Technical Specifications of Blood Bags 2018

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

27th September 2018

Three Meetings of the Technical Specification Committee were held to Review Specifications of ELISA and Rapid testing kits for use in Blood Banks on 13th August 2018, 30th August 2018 & 27th September 2018. Venue of meeting was Room No. 439 (A Wing), Nirman Bhawan, MoHFW, New Delhi under the chairmanship of Dr. A.K Gadpayle, Addl. DGHS.

The following members attended the meetings as detailed below:

Members	13th August 2018	30th August 2018	27th September 2018
Mr. Sella Senthil M, Asst. Drugs Controller, CDSCO, New Delhi	No	Yes	Yes
Mr. Yogesh Shelar, Asst. Drugs Controller, CDSCO, New Delhi	No	No	Yes
Dr. Madhuri Thakar, Scientist F & HOD, NARI, Pune	Yes	No	No
Dr. Manjula Singh, Scientist E, ICMR HQ, New Delhi	No	No	Yes
Dr Reba Chhabra, Scientist I, DD QC I/C (Diagnostics), NIB, NOIDA	Yes	Yes	No
Mr. N Nanda Gopal Scientist Grade III, NIB Noida	No	No	Yes
Dr. Sumati Muralidhar, Professor & Consultant, Apex STD Lab, VMCC, New Delhi	Yes	Yes	No
Dr Sandhya Kabra, Addl. Director, NCDC & I/C National Hepatitis Programme	Yes	Yes no change since meeting no told as chair not present	No
Dr. Kiran Chaudhary, HOD, Dept. of Transfusion Medicine, Dr.RML Hospital, New	Yes	Yes	No
Dr. Vanshree Singh, Director (Blood Bank), IRCS, New Delhi	Yes	Yes	Yes
Dr. Ekta Gupta, Associate Professor, ILBS, Delhi	No	Yes	Yes
Dr. Shobini Rajan, Director (NBTC)/ ADG (BTS), NACO	Yes	Yes	Yes
Dr. Bhawna Rao, Deputy Director, NACO	No	No	Yes
Dr. YaavarShafi, MO, NBTC/NACO	No	No	Yes
Mr. Jolly J Lazarus, PO(VBD), NBTC	Yes	Yes	Yes

Technical Specifications of Blood Bags 2018

Discussions were held in all three meetings amongst all members and the representatives from the manufacturers invited for the second meeting. All members were represented in at least one out of three meetings. Specifications were finalized in the third meeting based on discussions held in all three meetings and minuted as detailed below:

Point wise Meeting Agenda:-

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) All internal reports of manufacturer pertaining to the quality of blood bags must be provided along with each batch and a copy of the same should be available with each box/ carton of blood bags.

(e) All supportive documents, test reports and certificates provided in compliance to specifications should not be older than three years from the date of tender publication.

(f) The plastic blood bag should have a shelf-life of minimum 2 years. Stability reports from a recognized laboratory must be produced.

(g) Slit present at the bottom of the bag should be "adequate to hang the blood bag during transfusion".

(h) 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 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 30^0C". It should be the responsibility of the manufacturer to ensure proper transportation of the consignment of blood bags in temperature controlled conditions.

(i) External sterility of the plastic blood bags should be ensured. The outer surface should be moisture free.

(j) 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"

(k) Satisfactory Report from reputed Government users for last two years to be provided.

(l) At least five bags should be provided for the technical evaluation at the time of quotation.

(m) Should have a needle protection device to reduce the risk of needle stick injury which is easy to use with needle protector permanently sleeved over the needle once removed from the venepuncture site prior to disposal

(n) Disposal of the blood bags should be possible through modalities as per Biomedical Waste Management Rules 2016 as amended from time to time.

(o) In case of imported / indigenous manufacturers the product should be licensed under the provision of Drugs & Cosmetics Act and Rules and / or Medical Devices Rules 2017 in India.

(p) Lab Report from Authorized Laboratory should not be more than 5 years old, including the latest Report.

Technical Specifications of Blood Bags 2018

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. Non-pyrogenic
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.
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.

7. The needle should have protector to ensure safe blood collection. The edges of the protector should be smooth and round.

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/CPDA-1: The quantity of anticoagulant/ pre (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 4^0C 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.

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)

Technical Specifications of Blood Bags 2018

Design and shapes:

1. Flexible pre-sterilized
2. Non pyrogenic
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.
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.
7. The needle should have protector to ensure safe blood collection. The edges of the protector should be smooth and round.

External Port:

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

Technical Specifications of Blood Bags 2018

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/CPDA-1: The quantity of anticoagulant/ pre (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.

Resistance to distortion:

Filled to normal capacity,

- Bag shall withstand a acceleration of 5000g for 30 min at temperature 4^0C to 24^0C without becoming permanently distorted
- Bag should be able to withstand temperature upto -80^0C without breakage.

