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.		28B17Y3	
4	Mfg. Date		2017/02	
5	Expiry Date		2020/01	
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	2.25
	b	Dextrose (Monohydrate)	30.30 - 33.50	32.32
	c	Total Citrate (as Citric acid anhydrous)	19.16 - 21.18	19.97
	d	Sodium	6.21 - 6.86	6.51
	e	Adenine	0.247 - 0.303	0.292
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 : 16/03/2017

Prepared By: Anilkumar.K.S Asst. Manager (QC) 16.03.17	**Approved By:** Abhijith.R.R Analytical Chemist 16/03/17

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)

LOT CERTIFICATE

1	Name of product	**TERUMO** Blood bag with **CPDA-1** solution.	
2	Product Code	PB-1CD156M5S	
3	Lot No./Batch No.	28B17Y3	
4	Lot Size	4619 Nos.	
5	Expiry Date	2020/01	
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)	5.60

Judgment : Complies with USP/ISO 3826

Date : 16/03/2017 (DD/MM/YYYY)

Prepared By: Anilkumar.K.S Asst. Manager (QC) 16.03.17	**Approved By:** Abhijith.R.R Analytical Chemist 16/03/17