bag should be able to withstand temperature up to -80°C without breakage.

Agenda Item No.7: View of Technical Committee on Use of SAGM as additive in Triple (450ml.) Blood Bags.

1. The Committee recommended to use SAGM as additive in Triple (450ml.) Blood Bags, working out specifications for the same and recommended the procurement of such Blood Bags at National Level from the next procurement cycle.


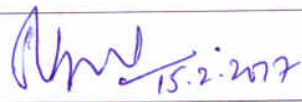
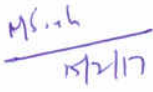

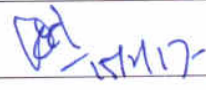
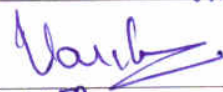
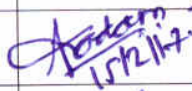
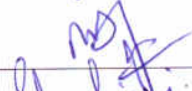
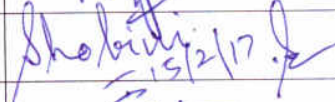

Agenda Item No. 8: View of Technical Committee Use of Blood Bags with higher specifications like needle protector, diversion pouches, leukoreduction filters etc.


1. The Committee recommended working out separate specifications of blood bags with needle protectors, diversion pouches and leukoreduction filters and



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recommended the procurement of such Blood Bags at National Level from the next procurement cycle.

S No	Name and Designation	Signature
1	Dr. Kiran Chaudhary, HOD, Dept. of Transfusion Medicine, Dr.RML Hospital, New Delhi	
2	Dr. Ravi Kant Sharma, Asst. Drugs Controller, CDSCO, New Delhi	 15.2.2017
3	Dr. Manjula Singh, Scientist D, ICMR HQ, New Delhi	 15/2/17
4	Dr. Reba Chhabra, Dy. Director QC Incharge, Diagnostics, NIB Noida	 15/2/17
5	Dr. Manjubala, Consultant & Professor, Safdarjung Hospital	
6	Dr. Bharat Singh, Director SBTC, New Delhi	 15/2/17
7	Dr. Vanshree Singh, Director (Blood Bank), IRCS, New Delhi	
8	Dr. Abhijit Kadam, Scientist B, NARI	 15/2/17
9	Dr. Meenu Bajpai, Addl. Professor, Transfusion Medicine, ILBS	
10	Dr. Shobini Rajan, Director (NBTC)/ ADG (BTS), NACO	 15/2/17
11	Dr. Shanoo Mishra, PO (QC), NBTC/NACO	

Chairperson	Signature
Dr. B.D Athani, Special Director General of Health Services	

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