

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, 1bag in an Aluminium pack.	
3	Batch No.	26H24Y1	
4	Mfg. Date	2024/08	
5	Expiry Date	2027/07	
6	Product Code	PB-1CD156M5S	
7	Batch Size	1830 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	2.21
b	Dextrose (Monohydrate)	30.30 - 33.50	31.01
c	Total Citrate (as Citric acid anhydrous)	19.16 - 21.18	20.32
d	Sodium	6.21 - 6.86	6.40
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	5.65
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 : 11/09/2024 (DD/MM/YYYY)			
Prepared By: ARAVINDSIVA S Senior Executive QC		Approved By: SREEJITH NEMATHILLAM 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, 1bag in an Aluminium pack.	
3	Lot No./Batch No.	26H24Y1	
4	Mfg. Date	2024/08	
5	Expiry Date	2027/07	
6	Product Code	PB-1CD156M5S	
7	Lot Size	1830 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.	
QC specification and inspection result			
12	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 : 11/09/2024 (DD/MM/YYYY)			
Prepared By: ARAVINDSIVA S Senior Executive QC 		Approved By: SREEJITH NEMATHILLAM Analytical Chemist 	

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