Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 041938 0007 Rev. 00

Manufacturer:

POLY MEDICURE LIMITED
Plot No. 104-105, Sector-59
HSIIDC Industrial Area, Ballabhgarh
Faridabad, Haryana 121004
INDIA

Product Category(ies):

IV Cannula/ Catheter with / without Safety Features, Infusion Sets, Burette Infusion Sets, Flow Regulators, Extension Lines, Luer Caps, Stylet (Obturators), CVP Manometers, Stop cock with/without extension line, Needle free connectors with/without extension line, Scalp vein (Winged Infusion) Set (with / without safety features), Insulin Syringe, Huber Infusion set with / without safety features, Over the Needle (OTN) Catheter, Arterial Cannula with/without Safety Features, Manifolds with/without Extension line, Mini-midline Catheter (Peripheral catheter), Transfusion Pump Set, Luer Adaptors, Blood Bags, Blood Collection Set with / without Safety Features, Blood Collection Needle & Holder, Transfusion Sets (BT Sets), Closed Wound Suction Unit, Yankaur Suction Set (Suction tube and/or Handle), Thoracic Drainage Catheter (with/without Trocar), Redon Drainage Tube, Abdominal Drainage Set, Under Water Seal Drainage System, Female catheter, Nelaton catheter, Foley Balloon Catheter, Irrigation Set, Levins tube, Infant Feeding Tube, Ryle's Tube, Stomach Tube, Umbilical Catheter, Feeding Bag, Mucus Extractor with/without Bacterial Filter, Suction Catheter, Nasal Oxygen Catheter/ Cannula, Oxygen Catheter, Guedel Airways, Endotracheal Tubes (Plain, Cuffed, Reinforced), Catheter Mount, Oxygen Mask, Nebulizer Mask, Venturi Mask, Blood Line Set, Fistula Needle with / without Safety features, Peritoneal Dialysis Transfusion Set, Peritoneal Dialysis Catheter Kit, High Pressure Vacuum Drainage Bottle.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: IND2019081_CN

Valid from: 2020-06-17
Valid until: 2024-05-26

Date, 2020-06-17

Digitally signed by Granaci Boris
Date: 2022.11.25 16:30:35 EET
Reason: MoldSign Signature
Location: Moldova

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 041938 0001 Rev. 00

Holder of Certificate: **POLY MEDICURE LIMITED**
Plot No. 104-105, Sector-59
HSIIDC Industrial Area, Ballabhgarh
Faridabad, Haryana 121004
INDIA

Certification Mark:

Scope of Certificate: **Design & Development, Manufacture, Sales and Distribution of Sterile & Non-Sterile Non Active Non Implantable Medical Devices for Infusion, Transfusion, General Surgery, Anaesthesia, Gynecology, Gastroenterology, Respiratory, Urology, Dialysis by Injection Moulding, Plastic Extrusion, Assembly, Packing and Sterilization.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: IND2019081

Valid from: 2020-06-01
Valid until: 2023-03-13

Date, 2020-06-01

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 041938 0001 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

POLY MEDICURE LIMITED
Plot No. 104-105, Sector-59, HSIIDC Industrial Area, Ballabhgarh, Faridabad, Haryana 121004, INDIA

POLY MEDICURE LIMITED
Plot No.115-116, Sector-59, HSIIDC Industrial Area, Ballabhgarh, Faridabad, Haryana 121004, INDIA

POLY MEDICURE LIMITED
Unit III: Plot No. 17, Sector-3, SIDCUL, Integrated Industrial Estate, Haridwar, Uttarakhand 249403, INDIA

-/-

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

1 PURPOSE

This document describes the product design and technical requirements of the In Vitro Diagnostic medical disposable product. As per Council Directive 98/79/EEC of 27th October 1998 concerning In Vitro Diagnostic devices, Blood Collection Tubes are classified as Low Risk General Class I IVD device and this product shall comply with essential requirements of In Vitro Diagnostic Device Directives 98/79/EC and EN 14820:2004 product standards.

2 INTENDED USE OF PRODUCT

Blood Collection Tubes (Haemochek & Novac) - The products are used together with Blood Collection Holders and Needles, as a system for the collection of venous blood. The tubes are used to collect, transport and process blood for testing serum, plasma or whole blood in the clinical laboratory.

3 PRODUCT DESCRIPTION & FEATURES

3.1 Vacuum blood collection tubes are made of PET having unique biocompatibility.

3.2 Reduce the potential for tube breakage and specimen spillage, thereby reducing the potential for exposure to blood borne pathogens. Tube interiors are sterile by irradiation.

3.3 Easy, quick & safe venous blood collection with improved patient comfort.

3.4 Allows higher centrifugation speeds with faster test results.

3.5 Accurate therapeutic & diagnostic analysis. Improved lab efficiency & cost reduction.

3.6 Color coded for safe, reliable identification, handling & analysis.

3.7 Available in various sizes for adult and pediatric phlebotomies.

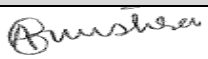
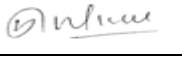
3.8 **Product Features**:

3.8.1 Serum Tubes *with Blood Clot activator* - Coated with micronized silica which acts as clot activator. Suitable for *clinical* serum and blood donor screening chemistry tests.

Draw Volume	Cap color	Tube Size (in mm)	Additive	Packaging (Tray Pack)
2.0 ml	Red	13 x 75	Clot Activator	100 Pcs.
3.0 ml	Red	13 x 75	Clot Activator	100 Pcs.
4.0 ml	Red	13 x 75	Clot Activator	100 Pcs.
5.0 ml	Red	13 x 100	Clot Activator	100 Pcs.
6.0 ml	Red	13 x 100	Clot Activator	100 Pcs.
7.0 ml	Red	16 x 100	Clot Activator	100 Pcs.
10.0 ml	Red	16 x 100	Clot Activator	100 Pcs.

3.8.2 Serum Separating Tubes with Gel Separator- SST tubes are coated with micronized silica that causes blood to clot rapidly and a gel is added that separates blood cells from serum. Suitable for Serum clinical chemistry & Immunology analysis.

Draw Volume	Cap color	Tube Size (in mm)	Additive	Packaging (Tray Pack)
2.0 ml	*Golden*	13 x 75	Gel + Clot Activator	100 Pcs.
3.0 ml	*Golden*	13 x 75	Gel + Clot Activator	100 Pcs.
3.5 ml	*Golden*	13 x 75	Gel + Clot Activator	100 Pcs.
4.0 ml	*Golden*	13 x 75	Gel + Clot Activator	100 Pcs.

Approvals	Name	Designation	Signature	Date
Prepared By	Ashutosh Mishra	Asst. Manager - QA		09.12.2019
Checked By	RD Sharma	DGM - QA		09.12.2019
Approved By	SS Rawat	Head - QA		09.12.2019

Draw Volume	Cap color	Tube Size (in mm)	Additive	Packaging (Tray Pack)
5.0 ml	*Golden*	13 x 100	Gel + Clot Activator	100 Pcs.
6.0 ml	*Golden*	13 x 100	Gel + Clot Activator	100 Pcs.
7.0 ml	*Golden*	16 x 100	Gel + Clot Activator	100 Pcs.
8.0 ml	*Golden*	16 x 100	Gel + Clot Activator	100 Pcs.
8.5 ml	*Golden*	16 x 100	Gel + Clot Activator	100 Pcs.
9.0 ml	*Golden*	16 x 100	Gel + Clot Activator	100 Pcs.
10.0 ml	*Golden*	16 x 100	Gel + Clot Activator	100 Pcs.

3.8.3. Coagulation (Citrate) Tubes- Coagulation tubes contain 3.2% buffered sodium citrate solution. Suitable for examination of coagulation parameters.

Draw Volume	Cap color	Tube Size (in mm)	Additive	Packaging (Tray Pack)
1.8 ml	Light Blue	13 x 75	3.2% Buffered Sodium Citrate 9 NC	100 Pcs.
2.7 ml	Light Blue	13 x 75	3.2% Buffered Sodium Citrate 9 NC	100 Pcs.
3.6 ml	Light Blue	13 x 75	3.2% Buffered Sodium Citrate 9 NC	100 Pcs.
4.5 ml	Light Blue	13 x 75	3.2% Buffered Sodium Citrate 9 NC	100 Pcs.

3.8.4 Hematology Tubes / EDTA (K_2/K_3) Tubes - EDTA tubes are offered as either K_2EDTA or K_3EDTA tubes. EDTA binds the calcium ions and therefore blocks the coagulation cascade. They are widely used to collect blood for clinical hematology examinations. Suitable for *whole blood Hematology Testing,* Immunohematology testing & blood donor screening.

Draw Volume	Cap color	Tube Size (in mm)	Additive	Packaging (Tray Pack)
1.0 ml	Lavender	13 x 75	K_2EDTA	100 Pcs.
2.0 ml	Lavender	13 x 75	K_2EDTA	100 Pcs.
2.5 ml	Lavender	13 x 75	K_2EDTA	100 Pcs.
3.0 ml	Lavender	13 x 75	K_2EDTA	100 Pcs.
4.0 ml	Lavender	13 x 75	K_2EDTA	100 Pcs.
5.0 ml	Lavender	13 x 100	K_2EDTA	100 Pcs.
6.0 ml	Lavender	13 x 100	K_2EDTA	100 Pcs.
7.0 ml	Lavender	16 x 100	K_2EDTA	100 Pcs.
8.0 ml	Lavender	16 x 100	K_2EDTA	100 Pcs.
9.0 ml	Lavender	16 x 100	K_2EDTA	100 Pcs.
10.0 ml	Lavender	16 x 100	K_2EDTA	100 Pcs.

