

FR-QCD-64/B

CERTIFICATE OF ANALYSIS

1	Name of product		Blood Bag CPDA-1; 150 ml , Single Bag;	
2	Description of product		SINGLE Blood bag with donor tube and donor needle of 16G; with Needle Injury Protector, 1 bag in an Aluminium pack.	
3	Batch No.		26I24Y3	
4	Mfg. Date		2024/09	
5	Expiry Date		2027/08	
6	Product Code		PB-1CD156M5S	
7	Batch Size		3240 Nos.	
Quantitative assay per dosage form				
8	Ingredients (g/L)			
	CPDA-1 Solution -USP		Acceptance Limit	Assay Result
	a	Monobasic Sodium Phosphate (Monohydrate)	2.11 - 2.33	2.22
	b	Dextrose (Monohydrate)	30.30 - 33.50	31.09
	c	Total Citrate (as Citric acid anhydrous)	19.16 - 21.18	20.53
	d	Sodium	6.21 - 6.86	6.59
	e	Adenine	0.275 - 0.303	0.290
9	Other tests or requirements			
	CPDA-1 Solution -USP		Acceptance Limit	Result
	a	Chloride	Not more than 35 ppm	Passed
	b	pH	5.0 - 6.0	5.73
	c	Volume of Anticoagulant solution	20 - 23 mL	22
	d	Bacterial Endotoxin Test	Not more than 5.56 EU/mL	Passed
	e	Sterility	No growth of microorganisms	Passed
	f	Particulate matter	Shall comply USP <788>	Passed
10	Functional test for PVC container according to ISO 3826-1:2019		Shall comply with ISO 3826-1	Passed
Judgment : Complies with USP NF 2023 & ISO 3826-1:2019				
Date : 14/10/2024 (DD/MM/YYYY)				
Prepared By: NIMESH K N Executive QC		Approved By: AKHIL K S Analytical Chemist		

Terumo Penpol Private Limited CIN: U33112KL1985PTC004531, E-Mail: Penpol.info@terumobct.com

Registered Office

: Bhadra Towers, TC 29/2923, Cotton Hill Road, Vazhuthacaud, Thycaud P.O., Thiruvananthapuram, Kerala - 695014, India.
Phone: +91 471-3015500, +91 471-7145500

Blood Bag Factory

: VP 1/520, Thiruvananthapuram – 695573, Kerala, India. Phone: +91 471-3052022 /7192210 / 3015600 / 3015606 / 3015609

Medical Systems Group

: T.C. 27/373, Andoor Buildings, General Hospital Road, Thiruvananthapuram–695035, Kerala, India. Phone: +91 471-7135800

Regional Office

: 3rd Floor, No-05, Pocket B-3, Sector-17, Dwarka–110 075, New Delhi, India. Phone: +91 11-46921062

FR-QCD-77/A

LOT CERTIFICATE

1	Name of product	Blood Bag CPDA-1; 150 ml , Single Bag;	
2	Description of product	SINGLE Blood bag with donor tube and donor needle of 16G; with Needle Injury Protector, 1 bag in an Aluminium pack.	
3	Lot No./Batch No.	26I24Y3	
4	Mfg. Date	2024/09	
5	Expiry Date	2027/08	
6	Product Code	PB-1CD156M5S	
7	Lot Size	3240 Nos.	
8	Intended use	Blood bag is a sterile medical device for single use only and used for collecting whole blood as well as for separation & storage of blood components.	
9	Obtained certificates	CE Mark-Approval of EC Directive 93/42/EEC on medical devices, Annex II (excluding section 4), Certificate no. IN19/818843705 issued by SGS Belgium NV, Notified Body 1639. Quality Management System ISO 9001:2015 certificate number FM747384 and ISO 13485:2016 certificate number MD 766508 issued by BSI.	
10	Type of sterilization	Moist heat sterilization and the sterilization process has been validated and is controlled as specified in ISO-17665-1 with a SAL of 10 ⁻⁶ .	
11	Material validation	Quality of plastics is validated according to ISO 3826 and United States Pharmacopoeia.	
12	QC specification and inspection result		
	a	Chemical test for anticoagulant solution as per USP	Passed
	b	Functional test for PVC container according to ISO 3826	Passed
	c	Biological test (Bacterial Endotoxin Test) according to USP	Passed
	d	Microbiological test (Sterility test) according to USP	Passed
Judgment : Complies with USP NF 2023 & ISO 3826-1:2019			
Date : 14/10/2024 (DD/MM/YYYY)			
Prepared By: NIMESH K N Executive QC		Approved By: AKHIL K S Analytical Chemist	

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