TERUMO PENPOL®

Registered Office: **TERUMO PENPOL Private Limited,** P.B. No. 6105, 1-2,Jawahar Nagar, Kowdiar P.O., Thiruvananthapuram - 695 003, Kerala, India.
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CIN: U33112KL1985PTC004531

FR-QCD-64/B

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.		11I20Y1	
4	Mfg. Date		2020/09	
5	Expiry Date		2023/08	
6	Product Code		PB-1CD156M5S	
7	Batch Size		1890 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	2.21
	b	Dextrose (Monohydrate)	30.30 - 33.50	32.08
	c	Total Citrate (as Citric acid anhydrous)	19.16 - 21.18	20.32
	d	Sodium	6.21 - 6.86	6.60
	e	Adenine	0.247 - 0.303	0.269
9	**Other tests or requirements**			
	CPDA-1 Solution – USP		**Acceptance Limit**	**Result**
	a	Chloride	Not more than 35 ppm	Passed
	b	pH	5.0 – 6.0	5.65
	c	Volume of Anticoagulant solution	20 – 23 mL	22
	d	Bacterial Endotoxin Test	Not more than 5.56 EU/mL	Passed
	e	Sterility	No growth of microorganisms	Passed
	f	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 40 & ISO 3826-1:2013

Date : 28/09/2020 (DD/MM/YYYY)

Prepared By: V.V.Kumari Deputy Manager (QC) 28/09/2020	**Approved By:** Arun.M.K Analytical Chemist 28/09/2020

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CIN: U33112KL1985PTC004531

FR-QCD-77/A

LOT CERTIFICATE

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	Lot No./Batch No.	11I20Y1
4	Mfg. Date	2020/09
5	Expiry Date	2023/08
6	Product Code	PB-1CD156M5S
7	Lot Size	1890 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.IN19/818843705 issued by SGS Belgium NV, Notified Body 1639. Full Quality Assurance System ISO 9001, Certificate no.IN18/05791. Quality System Certificate ISO 13485, Certificate no.IN06/70701. 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 40 & ISO 3826-1:2013

Date : 28/09/2020 (DD/MM/YYYY)

Prepared By: V.V.Kumari Deputy Manager (QC) 28/09/2020	**Approved By:** Arun.M.K Analytical Chemist 28/09/2020