Draw Volume	Cap color	Tube Size (in mm)	Additive	Packaging (Tray Pack)
2.0 ml	Lavender	13 x 75	K_3EDTA	100 Pcs.
2.5 ml	Lavender	13 x 75	K_3EDTA	100 Pcs.
3.0 ml	Lavender	13 x 75	K_3EDTA	100 Pcs.
4.0 ml	Lavender	13 x 75	K_3EDTA	100 Pcs.
5.0 ml	Lavender	13 x 100	K_3EDTA	100 Pcs.
6.0 ml	Lavender	13 x 100	K_3EDTA	100 Pcs.
7.0 ml	Lavender	16 x 100	K_3EDTA	100 Pcs.
8.0 ml	Lavender	16 x 100	K_3EDTA	100 Pcs.
9.0 ml	Lavender	16 x 100	K_3EDTA	100 Pcs.
10.0 ml	Lavender	16 x 100	K_3EDTA	100 Pcs.

3.8.5 Glucose Estimation Tubes - The Glycaemia tubes contain anticoagulant and a glycolytic inhibitor. Suitable for blood sugar and lactate determinations.

Draw Volume	Cap color	Tube Size (in mm)	Additive	Packaging (Tray Pack)
2.0 ml	Grey	13 x 75	Sodium Fluoride / *Na2 EDTA*	100 Pcs.
2.5 ml	Grey	13 x 75	Sodium Fluoride / *Na2 EDTA*	100 Pcs.
3.0 ml	Grey	13 x 75	Sodium Fluoride / *Na2 EDTA*	100 Pcs.
4.0 ml	Grey	13 x 75	Sodium Fluoride / *Na2 EDTA*	100 Pcs.
5.0 ml	Grey	13 x 100	Sodium Fluoride / *Na2 EDTA*	100 Pcs.
6.0 ml	Grey	13 x 100	Sodium Fluoride / *Na2 EDTA*	100 Pcs.

3.8.6 ESR (Erythrocyte Sedimentation Rate) Tubes - ESR tubes contains 3.8% buffered sodium citrate (4NC) for westergren sedimentation rate determinations.

Draw Volume	Cap color	Tube Size (in mm)	Additive	Packaging (Tray Pack)
1.6 ml	Black	13 x 75	3.2% Buffered Sodium Citrate (4NC)	100 Pcs.

3.8.7 Sodium/Lithium Heparin Tubes – The interior of tube wall is coated with Sodium or Lithium Heparin. The anticoagulant heparin activates antithrombins, thus blocking the coagulation cascade and producing a whole blood. Suitable for plasma determinations in chemistry.

Draw Volume	Cap color	Tube Size (in mm)	Additive	Packaging (Tray Pack)
2.0 ml	Green	13 x 75	Sodium Heparin	100 Pcs.
3.0 ml	Green	13 x 75	Sodium Heparin	100 Pcs.
4.0 ml	Green	13 x 75	Sodium Heparin	100 Pcs.
5.0 ml	Green	13 x 100	Sodium Heparin	100 Pcs.

Approvals	Name	Designation	Signature	Date
Prepared By	Ashutosh Mishra	Asst. Manager - QA		09.12.2019
Checked By	RD Sharma	DGM - QA		09.12.2019
Approved By	SS Rawat	Head - QA		09.12.2019

Draw Volume	Cap color	Tube Size (in mm)	Additive	Packaging (Tray Pack)
6.0 ml	Green	13 x 100	Sodium Heparin	100 Pcs.
7.0 ml	Green	16 X 100	Sodium Heparin	100 Pcs.
9.0 ml	Green	16 X 100	Sodium Heparin	100 Pcs.
10.0 ml	Green	16 x 100	Sodium Heparin	100 Pcs.

Draw Volume	Cap color	Tube Size (in mm)	Additive	Packaging (Tray Pack)
2.0 ml	Green	13 x 75	Lithium Heparin	100 Pcs.
3.0 ml	Green	13 x 75	Lithium Heparin	100 Pcs.
4.0 ml	Green	13 x 75	Lithium Heparin	100 Pcs.
5.0 ml	Green	13 x 100	Lithium Heparin	100 Pcs.
6.0 ml	Green	13 x 100	Lithium Heparin	100 Pcs.
7.0 ml	Green	16 X 100	Lithium Heparin	100 Pcs.
9.0 ml	Green	16 X 100	Lithium Heparin	100 Pcs.
10.0 ml	Green	16 x 100	Lithium Heparin	100 Pcs.

3.8.8 CPDA Tubes - During Blood Collection into CPDA tubes 6 volumes of blood are added to 1 volume of CPDA solution (Mixing Ratio 6:1). CPDA tube is used for blood grouping determinations and cell preservation.

Draw Volume	Cap color	Tube Size (in mm)	Additive	Packaging (Tray Pack)
4.0 ml	Yellow	13 x 75	CPDA solution	100 Pcs.
5.0 ml	Yellow	13 x 100	CPDA solution	100 Pcs.
6.0 ml	Yellow	16 x 100	CPDA solution	100 Pcs.

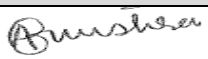
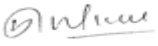
3.8.9 ACDA Tubes – ACD tubes are used for drawing whole blood for special tests such as HLA phenotyping, and DNA and paternity testing.

Draw Volume	Cap color	Tube Size (in mm)	Additive	Packaging (Tray Pack)
4.0 ml	Yellow	13 x 75	ACDA solution	100 Pcs.
5.0 ml	Yellow	13 x 100	ACDA solution	100 Pcs.
6.0 ml	Yellow	16 x 100	ACDA solution	100 Pcs.

4. REFERENCE DOCUMENTS

Approvals	Name	Designation	Signature	Date
Prepared By	Ashutosh Mishra	Asst. Manager - QA		09.12.2019
Checked By	RD Sharma	DGM - QA		09.12.2019
Approved By	SS Rawat	Head - QA		09.12.2019

S. No.	Document Code	Document Description
Harmonized Standards		
4.1	*EN ISO 13485:2016*	Medical devices- Requirements for the Regulatory Purposes
4.2	98/79/EC	European Council Directive
4.3	EN 14820:2004	Single-use containers for human venous blood specimen collection
4.4	QP/ECD/01	EC Vigilance
4.5	EN ISO 14971:2012	Application of Risk Management to medical devices
4.6	EN ISO 11137-1:2015	Requirements for development, validation and routine control of a sterilization process for medical devices
4.7	EN ISO 11137-2:2015	Sterilization of health care products, Radiation, Establishing the sterilization dose
4.8	EN ISO 15223-1:2016	Symbols to be used with medical devices labels
4.9		
4.10	EN 1041:2008	Terminology, Symbols and information provided with Medical Devices; Information supplied by the manufacturer with medical devices
Non-Harmonized Standards		
4.11	ISO 9001:2015	Quality Management System - Requirements
4.12	*ISO 14644-1:2015*	*Clean room and associated controlled environments - Classification of air cleanliness*
4.13	*ISO 14644-2:2015*	*Clean room and associated controlled environments - Specifications for testing and monitoring to prove continued compliance with ISO 14644-1.*
4.14	QP/IMT/01	Control of Inspection Measuring and Test Equipment
4.15	USP / IP	United States Pharmacopoeia / Indian Pharmacopoeia
4.16	QP/QPL/01	Quality Planning
4.17	GTP/QC/4.09	Sterility Test
4.18	GTP/QC/4.14	Monitoring of Bio-burden of clean room manufacturing area
4.19	WI/BCT/01	Preparation of different type of solutions
4.20	WI/BCT/02	Silicon coating of test tube & rubber stopper
4.21	WI/BCT/03	Equipment handling & cleaning procedures
4.22	Drg. No. Assly. 8003	Assembly Blood Collection Tube
4.23	Drg. No. Assly. 8005	Assembly Blood Collection Tube (NOVAC)
4.24	Drg. No. Comp 8005.01	Tube (Novac)
4.25	Drg. No. Comp 8005.02	Stopper (Haemocheck)
4.26	Drg. No. Comp 8005.05	Rubber Cap – 10ml
4.27	Drg. No. Comp 8005.06	Tube (Haemocheck)
4.28	Drg. No. Comp 8005.07	Stopper Novac
4.29	Drg. No. Comp 8005.10	Rubber Cap – 10ml (long)
4.30	Drg. No. Comp 8005.02	Rubber Cap
4.31	Drg. No. Comp 8005.03	Safety cover

Approvals	Name	Designation	Signature	Date
Prepared By	Ashutosh Mishra	Asst. Manager - QA		09.12.2019
Checked By	RD Sharma	DGM - QA		09.12.2019
Approved By	SS Rawat	Head - QA		09.12.2019

S. No.	Document Code	Document Description
4.32	Drg. No. Comp 85110.01	Red Cap Novac 2
4.33	Drg. No. Comp 85120.01	Light Blue Cap Novac 2
4.34	Drg. No. Comp 85110.01	Red Cap Novac 2
4.35	Drg. No. Comp 85120.01	Light Blue Cap Novac 2
4.36	Drg. No. Comp 85130.01	Lavender Novac 2
4.37	Drg. No. Comp 85140.01	Grey Cap Novac 2
4.38	Drg. No. Comp 85150.01	Gold Cap Novac 2

5. SHELF LIFE

The Finished products shall conform to the specifications and functional requirements for a maximum of 2 yrs. (depending on the type of additives) from the date of manufacturing.

