File No.GEM/TP/Blood Bags/2019 (Version 3.0)										DRAFT T/P	
LEVEL 1 CATEGORY: Laboratory and Measuring and Observing and Testing Equipment - UNSPS Code 41000000											
LEVEL 2 CATEGORY: Laboratory and Scientific Equipment - UNSPS Code 41100000											
LEVEL 3 CATEGORY : Specimen Collection and Transport Containers and Supplies - UNSPS Code 41104100											
Level 4 Category : Blood Bags - UNSPS Code 41104109										GEM Version 3.0	
S.NO	**PARAMETER**	**HINT**	**TYPE OF FIELD**	**VALUES**					**UNIT**	**CATEGORY OF FIELD**	**REMARKS**
GENERAL FEATURES											
1	Product Description	--	ENUMERABLE	Blood Bags					--	MANDATORY	
2	Clinical Purpose	--	ENUMERABLE	Collection, processing and storage of whole blood and blood components					--	MANDATORY	
3	Disposable	--	ENUMERABLE	Yes					--	MANDATORY	
PRODUCT INFORMATION											
1	Conformity to standard for Blood Bag	--	ENUMERABLE	ISO 3826/IS 15102: Latest Revision					--	MANDATORY	
2	Type of blood bag	--	ENUMERABLE	Single	Double	Triple	Quadruple (top and top)	Quadruple (top and bottom)	--	GOLDEN	
3	Capacity of blood Bag	--	ENUMERABLE	100 ml	350 ml	450 ml			--	GOLDEN	
4	Material of Bag (Medical grade)	--	ENUMERABLE	DEHP Plasticized PVC					--	MANDATORY	
5	Blood Collection Bags should be collapsible non vented sterile containers complete with collecting tube for completely closed system to avoid the chances of contamination	--	ENUMERABLE	Yes					--	MANDATORY	
6	Flexible pre-sterilized and pyrogen free	--	ENUMERABLE	Yes					--	MANDATORY	
7	Non toxic, non haemolytic, biocompatible material	--	ENUMERABLE	Yes					--	MANDATORY	
8	There should be no risk of contamination and air embolism (closed system) with all leak proof seals (Disposable bags)	--	ENUMERABLE	Yes					--	MANDATORY	
9	Slit on both sides of the bags should be enough to accommodate 5 -10 ml volume test tubes	--	ENUMERABLE	Yes					--	MANDATORY	
10	The capacity of the bag should be enough to prevent any bollooning/ripture of the abg from the seam when it is filled up with the requisite volume of blood	--	ENUMERABLE	Yes					--	MANDATORY	
TUBING OF BAG											
1	Flexible kink resistant tubing	--	ENUMERABLE	Yes					--	MANDATORY	
2	Non sticking	--	ENUMERABLE	Yes					--	MANDATORY	
3	Transparent	--	ENUMERABLE	Yes					--	MANDATORY	
4	Leak Proof	--	ENUMERABLE	Yes					--	MANDATORY	

5	Length of tubing from primary bag to needle	--	MEASURABLE	≥ 80 Cm					--	MANDATORY	
6	The tubing should have same ID/segment number as that on the bag	--	ENUMERABLE	Yes					--	MANDATORY	
7	The tubes should have multiple printed ID/segment numbers	--	ENUMERABLE	Yes					--	MANDATORY	
8	Clamp provided for closed system	--	ENUMERABLE	Yes					--	MANDATORY	
	NEEDLE										
1	Needle Size	--	ENUMERABLE	16 G					--	MANDATORY	
2	Ultra thin walled and straight to reduce penetration force and enable painless vein puncture	--	ENUMERABLE	Yes					--	MANDATORY	
3	Sharp, regular and smooth margins and bevelled tip	--	ENUMERABLE	Yes					--	MANDATORY	
4	Rust proof	--	ENUMERABLE	Yes					--	MANDATORY	
5	Tightly fixed with hub covered with sterile guard	--	ENUMERABLE	Yes					--	MANDATORY	
6	Hermetically sealed	--	ENUMERABLE	Yes					--	MANDATORY	
7	The needle should not separate from the tube at any point of time, especially while removing it from the vein for donor safety	--	ENUMERABLE	Yes					--	MANDATORY	
8	The needle must confirm to ISO 1135-3 standard	--	ENUMERABLE	Yes					--	MANDATORY	
	EXTERNAL PORT										
1	Tamper proof and should not be re-capped	--	ENUMERABLE	Yes					--	MANDATORY	
2	Easily accessible	--	ENUMERABLE	Yes					--	MANDATORY	
	ANTICAOGULANT AND PRESERVATIVE SOLUTION										
1	Type of anticoagulant	--	ENUMERABLE	CPDA-1		CPD			--	GOLDEN	
2	Quantity of anticoagulant solution	--	ENUMERABLE	14 ml per 100 ml of blood					--	MANDATORY	
3	solution should be clear and colorless	--	ENUMERABLE	Yes					--	MANDATORY	
4	There should be no discoloration of solution on storage at room temperature	--	ENUMERABLE	Yes					--	MANDATORY	
5	Additive soultion present	--	ENUMERABLE	Yes	No				--	GOLDEN	
6	Type of additive solution	--	ENUMERABLE	SAGM	NA for Single and double blood bags				--	MANDATORY, FILTER	
7	Quantity of Additive solutiom	--	MEASURABLE	80	100	NA for Single and double blood bags			ml	MANDATORY, FILTER	
8	Anticoagulant and/or additive solution should be sterile and pyrogen free	--	ENUMERABLE	Yes					--	MANDATORY	
9	Availability of anticoagulant/additive quality check certificate from manufacture (proof of same to be submitted to buyer)	--	ENUMERABLE	Yes					--	MANDATORY	
	LABEL										
1	Non-peel off	--	ENUMERABLE	Yes					--	MANDATORY	
2	Heat sealed/ Pressure embossed label	--	ENUMERABLE	Yes					--	MANDATORY	