Diversion pouch with multiple sampling device:

- For the safe inline blood sampling
- Diversion pouch and Luer adapter holder to be integrated with the primary collection tube for maintaining sterility of the collected blood and sample collection
- The sampling pouch should be of 20- 35ml capacity and length of 350 mm from Needle hub to U Connector.
- It should be easy to insert Vacuum tubes for blood sampling

Agenda Item No.4: Review of Technical Specifications of Triple Blood Bags (350ml/ 450ml.) (without SAGM):

The following technical specifications were approved by the Committee:

Technical Specifications of Blood Bags 2018

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. Non-pyrogenic
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.
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.
7. The needle should have protector to ensure safe blood collection. The edges of the protector should be smooth and round.

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/CPDA-1: The quantity of anticoagulant/ pre (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 4^0C 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 a acceleration of 5000g for 30 min at temperature 4^0C to 24^0C without becoming permanently distorted
- Bag should be able to withstand temperature up to -80^0C without breakage.

Diversion pouch with multiple sampling device:

- For the safe inline blood sampling

27th September 2018

- Diversion pouch and Luer adapter holder to be integrated with the primary collection tube for maintaining sterility of the collected blood and sample collection
- The sampling pouch should be of 20- 35ml capacity and length of 350 mm from Needle hub to U Connector.
- It should be easy to insert Vacuum tubes for blood sampling

Agenda Item No.5: Technical Specifications of Triple Blood Bags (350ml./ 450ml.) (with SAGM):

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) with additive solution for red cell storage upto 42 days

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

Design and shapes:

1. Flexible pre-sterilized
2. Non-pyrogenic
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.

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.
7. The needle should have protector to ensure safe blood collection. The edges of the protector should be smooth and round.

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. CPD: (49 ml for 350 ml/ 63 ml for 350 ml.) in primary bag
2. SAGM (78 ml/100 ml) in first satellite 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 4^0C 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 a acceleration of 5000g for 30 min at temperature 4^0C to 24^0C without becoming permanently distorted
- Bag should be able to withstand temperature up to -80^0C without breakage.

Diversion pouch with multiple sampling device:

- For the safe inline blood sampling
- Diversion pouch and Luer adapter holder to be integrated with the primary collection tube for maintaining sterility of the collected blood and sample collection
- The sampling pouch should be of 20- 35ml capacity and length of 350 mm from Needle hub to U Connector.
- It should be easy to insert Vacuum tubes for blood sampling

Agenda Item No.6: Review of Technical Specifications of Quadruple Blood Bags (350ml. / 450ml.) (with SAGM):

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 with 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
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.
7. The needle should have protector to ensure safe blood collection. The edges of the protector should be smooth and round.

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:

Technical Specifications of Blood Bags 2018

1. CPD: (49 ml for 350 ml/ 63 ml for 350 ml.) in primary bag
2. SAGM (78 ml for 350 ml/100 ml for 450 ml) in first satellite 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 4^0C 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 a acceleration of 5000g for 30 min at temperature 4^0C to 24^0C without becoming permanently distorted
- Bag should be able to withstand temperature up to -80^0C without breakage.

Diversion pouch with multiple sampling device:

- For the safe inline blood sampling
- Diversion pouch and Luer adapter holder to be integrated with the primary collection
- tube for maintaining sterility of the collected blood and sample collection
- The sampling pouch should be of 20- 35ml capacity and length of 350 mm from Needle hub to U Connector.
- Easy to insert Vacuum tubes during blood sampling

Technical Specifications of Blood Bags 2018

S No	Name and Designation of Members	Signature
1	Mr. Sella Senthil M, Asst. Drugs Controller, CDSCO, New Delhi	
2	Mr. Yogesh Shelar, Asst. Drugs Controller, CDSCO, New Delhi	
3	Dr. Madhuri Thakar, Scientist F & HOD, NARI, Pune	
4	Dr. Manjula Singh, Scientist E, ICMR HQ, New Delhi	
5	Dr. Reba Chhabra, Dy. Director QC Incharge, Diagnostics, NIB Noida	
6	Mr. N Nanda Gopal Scientist Grade III, NIB Noida	
7	Dr. Sumathi Murlidhar, Consultant, Microbiologist, Apex Center, Safdarjung Hospital New Delhi	
8	Dr. Sandhya Kabra, Addl. Director, NCDC, New Delhi	13/8/18
9	Dr. Kiran Chaudhary, HOD, Dept. of Transfusion Medicine, Dr.RML Hospital, New Delhi	
10	Dr. Vanshree Singh, Director (Blood Bank), IRCS, New Delhi	
11	Dr. Ekta Gupta, Associate Professor, ILBS, Delhi	
12	Dr. Shobini Rajan, Director (NBTC)/ ADG (BTS), NACO	
13	Dr. Bhawna Rao, Deputy Director, NACO	
14	Dr. Yaavar Shafi, MO, NBTC/NACO	
15	Mr. Jolly J Lazarus, PO(VBD), NBTC / NACO	
	Chairperson	**Signature**
	Dr. A.K Gadpayle, **Addl. Director General of Health Services**	