FR-QCD-64/B

CERTIFICATE OF ANALYSIS

1	Name of product		Blood Bag CPDA-1; 150 ml; Single Bag;	
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.		19A22Y3	
4	Mfg. Date		2022/01	
5	Expiry Date		2024/12	
6	Product Code		PB-1CD156M5S	
7	Batch Size		1860 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	2.23
	b	Dextrose (Monohydrate)	30.30 - 33.50	31.71
	c	Total Citrate (as Citric acid anhydrous)	19.16 - 21.18	20.71
	d	Sodium	6.21 - 6.86	6.48
	e	Adenine	0.247 - 0.303	0.266
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	5.64
	c	Volume of Anticoagulant solution	20 – 23 mL	21
	d	Bacterial Endotoxin Test	Not more than 5.56 EU/mL	Passed
	e	Sterility	No growth of microorganisms	Passed
	f	Particulate matter	Shall comply USP <788>	Passed
10	Functional test for PVC container according to ISO 3826-1: 2019		Shall comply with ISO 3826-1	Passed
Judgment : Complies with USP 43 & ISO 3826-1:2019				
Date : 04/02/2022 (DD/MM/YYYY)				

Prepared By:
V.V.Kumari
Deputy Manager (QC) 04/02/2022

Approved By:
Sreejith Nemathillam
Analytical Chemist
04/02/2022

FR-QCD-77/A

LOT CERTIFICATE

1	Name of product	Blood Bag CPDA-1; 150 ml; Single Bag;	
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.	19A22Y3	
4	Mfg. Date	2022/01	
5	Expiry Date	2024/12	
6	Product Code	PB-1CD156M5S	
7	Lot Size	1860 Nos.	
8	Intended use	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. Quality Management System BSI ISO 9001:2015 certificate number FM747384 issued by BSI Assurance UK Limited, England, UK & IN06/70701 (ISO 13485) issued by SGS United Kingdom Ltd, Under UKAS accreditation.	
10	Type of sterilization	Moist heat sterilization and the sterilization process has been validated and is controlled as specified in ISO-17665-1 with a SAL of 10^{-6}.	
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 43 & ISO 3826-1:2019			
Date : 04/02/2022 (DD/MM/YYYY)			
Prepared By: V.V.Kumari Deputy Manager (QC) 04/02/2022		**Approved By:** Sreejith Nemathillam Analytical Chemist 04/02/2022	