6. STERILIZATION

6.1 Evacuated (Haemocheck) tubes shall be sterilized with Gamma Radiation as per standardized and validated sterilization cycle as per EN ISO 11137-2:2015 by M/s. Jhunsons Chemicals Private Limited, Bhiwadi. The detailed record of routine monitoring is maintained with the QA as well as production department. All tubes are exposed to *average* 8 kilo grays (kGy) of Gamma radiation.

6.2 Tubes are irradiated to achieve sterility. These tubes are sterile on the interior only. We cannot recommend re-sterilizing the tubes, primarily due to pressure changes that take place during the re-sterilization cycle. Our tubes are under a specific negative pressure. During the re-sterilization cycle this negative pressure may be disrupted and therefore the tubes may not draw the proper blood volume.

6.3 Product appearance and functional performance is not compromised by sterilization cycles as the product is sterilized and the package of product remained intact.

6.4 Non-evacuated (Novac) tubes are unsterile as the interior of tubes are not in direct contact of blood flow or circulating blood.

7. MATERIAL

7.1 All component materials selected comply with the specification and free from any constituent of animal origin.

S. No.	Part Where material is used	Base Material	Grade
1	Tube (Novac)	Polypropylene	SRM100NC
2	Tube (Vacuum)	Polyester Chips (PET)	CD -603 L
3	Safety cover	LDPE	24FS040/LDF201FG
4	Rubber cap	BBR/SBR	N/A
5	Medical Silicon	Silicon	DC - 360
6	Solution for Anticoagulant	K_2EDTA	LR grade
		K_3EDTA	LR grade
		Sodium Heparin	LR grade

Approvals	Name	Designation	Signature	Date
Prepared By	Ashutosh Mishra	Asst. Manager - QA		09.12.2019
Checked By	RD Sharma	DGM - QA		09.12.2019
Approved By	SS Rawat	Head - QA		09.12.2019

S. No.	Part Where material is used	Base Material	Grade
		Lithium Heparin	LR grade
		Tri-sodium Citrate	LR grade
7	Powder Coating	Sodium Fluoride	LR grade
		Na_2 EDTA	LR grade
8	Serum Gel Separator	Serum Separator Gel	LR grade
9	Sterilized by Radiation	Gamma Radiation	Cobalt 60

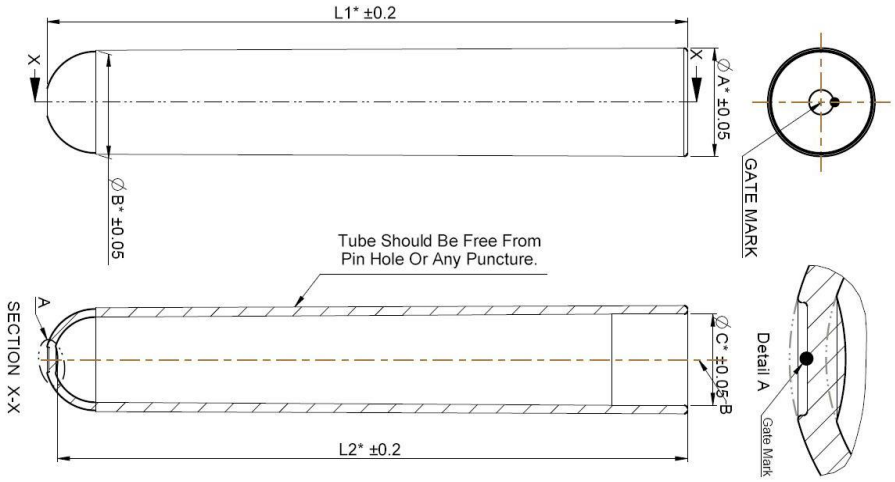
8. COMPONENT AND PROCEDURE FOR MANUFACTURING

8.1 Blood Collection Tubes

8.1.1 Components

(i) Tube - Injection molding
(ii) Safety Cap - Injection molding
(iii) Rubber Cap - Injection molding

8.1.2



Manufacturing – Manufacturing of Blood Collection tube is done as per WI/BCT/01 in controlled environment conditions.

9. FUNCTIONAL SPECIFICATIONS

9.1 Blood Collection Tubes

9.1.1 Blood collection Tube

- Material clear to transparent to allow visualization through walls to inside.
- Technical specifications of blood collection tubes given as under –

Approvals	Name	Designation	Signature	Date
Prepared By	Ashutosh Mishra	Asst. Manager - QA		09.12.2019
Checked By	RD Sharma	DGM - QA		09.12.2019
Approved By	SS Rawat	Head - QA		09.12.2019

Size of Test tube	O.D (mm)	I.D (mm)	Tube volume	Length (mm)	Bottom wall (mm)
2 ml	12.5 ± 0.075	10.75 ± 0.075	5.0 ml	75.5 ± 0.5	0.9 to 1.1
3 ml	12.5 ± 0.075	10.75 ± 0.075	5.0 ml	75.5 ± 0.5	0.9 to 1.1
4 ml	12.5 ± 0.075	10.75 ± 0.075	5.0 ml	75.5 ± 0.5	0.9 to 1.1
5 ml	12.5 ± 0.075	10.75 ± 0.075	5.0 ml	75.5 ± 0.5	0.9 to 1.1
6 ml	12.5 ± 0.075	10.75 ± 0.075	7.5 ml	100.5 ± 0.5	0.9 to 1.1
7 ml	12.5 ± 0.075	10.75 ± 0.075	7.5 ml	100.5 ± 0.5	0.9 to 1.1
10 ml	15.8 ± 0.075	13.7 ± 0.075	15.0 ml	100.5 ± 0.5	1.0 to 1.2

9.1.2 Safety Cap

- Safety cap is able to fit on rubber cap and it should be free from any kind of particles or flashes. It should not detach from rubber cap during handling.

9.1.3 Rubber Cap (Stopper)

- The fitting with the tube should be such that it provides easy two hand removal for use but should also prevent accidental detachment during handling, shipping and storage. Free from sharp edges, projection or surface roughness.

Approvals	Name	Designation	Signature	Date
Prepared By	Ashutosh Mishra	Asst. Manager - QA		09.12.2019
Checked By	RD Sharma	DGM - QA		09.12.2019
Approved By	SS Rawat	Head - QA		09.12.2019

9.2 **Filling of anticoagulant solution / powder /Siliconization into the Empty blood collection tube**: A brief description of siliconization / filling of anticoagulant solution / powder is given below:

9.2.1 **Preparation of Anticoagulant solution**: The anticoagulant solution is prepared by chemist. Freshly prepared distilled water is collected into the SS flask and required amount of chemical raw materials is dissolved in stainless steel flask. QC tests the sample for proper mixing of ingredients and if found ok the solution is sent for filling.

9.2.2 **Filling of solution / Powder / Siliconization:** The filling / siliconization is done by using automatic machine with double nozzle by evacuating the air from empty tube first and then filling required amount of volume. The rubber cap with tube is then fixed with the tube. The tube is then checked for any leakage under vacuum, particle and other defects. Trays are then packed in corrugated boxes and sent for sterilization to an external agency.

9.2.3 **Volumetric & Siliconization of Blood Collection Tube**: Siliconization of sodium citrate tubes is done as per WI/BCT/02 & volumetric chart for all the tubes is given in F/BCT/08 & F/BCT/09.

9.2.4 **Sterilization**: Products after final packaging are sent on closed boxes to go through Gamma radiation. Tubes sterilization is made by a third party company i.e. M/s. Jhunsons Chemicals Private Limited as per their validated cycle and the cycle is monitored for proper sterilization by using chemical and biological indicators. Sterilization is made by Gamma Cobalt-60 radiation; gamma rays passes through the products sterilizing them. Radiation dosage varies according to product. All tubes are exposed to *average* 8 kilo grays (kGy) of Gamma radiation.

10. ENVIRONMENT FOR ASSEMBLY OF PRODUCT

- The product is manufactured in controlled conditions. Air handling units are provided with high efficiency particulate air filter (HEPA) and controlled temperature and humidity.
- The manufacturing areas are continuously monitored for environmental bio burden by using settling plate method. The bio burden method, frequency and limit of colony forming unit (CFU) are defined in GTP/QC/4.14.

Approvals	Name	Designation	Signature	Date
Prepared By	Ashutosh Mishra	Asst. Manager - QA		09.12.2019
Checked By	RD Sharma	DGM - QA		09.12.2019
Approved By	SS Rawat	Head - QA		09.12.2019

- The bio burden on the equipment, fixture, dresses of workers etc. is also frequently monitored. The bio burden method, frequency and limit of colony forming unit (CFU) are defined in GTP/QC/4.14.

11. CLASSIFICATION

- According to IVD Directive 98/79/EC the reagents, Kits, instruments, dedicated software, specimen receptacles are classified in General low risk category devices. The blood collection tubes are used as specimen receptacle for In Vitro Diagnostic purposes. Hence the device Blood Collection Tubes are classified as **Low risk General Class I** IVD devices.

