TERUMO PENPOL®

Registered Office : **TERUMO PENPOL Private Limited,** P.B. No. 6105, I-2, Jawahar Nagar, Kowdiar P.O., Thiruvananthapuram - 695 003, Kerala, India.
Phone : +91 471 - 3015500 / 3015501 Fax : +91 471-2721519, E-mail : penpol.info@terumobct.com Website : www.terumopenpol.com
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.		12A20Y3	
4	Mfg. Date		2020/01	
5	Expiry Date		2022/12	
6	Product Code		PB-1CD156M5S	
7	Batch Size		1860 Nos.	
8	**Quantitative assay per dosage form**			
	Ingredients (g/L)			
	CPDA-1 Solution – USP		**Acceptance Limit**	**Assay Result**
	a	Monobasic Sodium Phosphate (Monohydrate)	2.11 - 2.33	2.20
	b	Dextrose (Monohydrate)	30.30 - 33.50	32.23
	c	Total Citrate (as Citric acid anhydrous)	19.16 - 21.18	20.19
	d	Sodium	6.21 - 6.86	6.44
	e	Adenine	0.247 - 0.303	0.276
9	**Other tests or requirements**			
	CPDA-1 Solution – USP		**Acceptance Limit**	**Result**
	a	Identification	Positive	Passed
	b	Chloride	Not more than 35 ppm	Passed
	c	pH	5.0 – 6.0	5.78
	d	Volume of Anticoagulant solution	20 – 23 mL	21
	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 : 28/01/2020				
Prepared By: V.V.Kumari Deputy Manager (QC) 28/01/2020			**Approved By:** Arun.M.K Analytical Chemist 28/01/2020	

TERUMO PENPOL®

Registered Office : **TERUMO PENPOL Private Limited,** P.B. No. 6105, I-2, Jawahar Nagar, Kowdiar P.O., Thiruvananthapuram - 695 003, Kerala, India.
Phone : +91 471 - 3015500 / 3015501 Fax : +91 471-2721519, E-mail : penpol.info@terumobct.com Website : www.terumopenpol.com
CIN : U33112KL1985PTC004531

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.	12A20Y3
4	Mfg. Date	2020/01
5	Expiry Date	2022/12
6	Product Code	PB-1CD156M5S
7	Lot Size	1860 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 : 28/01/2020 (DD/MM/YYYY)		
Prepared By: V.V.Kumari, Deputy Manager (QC) 28/01/2020	**Approved By:** Arun.M.K, Analytical Chemist 28/01/2020	