TERUMO PENPOL®

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

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; 1 bag in an Aluminium pack.	
3	Batch No.		13C17Y3	
4	Mfg. Date		2017/03	
5	Expiry Date		2020/02	
6	Product Code		PB-1CD156M5S	
7	**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	2.21
	b	Dextrose (Monohydrate)	30.30 - 33.50	31.94
	c	Total Citrate (as Citric acid anhydrous)	19.16 - 21.18	20.85
	d	Sodium	6.21 - 6.86	6.37
	e	Adenine	0.247 - 0.303	0.269
8	**Other tests or requirements**			
	CPDA-1 Solution – USP		**Acceptance Limit**	**Assay Result**
	a	Identification	Positive	Passed
	b	Chloride	Not more than 35 ppm	Passed
	c	Bacterial Endotoxin Test	Not more than 5.56 Eu/mL	Passed
	d	Sterility	No contamination found	Passed

Judgment : Complies with USP/ISO 3826

Date : 29/03/2017

Prepared By: V.V.Kumari Deputy Manager (QC)	**Approved By:** Abhijith.R.R Analytical Chemist

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LOT CERTIFICATE

1	Name of product	**TERUMO** Blood bag with **CPDA-1** solution.	
2	Product Code	PB-1CD156M5S	
3	Lot No./Batch No.	13C17Y3	
4	Lot Size	4846 Nos.	
5	Expiry Date	2020/02	
6	Product Description	Blood bag containing CPDA-1 solution.	
7	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.	
8	Obtained certificates	CE Mark-Approval of EC Directive 93/42/EEC on medical devices, Annexure - II (excluding section: 4), Certificate no.GB00/51804; full Quality Assurance System-ISO 9001-Certificate no.GB00/51806; Quality System Certificate ISO 13485, Certificate no.GB06/70701. The above certificates issued by SGS Yarsley. International Certification Services, notified under No. 0120.	
9	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.	
10	Material validation	Quality of plastics is validated according to ISO 3826 and United States Pharmacopoeia.	
11	**QC specification and inspection result**		
	a	Chemical test for PVC material according to ISO 3826 and USP	Passed
	b	Chemical test for anticoagulant solution as per USP	Passed
	c	Functional test for PVC container according to ISO 3826	Passed
	d	Biological test (Bacterial Endotoxin Test) according to USP	Passed
	e	Microbiological test (Sterility test) according to USP	Passed
12	**Chemical testing for the anticoagulant CPDA-1**		
	a	Volume of anticoagulant (± 5%)	Passed
	b	Identification and assay of the ingredients	Passed
	c	Chloride	Passed
	d	pH (Limit : 5.0 – 6.0)	5.63

Judgment : Complies with USP/ISO 3826

Date : 29/03/2017 (DD/MM/YYYY)

Prepared By: V.V.Kumari Deputy Manager (QC) 29/03/17	**Approved By:** Abhijith.R.R Analytical Chemist 29/03/17