12. QUALITY PLAN

- A three tier Quality System is followed consisting of the Quality System Manual, the Standard Operating Procedures (SOPs), Work Instructions and Formats.
- These take care of all the functional responsibilities of the management and company employees, production and quality control at various stages. It also takes care of the Quality Assurance needs and compliance with various National and International standards and regulations. Quality planning is done as per QP/QPL/01.
- The Quality Plan covers all incoming, in process and finished products. The control and processes are defined in the SOPs and Work Instructions and the observations are recorded in Formats and Registers.

REVISION SUMMARY

Supersedes	Effective Date	Reason for Review/Revision
04	13.02.2016	To update reference documents & change made in Point No. 3.8.
05	11.08.2016	Reference documents updated.
06	*26.09.2016*	*Updated in Clause 3.8.1, 3.8.2, 3.8.4, 3.8.5, 4.0, 6.1 and remove 15 ml tube size in clause 9.1.1*

Approvals	Name	Designation	Signature	Date
Prepared By	Ashutosh Mishra	Asst. Manager - QA		09.12.2019
Checked By	RD Sharma	DGM - QA		09.12.2019
Approved By	SS Rawat	Head - QA		09.12.2019

1. **PURPOSE:**

This document describes the product design and technical requirements of the Blood Bags. As per Council Directive 93/42/EEC of 14th June 1993 as amended by council directive 2007/47/EC concerning medical devices blood bags are classified as class IIb device. The blood bag shall comply with essential requirements of Medical Devices Directive 93/42/EEC as amended by council directive 2007/47/EC and product Standard ISO 3826-1:2019 & EN ISO 3826-3:2007.

2. **INTENDED USE OF PRODUCT**

The product is used to collect and store whole human blood and blood components. Blood bag safety needle shield enhances safety against the accidental needle stick injuries that can transmit HIV, Hepatitis B & C and other dangerous blood borne diseases.

3. **PRODUCT DESCRIPTION & FEATURES:**

3.1 The bag is made of Polyvinyl Chloride / Tri-Octyl-Tri-Mellitate (PVC / TOTM), which makes it flexible for easy separation of blood components by using centrifugal force.

3.2 Initial blood collected from the donor tends to contain skin particles, bacteria present at the site of venipuncture & dust particles. The pre-attached sampling bag enables to divert & collect this initial blood from donor. The rest of the blood, free from the impurities is collected in the main bag.

3.3 Siliconised ultra thin walled 16G sharp needle assures smooth & atraumatic venipuncture for maximum comfort & minimal pain to donor.

3.4 Soft, frosted & flexible kink resistant tubing with uniform wall thickness & inner diameter & unique identification number at intervals of 10cm.

3.5 Tamper proof, safe & easy to open port covers to prevent contamination.

3.6 Manufactured from high quality medical grade PVC / TOTM sheet having good transparency complying with ISO standard for blood bags, leading to accurate & easy blood monitoring during collection, transfer & transfusion.

3.7 Rounded corner of bags to minimize loss of blood components & smooth transfer of blood components during separation & transfusion.

3.8 Double, Triple and Quadruple blood bag systems are provided with snap tip and connector tube to allow smooth transfer of blood components and additive solution.

3.9 Pre-attached Luer adapter is being provided with sampling bag to have safe in-line multiple sampling from donor. It is compatible with all types of vacuum blood collection tubes & prevents the risk of needle stick injuries.

3.10 Needle protective cover is made of two parts, outer part made of translucent blue color hard polypropylene to maintain the integrity of the needle during storage & transportation. Inner part made of translucent PVC that fits with the needle hub and provides effortless removal of the cover.

3.11 Tamper evident label that is durable during transportation, handling or high-speed centrifugation. It cannot be removed or tampered. Label surface allows easy marking / writing of relevant information.

3.12 Individually packed in special multi layer pouch and multiples packed in moisture barrier aluminum pouch.

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.02.2022
Checked By	RD Sharma	DGM – QA & RA		01.02.2022
Approved By	SS Rawat	Head - Quality		01.02.2022

3.13 Anticoagulant CPD solution Store whole blood up-to 21 days, CPDA solution store whole blood up-to 35 days and SAGM solution store RBC up-to 42 days.

3.14 Convenient hanger slits & holes allow easy suspension of the bags during collection & storage.

3.15 TOTM Plasticized Platelet Transfer bag with enough gas permeability is suitable for extended storage of viable platelets for approx. 5 days at 22°C.

3.16 Product classification as per EN ISO 10993-1:2009/AC:2010

3.16.1 **Device Connected with** – Port connected with Blood Transfusion Set

3.16.2 **Contact Duration** – Limited Exposure

3.16.3 **Categorization of Device** - External Communicating Device.

3.16.4 **Area of Contact** – Circulating Blood.

3.16.5 **Applicable Biocompatibility Tests** - Cytotoxicity, Skin Irritation, Skin Sensitization, Acute systemic Toxicity, Hemocompatibility.

3.17 **Product Features** –

3.17.1 **Single Blood Bag System** is used for collection of whole human blood having anticoagulant CPDA-1/ CPD solutions USP.

Bag Capacity (ml)	Type of Anticoagulant	Quantity	Packing Inner / Outer
100 ml	CPD / CPDA-1	14 ml	1 x 10 / 100
250 ml	CPD / CPDA-1	35 ml	1 x 10 / 100
300 ml	CPD / CPDA-1	42 ml	1 x 10 / 100
350 ml	CPD / CPDA-1	49 ml	1 x 10 / 100
450 ml	CPD / CPDA-1	63 ml	1 x 10 / 100
500 ml	CPD / CPDA-1	70 ml	1 x 10 / 100

3.16.2 **Double Blood Bag System** is used for separation of two components from whole human blood. The Double Blood Bag system includes one primary bag having anticoagulant CPDA-1/ CPD Solutions USP and one empty satellite bag.

Bag Capacity (ml)		Type of Anticoagulant	Quantity	Packing Inner / Outer
Primary	Satellite			
250 ml	300 ml	CPD / CPDA-1	35 ml	1 x 6 / 60
350 ml	300 ml	CPD / CPDA-1	49 ml	1 x 6 / 60
450 ml	300 ml	CPD / CPDA-1	63 ml	1 x 6 / 60
500 ml	300 ml	CPD / CPDA-1	70 ml	1 x 6 / 60

3.16.3 **Triple Blood Bag System** is used for separation of three components from whole human blood. The Triple Blood Bag system includes one primary bag having anticoagulant CPDA-1/ CPD solution USP and two empty satellite bags.

Bag Capacity (ml)		Type of Anticoagulant	Quantity	Packing Inner / Outer
Primary	Satellite			
300 ml	300 ml	CPD / CPDA-1	42 ml	1 x 4 / 40

Bag Capacity (ml)		Type of	Quantity	Packing
350 ml	300 ml	CPD / CPDA-1	49 ml	1 x 4 / 40
450 ml	300 ml	CPD / CPDA-1	63 ml	1 x 4 / 40
500 ml	300 ml	CPD / CPDA-1	70 ml	1 x 4 / 40

The Triple Blood Bag system also includes one primary bag having anticoagulant CPD Solution USP and SAGM solution in another bag and one empty satellite bags.

3.16.4 **Quadruple Blood Bag System** is used for separation of four components from whole human blood. The Quadruple Blood Bag system includes one primary bag having Anticoagulant CPDA-1/ CPD solution USP and three empty satellite bags.

Bag Capacity (ml)		Type of Anticoagulant	Quantity	Packing Inner / Outer
Primary	Satellite			
350 ml	300 ml	CPD / CPDA-1	49 ml	1 x 3 / 30
450 ml	300 ml	CPD / CPDA-1	63 ml	1 x 3 / 30
500 ml	300 ml	CPD / CPDA-1	70 ml	1 x 3 / 30

Quadruple Blood Bag system also includes one primary bag having anticoagulant CPD solution USP and SAGM solution in another bag and two empty satellite bags.

3.16.5 **Penta Blood Bag System** is used for separation of five components from whole human blood. The Quadruple Blood Bag system includes one primary bag having Anticoagulant CPDA-1/ CPD solution USP and four empty satellite bags.

Bag Capacity (ml)		Type of Anticoagulant	Quantity	Packing Inner / Outer
Primary	Satellite			
350 ml	300 ml	CPD / CPDA-1	49 ml	1 x 3 / 30
450 ml	300 ml	CPD / CPDA-1	63 ml	1 x 3 / 30
500 ml	300 ml	CPD / CPDA-1	70 ml	1 x 3 / 30

Penta Blood Bag system also includes one primary bag having anticoagulant CPD solution USP and SAGM solution in another bag and three empty satellite bags.

3.16.6 **Transfer Bag** is used for collection of blood components. It can also be attached with primary collection bag for blood processing; it has two entry ports and a single lead with a transfer spike.

Bag Capacity (ml)	Packing (Inner / Outer)
150 ml	1 x 10 / 100
250 ml	1 x 10 / 100
300 ml	1 x 10 / 100
400 ml	1 x 10 / 100
500 ml	1 x 10 / 100

3.16.7 **CPD - SAGM - TOTM bag system** is used for separation of blood components from whole human blood. The product includes one primary bag having Anticoagulant CPD solution 63 ml USP and SAGM solution 100ml in another bag and one or two empty 300 ml satellite bags. Additive solution containing Saline Adenine Glucose Mannitol (SAGM) provides extended shelf life of RBC up to 42 days with increased functional viability. Reduced density of RBC concentrate on addition of SAGM solution allows better flow property of Red Blood Cell & better transfusion. It allows larger volume of plasma to be collected and hence better yield of components like platelets, Fresh Frozen Plasma & Cryoprecipitate. It maintains the high level of ATP in RBC as red cell viability is increased because of SAGM solution & maintains 80% post transfusion RBC survival rate.

