TERUMO PENPOL®

Registered Office: **TERUMO PENPOL Private Limited,** P. B. No. 6105, I-2, Jawahar Nagar, Thiruvananthapuram 695 003, Kerala, India.
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CIN: U33112KL1985PTC004531 (Formerly Known as TERUMO PENPOL Limited)

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; 1 bag in an Aluminium pack.	
3	Batch No.		15E17Y1	
4	Mfg. Date		2017/05	
5	Expiry Date		2020/04	
6	Product Code		PB-1CD156M5S	
7	Batch Size		6456 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	2.26
	b	Dextrose (Monohydrate)	30.30 - 33.50	32.01
	c	Total Citrate (as Citric acid anhydrous)	19.16 - 21.18	20.98
	d	Sodium	6.21 - 6.86	6.55
	e	Adenine	0.247 - 0.303	0.284
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	5.65
	d	Volume of Anticoagulant solution	20 – 23 mL	22
	e	Bacterial Endotoxin Test	Not more than 5.56 Eu/mL	Passed
	f	Sterility	No contamination found	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 : 31/05/2017				

Prepared By: V.V.Kumari Deputy Manager (QC) 31/05/17	**Approved By:** Arun.M.K Analytical Chemist 31/05/17

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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.	15E17Y1
4	Mfg. Date	2017/05
5	Expiry Date	2020/04
6	Product Code	PB-1CD156M5S
7	Lot Size	6456 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, 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.
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 : 31/05/2017 (DD/MM/YYYY)		
Prepared By: V.V.Kumari Deputy Manager (QC) 31/05/17		**Approved By:** Arun.M.K Analytical Chemist 31/05/17