3	The label should remain attached between room temperature to - 80°C with a tranparent adhesive	--	ENUMERABLE	Yes					--	MANDATORY	
4	Date of manufacturing, date of expiry and batch number must be mentioned on each bag	--	ENUMERABLE	Yes					--	MANDATORY	
RESISTANCE TO DISTORTION											
1	Bag (Fiiled to normal capacity) shall withstand a acceleration of 5000 g for 30 min at temperature 4°C to 24°C without becoming permanently distorted	--	ENUMERABLE	Yes					--	MANDATORY	
2	Bag (Fiiled to normal capacity) should be able to withstand temperature upto - 80°C without breakage	--	ENUMERABLE	Yes					--	MANDATORY	
PACKAGING											
1	Individual bag packed in plastic pack and multiple bags packed in moisture proof aluminum foil (Protective dual packaging) eliminating microbial contamination on surface maintaining the contents of the bag	--	ENUMERABLE	Yes					--	MANDATORY	
2	The supplier should ensure proper transportation of the consignment of blood bags in temperature controlled conditions (Storage temperature should not exceed 30°C)	--	ENUMERABLE	Yes					--	MANDATORY	
CERTIFICATIONS & REPORTS											
1	Availability of valid drug license issued from competent authority defined under Drugs and Cosmetics Act, 1940 (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	For Manufacture		For Sale			--	MANDATORY, FILTER	Multi Select
2	Drug License Number	Must Declare	TEXT						--	MANDATORY	AKBNV
3	Drug License Date	Must Declare	TEXT						--	MANDATORY	AKBNV
4	Manufacturer certifications (Proof of the same to be submitted to the buyer on demand)	--	ENUMERABLE	ISO 13485	GMP	WHO GMP			--	GOLDEN	Multi Select
5	Certification Number	Must Declare	TEXT						--	MANDATORY	AKBNV
6	Certification Date	Must Declare	TEXT						--	MANDATORY	AKBNV
7	Product Certifications (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	ISO	BIS	EU-CE	US-FDA		--	GOLDEN	Multi Select
8	Product Certification Number	Must Declare	TEXT						--	MANDATORY	AKBNV
9	Product Certification Date	Must Declare	TEXT						--	MANDATORY	AKBNV
10	Certificate issuing Authority	Must Declare	TEXT						--	MANDATORY	AKBNV
11	Each batch supplied should be accompanied with quality assurance test report from NABL approved lab/any lab approved fron govt of India as well as in house lab	--	ENUMERABLE	Yes					--	MANDATORY	
12	Biocompatibility of the material of the plastic blood bags must be certified by the manufacturer and must be supported by the test reports of cell culture cytotoxicity, hemolysis, systemic infections (acute toxicity), sensitization, Inra-cutaneous injection (irritation), pyrogen test and Sterility (test report for the same to be submitted for each batch)	--	ENUMERABLE	Yes					--	MANDATORY	

13	Submission of manufacturer's documented evidence of biochemical parameters (plasma pH, ATP % of initial volume, 2-3 DPG % of initial volume, plasma K+, % of viable red cells, DEHP leaching mg/100 ml, DEHP should not be more than 0.01% w/v in the PVC) 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	--	ENUMERABLE	Yes					--	MANDATORY	
SHELF LIFE											
1	Shelf Life from the date of manufacture (in months)	--	NUMERIC	24	30	36			Months	GOLDEN	
2	Stability report from a recogniozed laboratory must be submitted to the buyer at the time of supply	--	ENUMERABLE	Yes					--	MANDATORY	
3	The product should have atleast 3/4 of the total shelf life at the time of dispatch to the consignee	--	ENUMERABLE	Yes					--	MANDATORY	

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