3.16.8 **Blood bag with safety devices & sampling bag** - Blood Bag with safety needle shield enhances safety against the accidental needle stick injuries. Initial blood collected from the donor tends to contain skin particles, bacteria present at the site of venipuncture & dust particles. The pre-attached sampling bag enables to divert & collect this initial blood from donor. The rest of the blood, free from the impurities is collected in the main bag. The product is available in Single, Double, Triple & Quadruple with 250ml, 350ml & 450ml capacity. The Triple Blood Bag system includes one primary bag having anticoagulant CPDA-1 solution USP and two empty satellite bags.

3.16.9 **Blood Bag with Leukocyte Filter** is used for separation of blood components from whole human blood. One primary bag having anticoagulant CPD solution USP and SAGM solution in another bag.

3.16.10 **Available pre-filled solutions -** The detail of anticoagulant solution and their purpose, storage period, constituents, quantity of constituents and the purpose of use of constituents are given below. The constituents of Saline-Adenine-Glucose-Mannitol (SAGM) solution, which is used for Red Blood cells preservation is also given.

Solution	Purpose	Whole blood or Red cell storage period	Additive Concentrations (per 100 ml)		Purpose of use of Additive
			Raw material	Quantity	
CPDA- 1	Anti-coagulant & storage of blood	35 days	Sodium Citrate (Dihydrate)	2.63 gm	Prevents coagulant of blood as Citrate ion chelates Calcium
			Citric Acid (Anhydrous)	0.299 gm	
			Dextrose (Anhydrous)	2.9 gm	Nutrition source for red blood cell
			Sodium Phosphate (Monohydrate)	0.222 gm	Adjusts pH
			Adenine (Anhydrous)	0.0275 gm	Supports to maintain ATP level in RBC
CPD	Anti-coagulant & storage of blood	21 days	Sodium Citrate (Dihydrate)	2.63 gm	Prevents coagulant of blood as Citrate ion chelates Calcium
			Citric Acid (Anhydrous)	0.299 gm	

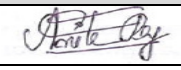
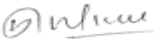
Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.02.2022
Checked By	RD Sharma	DGM – QA & RA		01.02.2022
Approved By	SS Rawat	Head - Quality		01.02.2022

Solution	Purpose	Whole blood or Red cell storage	Additive Concentrations (per 100 ml)		Purpose of use of Additive
			Dextrose (Anhydrous)	2.32 gm	Nutrition source for red cell
			Sodium Phosphate (Monohydrate)	0.222 gm	Adjusts pH
SAGM	Preservation of Red Blood Cells	42 days	Sodium Chloride	0.877 gm	Adjusts osmotic pressure
			Dextrose (Anhydrous)	0.818 gm	Nutrition source for red blood cell for continued metabolism
			Mannitol	0.525 gm	Supports integrity of red cell membrane (to avoid Haemolysis)
			Adenine (Anhydrous)	0.0169 gm	Supports to maintain high levels of ATP in Red Blood Cells
ACD	Preservation of blood specimens and used during Plasmapheresis	42 days	Sodium Citrate (Dihydrate)	2.20 gm	Prevents coagulant of blood as Citrate ion chelates Calcium
			Citric Acid (Anhydrous)	0.73 gm	
			Dextrose (Monohydrate)	2.45 gm	Nutrition source for red blood cell

4. REFERENCE DOCUMENTS

S. No.	Document Code	Document Description
Applicable Regulatory Standards		
4.1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for the Regulatory Purposes
4.2	MDD 93/42/EEC	European council directive for medical devices as amended by 2007/47/EC
4.3	EN ISO 14971:2012	Application of risk management to medical devices
4. 4	IEC 62366-1:2015 / Amd 1:2020	Medical devices — Part 1: Application of usability engineering to medical devices — Amendment 1
4. 5	ISO 3826-1:2019	Plastic collapsible containers for human blood and blood components
4.6	EN ISO 3826-2:2008	Plastic collapsible containers- Graphical symbols for use on labels and instruction leaflets
4.7	EN ISO 3826-3:2007	Blood bag systems with integrated features
4.8	EN ISO 17665-1:2006	Sterilization of medical devices – validation and routine control of moist heat sterilization
4.9	EN ISO 15223-1:2021	Symbols to be used with medical devices labels, labeling and information to be supplies
4.10	EN 15986:2011	Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates
4.11	EN 1041:2008	Terminology, Symbols and information provided with Medical Devices; Information supplied by the manufacture.
4.12	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices – requirements for

S. No.	Document Code	Document Description
		materials, sterile barrier & packaging systems.
4.13	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices – Validation requirements for forming, sealing and assembly process.
4.14	EN ISO 11737-1:2018/ A1:2021	Sterilization of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products.
4.15	EN ISO 11737-2:2020	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
4.16	EN ISO 10993 -1:2009 / AC:2010 / ISO 10993-1:2018	Biological evaluation of medical devices – Evaluation and testing within a risk management process.
4.17	EN ISO 10993-4:2009 / ISO 10993-4:2017	Biological evaluation of medical devices – Selection of tests for interaction with blood
4.18	EN ISO 10993-5:2009	Biological evaluation of medical devices – Tests for in vitro cytotoxicity
4.19	ISO 10993-10:2021	Biological evaluation of medical devices – Tests for Skin Sensitization
4.20	EN ISO 10993-11:2018	Biological evaluation of medical devices – Tests for systemic toxicity
4.21	EN ISO 10993-12:2021	Biological evaluation of medical devices – Sample preparation and reference materials
4.22	ISO 10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation
4.23	EN ISO 1135-4:2011 / ISO 1135-4:2015	Transfusion equipment for medical use - Part 4: Transfusion sets for single use, gravity feed
4.24	ISO 9626:2016	Stainless steel needle tubing for manufacture of medical devices
4.25	EN 868-5:2018	Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous and plastic film construction. Requirements and test methods.
4.26	ISO 2859-1:1999/Amd 1:2011	Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.
4.27	ISO 14644-1:2015	Cleanroom and associated controlled environments - Classification of air cleanliness
4.28	ASTM F 1980-2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
4.29	ISO 9001:2015	Quality management system – Requirements.
4.30	USP / IP	United Stated Pharmacopoeia / Indian Pharmacopoeia
Internal Standards / Documents		
4.31	QP/QPL/01	Quality Planning
4.32	QP/ECD/01	EC Vigilance
4.33	QP/BBP/01	Blood Bag System with Anticoagulant Solution
4.34	QP/BBP/08	Dispensing of Raw-Material for Manufacturing of Anticoagulant Solution
4.35	MF/BBP/01	Manufacturing of Blood Bag with Anticoagulant Citrate Phosphate Dextrose Adenine Solution
4.36	MF/BBP/06	Manufacturing of Blood Bag with Anticoagulant Citrate Phosphate Dextrose Solution
4.37	MF/BBP/07	Manufacturing of Blood Bag with Saline Adenine Glucose Mannitol Solution
4.38	MF/BBP/08	Manufacturing of Blood Bag with Anticoagulant Citrate Dextrose (ACD-A) Solution
4.39	FP/QA/53	Process Control for Blood Bag
4.40	SP/FP/QC/01	Physical Testing of Blood Bag
4.41	SP/FP/QC/02	Anticoagulant CPDA Solution USP

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.02.2022
Checked By	RD Sharma	DGM – QA & RA		01.02.2022
Approved By	SS Rawat	Head - Quality		01.02.2022

S. No.	Document Code	Document Description
4.42	SP/FP/QC/03	Anticoagulant CPD Solution USP
4.43	SP/FP/QC/04	Anticoagulant ACD (A) solution USP / IP
4.44	SP/FP/QC/05	Saline Adenine Glucose Mannitol (SAGM) Solution
4.45	SP/FP/QC/07	Anticoagulant (CPDA)Solution
4.46	SP/FP/QC/08	Anticoagulant CPD Solution I.P
4.47	PM/QA/07	C.P.P Pouch for unit packaging for blood bag
4.48	PM/QA/08	Aluminum pouch for Blood Bag
4.49	PM/QA/14	Printing Paper for Blood bag Tube
4.50	PM/QA/15	Pouch for Unit Packing of Product
4.51	RM/QA/41	Blood Bag filter
4.52	RM/QA/09	Plastic Raw Material
4.53	PML/MD/RA/16	Risk Analysis of Product
4.54	Drawing No Assy. 7001	Single blood bag
4.55	Drawing No Assy. 7002	Double blood bag
4.56	Drawing No Assy. 7003	Triple blood bag
4.57	Drawing No Assy. 7004	Quadruple blood bag
4.58	Drawing No Assy. 7005	Transfer bag
4.59	Drawing No Assy. 7006	Penta blood bag
4.60	Drawing No. Assy. 7007	Blood bag with special filter
4.61	Drawing No. Assy. 7100	Blood bag with Safety devices & Sampling bag
4.62	Drawing No. Assy. 7200	CPD - SAGM - TOTM Bag system
4.63	Drawing No. Assy. 7300	Top & Bottom Extraction Bag System

5. SHELF LIFE

5.1 The Finished products shall conform to the specifications and functional requirements for a maximum of three years from the date of manufacturing.

