

TERUMO PENPOL®

Registered Office : TERUMO PENPOL Private Limited, P.B. No. 6105, I-2, Jawahar Nagar, Kowdiar P.O., Thiruvananthapuram - 695 003, Kerala, India.
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CIN : U33112KL1985PTC004531

FR-QCD-64/A

CERTIFICATE OF ANALYSIS

1	Name of product	TERUMO Blood bag with CPDA-1 solution		
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.	10C20Y1		
4	Mfg. Date	2020/03		
5	Expiry Date	2023/02		
6	Product Code	PB-1CD156M5S		
7	Batch Size	3750 Nos.		
Quantitative assay per dosage form				
Ingredients (g/L)				
CPDA-1 Solution – USP		Acceptance Limit	Assay Result	
8	a	Monobasic Sodium Phosphate (Monohydrate)	2.11 - 2.33	2.24
	b	Dextrose (Monohydrate)	30.30 - 33.50	32.27
	c	Total Citrate (as Citric acid anhydrous)	19.16 - 21.18	20.30
	d	Sodium	6.21 - 6.86	6.41
	e	Adenine	0.247 - 0.303	0.271
Other tests or requirements				
CPDA-1 Solution – USP		Acceptance Limit	Result	
9	a	Identification	Positive	Passed
	b	Chloride	Not more than 35 ppm	Passed
	c	pH	5.0 – 6.0	5.63
	d	Volume of Anticoagulant solution	20 – 23 mL	22
	e	Bacterial Endotoxin Test	Not more than 5.56 EU/mL	Passed
	f	Sterility	No growth of microorganisms	Passed
	g	Particulate matter	To be passed	Passed
10	Functional test for PVC container according to ISO 3826-1: 2013	To be passed	Passed	
Judgment : Complies with USP/ISO 3826				
Date : 03/04/2020				
Prepared By: Arun Raj Sr. Executive (QC)		Approved By: Arun.M.K Analytical Chemist		

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FR-QCD-77/A

LOT CERTIFICATE

1	Name of product	TERUMO Blood bag with CPDA-1 solution.	
2	Description of product	Blood bag containing CPDA-1 solution.	
3	Lot No./Batch No.	10C20Y1	
4	Mfg. Date	2020/03	
5	Expiry Date	2023/02	
6	Product Code	PB-1CD156M5S	
7	Lot Size	3750 Nos.	
8	Intended use	TERUMO 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.IN/00/51804 Full Quality Assurance System. ISO 9001 Certificate no.IN/00/51806. Quality System Certificate ISO 13485, Certificate no.IN/06/70701. The above certificates issued by SGS United Kingdom Ltd, Systems & Services Certification, UK, notified under No. 0120.	
10	Type of sterilization	Moist heat sterilization and the sterilization process has been validated and is controlled as specified in ISO-17665-1. The sterilization assurance level of a validated sterilization process is 1 or less viable micro organisms per 1 x 10 ⁶ finished products, to be labelled "Sterile" as specified in EN 556.	
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/ISO 3826			
Date : 03/04/2020 (DD/MM/YYYY)			
Prepared By: Arun Raj Sr. Executive (QC)		Approved By: Arun.M.K Analytical Chemist	