

# 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/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.	06G20Y2		
4	Mfg. Date	2020/07		
5	Expiry Date	2023/06		
6	Product Code	PB-1CD156M5S		
7	Batch Size	1500 Nos.		
8	<b>Quantitative assay per dosage form</b>			
	<b>Ingredients (g/L)</b>			
	<b>CPDA-1 Solution – USP</b>		<b>Acceptance Limit</b>	<b>Assay Result</b>
	a	Monobasic Sodium Phosphate (Monohydrate)	2.11 - 2.33	2.17
	b	Dextrose (Monohydrate)	30.30 - 33.50	32.04
	c	Total Citrate (as Citric acid anhydrous)	19.16 - 21.18	20.51
	d	Sodium	6.21 - 6.86	6.73
	e	Adenine	0.247 - 0.303	0.273
9	<b>Other tests or requirements</b>			
	<b>CPDA-1 Solution – USP</b>		<b>Acceptance Limit</b>	<b>Result</b>
	a	Chloride	Not more than 35 ppm	Passed
	b	pH	5.0 – 6.0	5.66
	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	
<b>Judgment : Complies with USP 40 &amp; ISO 3826-1:2013</b>				
<b>Date : 23/07/2020 (DD/MM/YYYY)</b>				
<b>Prepared By:</b> V.V.Kumari Deputy Manager (QC)		<b>Approved By:</b> Arun.M.K Analytical Chemist		

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FR-QCD-77/A

## LOT CERTIFICATE

1	Name of product	<b>TERUMO</b> Blood bag with <b>CPDA-1</b> solution.	
2	Description of product	<b>SINGLE</b> 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.	06G20Y2	
4	Mfg. Date	2020/07	
5	Expiry Date	2023/06	
6	Product Code	PB-1CD156M5S	
7	Lot Size	1500 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 <sup>6</sup> 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	<b>QC specification and inspection result</b>		
	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
<b>Judgment : Complies with USP 40 &amp; ISO 3826-1:2013</b>			
<b>Date : 23/07/2020 (DD/MM/YYYY)</b>			
<b>Prepared By:</b> V.V.Kumari Deputy Manager (QC)		<b>Approved By:</b> Arun.M.K Analytical Chemist	