6. STERILIZATION

6.1 Product is sterilized with saturated steam as per standardized and validated sterilization cycle as per United State Pharmacopoeia, Indian Pharmacopoeia and EN ISO 17665-1:2006. The polyvinyl chloride bag contains the anticoagulant solution and is unit package. The PVC bag is than sterilized by using steam. The routine cycle is prescribed by both USP and IP. The parameters also complying EN ISO 17665-1:2006. The parameters are given in detail as below:

S. No.	PARAMETERS	LIMIT
1	Vacuum	-0.20 ±0.01 kg/cm^2
2	Number of vacuum pulses	2-3 Nos.
3	Sterilization hold temperature	118ºC - 121ºC
5	Sterilization HOLD time	30-32 Minutes
6	Air over pressure	1.35±0.01kg/cm2
7	Cooling temperature	50 ± 5 ºC
8	Cycle end chamber pressure	NMT 0.06 kg/cm^2

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.02.2022
Checked By	RD Sharma	DGM – QA & RA		01.02.2022
Approved By	SS Rawat	Head - Quality		01.02.2022

The detailed record of routine monitoring is maintained with Batch manufacturing record.

6.2 Product is sterilized only once and not re-sterilized.

6.3 Revalidation is done once in a year. The calibration of instruments like pressure gauge, temperature gauge, temperature indicator and controller, PT 100 etc. are done time to time as per their due date of calibration.

7. MATERIAL

7.1 All component materials should be such that components and product assemblies will pass material testing as specified in specifications.

S. No.	Parts Where material is used	Base Material	Grade	CAS No.
1	Blood Bag Sheet	Polyvinyl chloride sheet	N / A	9002-86-2
2	Blood Bag sheet	PVC TOTM	N / A	9002-86-2
3	Port cap	PVC compounds	IP-85	9002-86-2
4	Tubing	PVC compounds	IP 9-T/ BT-9F1	9002-86-2
5	Vacutainer Needle hub	Polycarbonate	201-15	25037-45-0
6	Vacutainer cap	Polypropylene	SM 498	9003-07-0
7	Vacutainer body	Polypropylene	SM 498	9003-07-0
8	Outer Cover	Polypropylene	SM 498	9003-07-0
9	Inner cover	PVC compounds	IP - 87	9002-86-2
10	U - connector	PVC compounds	IP 9 Super	9002-86-2
11	Long Tube	PVC compounds	IP 80mmb	9002-86-2
12	Click Valve	Polycarbonate	201-15/R144	25037-45-0
13	Extruded Small Tube	PVC compounds	IP 9-T	9002-86-2
14	Needle	Stainless steel	SS - 304	65997-19-5
15	Non-vented Spike	Acrylonitrile Butadiene Styrene	IFB 920 (Natural)	9003-56-9
16	Spike Cover	Polypropylene	SM-498	9003-07-0
17	Square hub	Polycarbonate	2858 / 201-15	25037-45-0
18	Click Clamp	Poly Acetal	1700P	66544-31-0
19	Safety cover	Polypropylene	H-110/6331	9003-07-0
20	Leukocyte Filters	Polyester+ Polycarbonate	Imported	27205-03-4
21	Chemical Raw Material for Anticoagulant & preservative solution.	Dextrose	USP / IP	50-99-7
		Sodium Phosphate	USP / IP	13472-35-0
		Citric Acid	USP / IP	77-92-9
		Sodium Citrate	USP / IP	6132-04-3
		Adenine	USP / IP	73-24-5
		Sodium Chloride	USP / IP	7440-23-5
		Mannitol	USP / IP	69-65-8
		Water for Injection	USP / IP	7732-18-5
22	Label	Adhesive Paper / plastic	N / A	-
23	Unit container	CPP	N / A	-
24	Multi-unit container	Aluminum pouch	N / A	-
25	Transit container	Corrugated box	N / A	-

8. COMPONENT AND PROCEDURE FOR ASSEMBLY & MANUFACTURING

A. Single Blood Bag System

(i)	PVC Bag	:	RF Sealing
(ii)	Needle hub	:	Injection Molding
(iii)	Inner part Needle cover	:	Injection Molding
(iv)	Outer part of Needle cover	:	Injection Molding
(v)	Port	:	Injection Molding
(vi)	Port cap	:	Injection Molding
(vii)	PVC tubing	:	Extrusion
(viii)	Needle		

B. Double Blood Bag System

(i)	PVC Bag	:	RF Sealing
(ii)	Needle hub	:	Injection Molding
(iii)	Inner part of Needle cover	:	Injection Molding
(iv)	Outer part of Needle cover	:	Injection Molding
(v)	Port	:	Injection Molding
(vi)	Port cap	:	Injection Molding
(vii)	Non-return valve	:	Injection Molding
(viii)	Connector (long)	:	Injection Molding
(ix)	Connector(small)	:	Injection Molding
(x)	PVC tubing	:	Extrusion
(xi)	Needle		

C. Triple Blood Bag System

(i)	PVC Bag	:	RF Sealing
(ii)	Needle hub	:	Injection Molding
(iii)	Inner part of Needle cover	:	Injection Molding
(iv)	Outer part of Needle cover	:	Injection Molding
(v)	Port	:	Injection Molding
(vi)	Port cap	:	Injection Molding
(vii)	Non-return valve	:	Injection Molding
(viii)	Connector (long)	:	Injection Molding
(ix)	Connector(small)	:	Injection Molding
(x)	U – connector	:	Injection Molding
(xi)	PVC tubing	:	Extrusion
(xii)	Needle		

D. Quadruple Blood Bag System

(i)	PVC Bag	:	RF Sealing
(ii)	Needle hub	:	Injection Molding
(iii)	Outer part of Needle cover	:	Injection Molding
(iv)	Inner part of Needle cover	:	Injection Molding
(v)	Port	:	Injection Molding
(vi)	Port cap	:	Injection Molding

(vii)	Non-return valve	:	Injection Molding
(viii)	Connector (long)	:	Injection Molding
(ix)	Connector(small)	:	Injection Molding
(x)	U - connector	:	Injection Molding
(xi)	PVC tubing	:	Extrusion
(xii)	Needle		

E. **Penta Blood Bag System**

(xiii)	PVC Bag	:	RF Sealing
(xiv)	Needle hub	:	Injection Molding
(xv)	Outer part of Needle cover	:	Injection Molding
(xvi)	Inner part of Needle cover	:	Injection Molding
(xvii)	Port	:	Injection Molding
(xviii)	Port cap	:	Injection Molding
(xix)	Non-return valve	:	Injection Molding
(xx)	Connector (long)	:	Injection Molding
(xxi)	Connector(small)	:	Injection Molding
(xxii)	U - connector	:	Injection Molding
(xxiii)	PVC tubing	:	Extrusion
(xxiv)	Needle		

F. **Transfer Bag**

(i)	PVC bag	:	RF Sealing
(ii)	Spike	:	Injection Molding
(iii)	Spike cover	:	Injection Molding
(iv)	Port	:	Injection Molding
(v)	Port cap	:	Injection Molding
(vi)	PVC tubing	:	Extrusion

G. **Blood Bag with special Filter**

(i)	PVC Bag	:	RF Sealing
(ii)	Needle hub	:	Injection Molding
(iii)	Outer part of Needle cover	:	Injection Molding
(iv)	Inner part of Needle cover	:	Injection Molding
(v)	Port cap	:	Injection Molding
(vi)	Non-return valve	:	Injection Molding
(vii)	Port	:	Injection Molding
(viii)	Connector (long)	:	Injection Molding
(ix)	Connector(small)	:	Injection Molding
(x)	U - connector	:	Injection Molding
(xi)	Y - injection site	:	Injection Molding
(xii)	Pinch clamp	:	Injection Molding
(xiii)	Roller clamp	:	Injection Molding
(xiv)	PVC tubing	:	Extrusion
(xv)	Needle		
(xvi)	Filter		

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Prepared By	Anila Raj K N	Asstt. Manager - QA		01.02.2022
Checked By	RD Sharma	DGM – QA & RA		01.02.2022
Approved By	SS Rawat	Head - Quality		01.02.2022

H. **Blood Bag with Safety Device & Sampling bag**

(i)	PVC Bag	:	RF Sealing
(ii)	Sampling Bag	:	RF Sealing
(iii)	Outer part of Needle cover	:	Injection Molding
(iv)	Inner part of Needle cover	:	Injection Molding.
(v)	Port cap	:	Injection Molding
(xvii)	Non-return valve	:	Injection Molding
(xviii)	Needle hub	:	Injection Molding
(xix)	Port	:	Injection Molding
(xx)	Connector (long)	:	Injection Molding
(xxi)	Connector(small)	:	Injection Molding
(xxii)	U - connector	:	Injection Molding
(xxiii)	Y - injection site	:	Injection Molding
(xxiv)	Pinch clamp	:	Injection Molding
(xxv)	Safety cover	:	Injection Molding
(xxvi)	PVC tubing	:	Extrusion
(xxvii)	Needle		
(xxviii)	Luer Adaptor		

8.1 **Filling of anticoagulant solution into the Empty blood bag:** A brief description of filling of anticoagulant solution is given below:

8.1.1 **Preparation of Anticoagulant solution**: The anticoagulant solution is prepared by manufacturing chemist approved by government. Freshly prepared distilled water is collected into the SS tank and required amount of chemical raw materials is dissolved in stainless steel mixing tank. QC tests the sample for proper mixing of ingredients and if found ok the solution is filtered by 2µ and than 0.2µ cartridge filter.

8.1.2 **Filling of solution**: The filling is done in class 100 under laminar air flow by using semi automatic filling machine with double nozzle by evacuating the air from empty blood bag first and then filling required amount of volume. The needle hub with needle is then glued with the tubing. The bag is then checked for leakage under pressure, particle and other defects. Approved bags are then labeled and packed in polybag. The air inside the polybag is then removed using vacuum. These bags are than kept in trays for sterilization.

8.1.3 **Sterilization**: The product is than sterilized with moist heat as per the validated cycle and the cycle is monitored for proper sterilization by using chemical and biological indicators in combination with physical parameters.

8.1.4 **Drying**: After sterilization bags are loaded into the dryers and dried at 70˚C (+5 /-2 ˚C) for *7* to 11 hours.

8.1.5 **Final Packing**: The product is dried in oven to remove the moisture. The bags are then packed in aluminum pouches and finally packed in corrugated boxes. The detail of packing is given below:

(i) **Unit Container**: The blood bag after filling of anticoagulant solution is packed in CPP (Cast Polypropylene) pouches. The air inside pouch is removed using vacuum. These pouches are suitable to sustain steam

sterilization and act as barrier to restrict the evaporation of water from the bag. CPP pouches are used in different dimensions as per the requirement of bag size.

(ii) **Multi Unit Container**: The CPP pouches after proper drying (no moisture inside) are then packed in aluminum pouches, which are made of aluminum foil and PP. The aluminum pouches are then subjected to nitrogen flushing and vacuum. The aluminum pouch acts as an effective barrier to further restrict the evaporation of water from the bag. Aluminum pouches are used in different dimensions as per the requirement of bag size.

(iii) **Transit Container**: Aluminum pouches are finally packed in corrugated boxes (Transit Container), which are made of 5 plies corrugation. The sizes used are according to the requirement of blood bag.

(iv) Aluminum and carton label shall be labeled for Batch No., MFG. date, EXP. date, reference code, MRP etc. and shall verified with approved artwork and unit label.

S. No.	Description	Blood bag without safety feature Quantity to be packed in Aluminum pouch	Blood bag with safety feature Quantity to be packed in Aluminum pouch
1	Single Blood Bag	10 CPP pouch packed Blood Bags	5 CPP pouch packed Blood Bags
2	Double Blood Bag	6 CPP pouch packed Blood Bags	5 CPP pouch packed Blood Bags
3	Triple Blood Bag	4 CPP pouch packed Blood Bags	4 CPP pouch packed Blood Bags
4	Quadruple Blood Bag	3 CPP pouch packed Blood Bags	3 CPP pouch packed Blood Bags
5	Transfer Bag	10 CPP pouch packed Blood Bags	NA

9 FUNCTIONAL SPECIFICATIONS

9.1 PVC / TOTM sheet for Blood Bag:

- Translucent PVC Sheet shall be free from foreign & inbuild particles.
- The bag is provided for easy blood monitoring during Collection, Transfer and Transfusion.
- The PVC sheet and bag shall comply all physical, chemical and biological test mention in ISO 3826-1.
- Bag is having rounded corner, which minimizes loss of blood components during Transfer and Transfusion.
- Convenient hanger slits and holes are provided for use during Blood Collection and Blood Transfusion, it also allows easy suspension of bag in vertical position.
- Inner surface is treated so carefully so as to significantly reduce platelet destruction and to prevent blood from clotting.
- Dimensions:

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Checked By	RD Sharma	DGM – QA & RA		01.02.2022
Approved By	SS Rawat	Head - Quality		01.02.2022

Capacity of Blood Bag	At sheet cutting stage	
	Length (+2 / - 1 mm)	Width (±5 mm)
150 ml	185 mm	295 mm
200 ml	166 mm	295 mm
250 ml	185 mm	295 mm
300 ml	185 mm	295 mm
350 ml	202 mm	295 mm
450 ml	230 mm	295 mm
450 ml Top & Bottom	218 mm	300 mm
500 ml	230 mm	295 mm

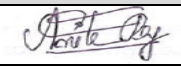
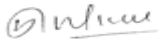
9.2 **Tubing**

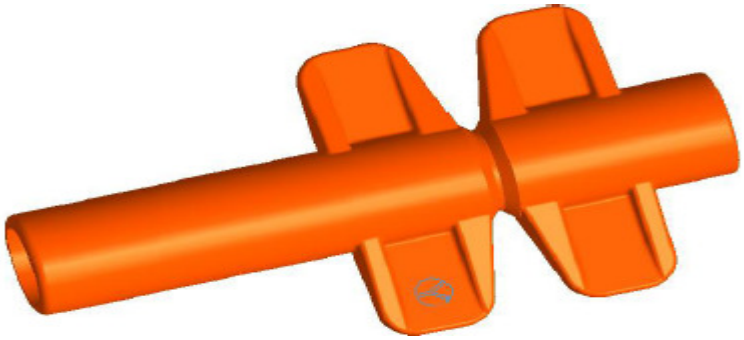
- The tubing shall be transparent or translucent, kink resistant and free from foreign particles.
- The dimension of tubing shall comply relevant specifications.
  Outer Diameter: 4.30 ± 0.05 mm
  Inner Diameter: 2.95 ± 0.05 mm
- The tube is printed with a number at different interval in each bag. The tube identification number in each tube shall be the same. The number shall be unique for each tube i.e. the number shall not match with any other tube.
- Codes & Tube length may also vary as per the specific requirement.
- Length of tubing's are as given below in table –

Type of tube	Length to be cut (mm)		No. of codes on Each Tube	
	Standard B. Bag	Dry donor line	Standard B. Bag	Dry donor line
Single	1200 (±20 mm)	900 (±20 mm)	NLT 14	NLT 11
Double	1800 (±20 mm)	1500 (±20 mm)	NLT 20	NLT 17
Triple	2200 (±20 mm)	1900 (±20 mm)	NLT 31	NLT 27
Triple (Top & bottom)	2350 (±20 mm)	2650 (±20 mm)	NLT 25	NLT 29
Quadruple	2800 (±20 mm)	2500 (±20 mm)	NLT 30	NLT 27
Quadruple (Top & bottom)	3250 (±20 mm)	3350 (±20 mm)	NLT 35	NLT 37

9.3 **Outlet port with cap (Flap port)**

- Outlet Port with cap shall be transparent, tamper evident, easy to open, free from foreign particle and flashes, dent marks & oily stains.

Approvals	Name	Designation	Signature	Date
Prepared By	Anila Raj K N	Asstt. Manager - QA		01.02.2022
Checked By	RD Sharma	DGM – QA & RA		01.02.2022
Approved By	SS Rawat	Head - Quality		01.02.2022



- The outlet port is divided into two sections from inside by a thin PVC membrane, which acts as a barrier between solution and outer environment to avoid contamination. This membrane shall be intact and without damage even in the form of pinholes.
- Port is provided to transfuse the collected blood hence the membrane shall easily puncture when pierced with the spike of blood transfusion set.
- It is provided with puncturable, non-resealable closure (film). When pierce with closure piercing device in accordance with ISO 1135-4, it provides leak proof connection.
- After filling, check that the connection between port tube & blood bag shall not leak when tested by squeezing between two plates at 6.0 kg ± 0.5kg air pressure.
- Flap port shall comply following test as given below:

S. No.	Parameters	Specification
1	Visual tests	• All the Sealing should be Proper; Unsealed Component should not be acceptable. • Damage should not be acceptable in the component • Fluid Path should be clear; PVC should not deposit in the fluid path after sealing • Flap should not be sealed into sealing area • Flap should not be more shifted towards side sealing & it should not be sealed with side sealing
2	Peel Open force (N)	Tensile Force NLT 10N
3	Flap holding length (L)	Not less than (NLT) 6.5 mm
4	Peel Open Condition	Flap should be Peeled Off properly, flap tearing without Peel open not acceptable.
5	Side Sealing thickness	0.45 mm ± 0.10 mm
6	Thickness of Flap Sheet	0.40 mm± 0.02 mm
7	Thickness of Upper sheet	0.34 mm ± 0.02 mm
8	Thickness of Lower sheet	0.40 mm ± 0.02 mm

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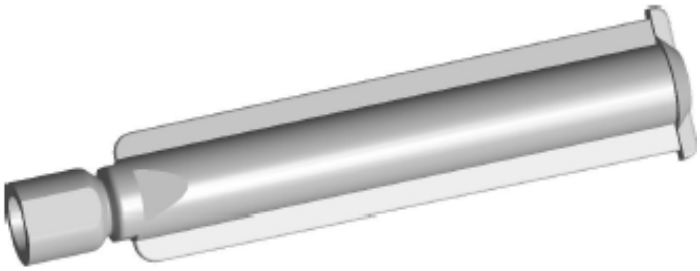
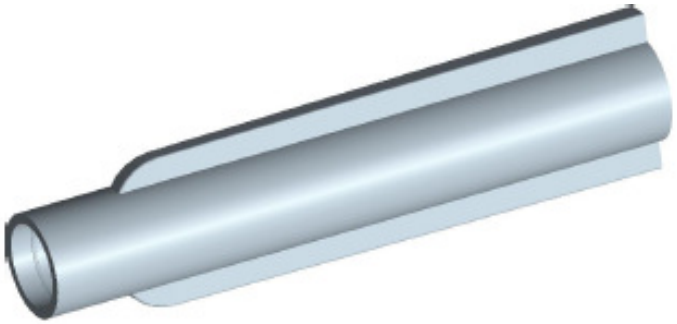
9.4 **Needle cover**

- Needle covers are transparent to translucent and free from any damage or foreign particle, flashes burr etc.
- Needle cover shall be easy to glue with needle hub by using cyclohexanone as gluing agent.
- The connection between needle cover and needle hub shall be leak proof so that the sterility of product could not be affected.
- Needle cover shall be easy to break when twisted in anti-clockwise or clockwise direction.
- Needle cover should be such to prevent re-use of bag.



⇦ Inner Cover



⇦ Outer Cover

9.5 **Needle hub**

- The hub is Clear & transparent & free from any damage, flashes or foreign particle.
- The bonding of needle with needle hub by using anabond shall be easy and smooth. The needle shall not detach from the hub when a tensile force of 20N is applied.
- The connection of needle hub with the tubing shall be leak proof and shall sustain a tensile force not less than 20N.
- Arrow mark given on hub for direction of needle bevel.

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Prepared By	Anila Raj K N	Asstt. Manager - QA		01.02.2022
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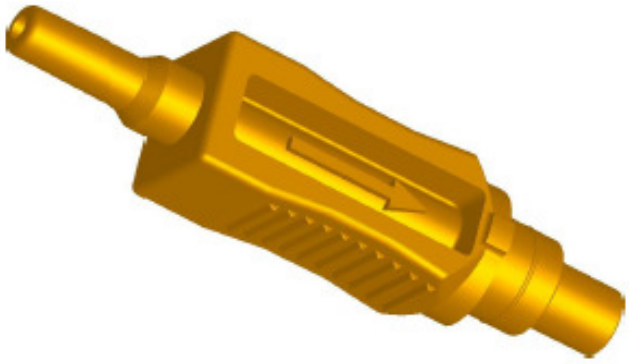
Approved By	SS Rawat	Head - Quality		01.02.2022



9.6 **Needle**

- Needle shall be with smooth surface without any damage and foreign particle. The bevel shall be without any damage, burr or particle when checked on magnified vision.
- Needle is made of stainless-steel grade 304.
- The needle shall not be blocked from inside.
- The 16G sharp pointed needle must be suitable for smooth and comfortable vein puncture to minimize patient discomfort.
- Effective Length: 36 ± 1 mm. Record shall be maintained in F/QA/11.
- OD: 1.65 ± 0.05 mm

9.7 **Long tube**

- Connects the primary bag with transfer bag and connects sampling bag with the primary bag (in case of safety feature). Consist valve inside which is easily breakable and once broken, allows the consistent flow of liquid.
- Fitment with tubing shall withstand a 20N force for 15 seconds.
- Long tube is assembled with Non-Return Valve by using a mixture of 70% Cyclohexanone and 30% Ethyl Methyl Ketone (EMK).

9.8 **Non-Return Valve (Break off valve)**

- Valve is fitted inside long tube and is tight enough to stop the flow of blood or blood components towards transfer bags unless it is broken.

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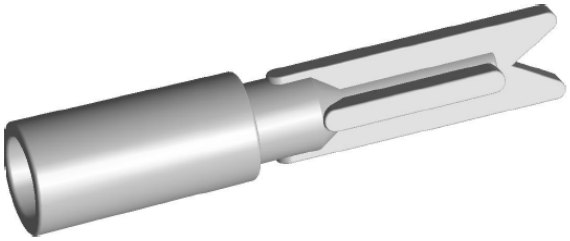


– Easily breakable and once broken shall allow the flow of blood components into transfer bag.

9.9 **U - Connector**

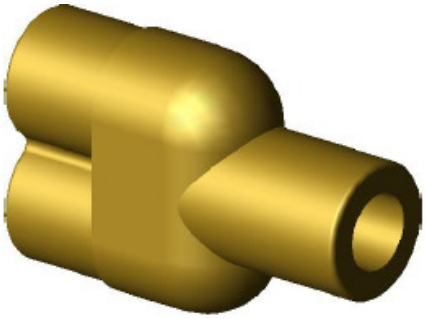
– Used in triple and quadruple bag to connect satellite bags.

– When connected with tubing provides a leak proof joint to facilitate easy transfer of blood or blood components to transfer bags.

– Shall be free from any visual defects, like foreign particles, damage & short pieces.

– Fitment of U-connector with tubing shall withstand a 20N force for 15 seconds.

– U-connector is glued with PVC Tube by 100% cyclohexanone.



9.10 **Closure-Piercing Device (Spike)**

– The closure-piercing device must conform the dimensional specifications as per ISO 1135

– The closure-piercing point must be sharp enough to pierce the closure easily.

– The windows of closure piercing device shall be clear and without any obstruction and flashes.

9.11 **Spike Cover**

– Shape is conical or cylindrical.

– Enough length to accommodate closure-piercing device.

– Material can be translucent or transparent.

– Interference fitting of the bottom of the cover with closure-piercing device.

– The fitting must be easy for hand removal but should not detach accidentally during handling, shipping & storage.

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Approved By	SS Rawat	Head - Quality		01.02.2022

9.12 **Y- Injection Site**

- Y-Connector shall be proper fitted in between of Blood sampling device and tubing.
- The whole assembly shall not show any leakage when tested with 0.5 bar air pressure.

9.13 **Roller Clamp**

- The roller clamp must be able to control the flow of the infusion fluid from zero to the maximum.
- Roller clamp must not damage the tubing during continuous use.
- Both roller clamp & tubing must not react during storage.

9.14 **Pinch Clamp**

- Clamp is provided to allow or restrict the flow of fluid from source of fluid to the graduated container / bag. The clamp is closed condition shall not allow the liquid to pass into the graduated container / bag.

9.15 **Leukocyte Filters:**

- Joint between filter & Tube shall withstand a 20N force for 15 seconds.

9.16 **Pre-donation Sampling Device –**

9.16.1 **Sampling bag**

9.16.1.1 The bag should not be leaked when tested at 0.2bar air pressure.
9.16.1.2 Its capacity shall be at least 35 ml.
9.16.1.3 The bag is provided for easy blood monitoring during Collection.

9.16.2 **Vacutainer Body**

9.16.2.1 Should be Translucent.
9.16.2.2 Component shall be free from air bubble, flash, black particle, oil, short filling or any other molding defect.

9.16.3 **Vacutainer Cap**

9.16.3.1 Should be Translucent.
9.16.3.2 Component shall be free from air bubble, flash, black particle, oil, short filling or any other molding defect.

9.16.4 **Vacutainer Needle hub**

9.16.4.1 Should be Translucent.
9.16.4.2 Needle should have slide fit in the gripping area provided for needle in needle hub.
9.16.4.3 Component shall be free from air bubble, flash, black particle, oil, short filling or any other molding defect.

9.16.5 **Vacutainer Needle**

Outer Diameter - 0.82 mm ± 0.01 mm
Effective length - 19±1 mm, shall be record in F/QA/11.

9.17 **Luer Adapter**

- A pre-attached Luer adapter is provided with sampling bag to have safe inline multiple sampling from donor.
- It is compatible with all types of vacuum collection tubes & prevents the risk of needle stick injuries.

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Approved By	SS Rawat	Head - Quality		01.02.2022

10 ASSEMBLY & MANUFACTURING OF EMPTY BLOOD BAG

- The product is assembled in clean room-controlled conditions. The clean room is class 7 (in static condition) meeting requirements set by ISO 14644-1:2015 for Clean Room. Filling of solution is done under laminar air flow surrounded by class-6 (in static condition). Clean rooms are provided with high efficiency particulate air filter (HEPA) and controlled temperature and humidity. The area is maintained as per WI/BBP/04.

- The clean rooms are continuously monitored for environmental bio burden by using settling plate method. The bio burden method, frequency and limit of colony forming unit (CFU) are defined in GTP/QC/14.

- The bio burden on the equipment, fixture, dresses of workers etc is also frequently monitored. The bio burden method, frequency and limit of colony forming unit (CFU) are defined in GTP/QC/14.

11. CLASSIFICATION

- As per the rule 18 of "Classification criteria" Annexure- IX of the Council Directive 93/42/EEC as amended by council directive 2007/47/EC the Blood Bag is classified as class IIb product.

12. QUALITY PLAN

- A three tier Quality system is followed consisting of the Quality System Manual, the Standard Operating Procedures (SOP) and Work Instructions and Formats.

- These take care of all the functional responsibilities of the management and company employees, production and quality control at various stages. It also takes care of the Quality Assurance needs and compliance with the various national and international standards and regulations. Quality planning is done as per QP/QPL/01.

- The Quality Plan covers all incoming, in-process and finished products. The control and process are defined in the Sops and Work Instructions and the observations are recorded in Formats and Registers.

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Checked By	RD Sharma	DGM – QA & RA		01.02.2022
Approved By	SS Rawat	Head - Quality		01.02.2022

REVISION SUMMARY

Supersedes	Effective Date	Reason for Review/Revision
Nil	-	New Issue
00	16.07.2019	• Changes made in Reference Documents, Section-4.0. • Changes made in Sterilization process parameters table, Section-6.0.
01	02.12.2019	• Section 4.0, reference documents updated.

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Prepared By	Anila Raj K N	Asstt. Manager - QA		01.02.2022
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