

Name of product	Single-use blood bag with CPD/SAGM solution
Code No.	BBQ243F
Description of product	QUADRUPLE bag with donor tube and donor needle of 16G; with Needle Injury Protector, Leukocyte filter, Sampling device ; 2units in a Aluminum pack.
Type	OQS-450SSFW
Batch No.	1903017
Batch size	1000sets
Mfg. Date	2019.03
Inspection Date	2019.03.18
Exp. Date	2022.02
Reference	ISO 3826-1:2013 Plastics collapsible containers for human blood and blood components -- Part 1: Conventional containers USP40

1. QUANTITATIVE ASSAY PER DOSAGE FORM

Ingredients(g/L)

CPD Solution	Acceptance limit	Assay result
a. Dextrose (C ₆ H ₁₂ O ₆ •H ₂ O)	24.22 - 26.78	25.42
b. Monobasic Sodium Phosphate (NaH ₂ PO ₄ •H ₂ O)	2.11 - 2.33	2.24
c. Total citrate	19.16 - 21.18	19.73
d. Sodium (Na ⁺)	6.21 - 6.86	6.30
SAGM Solution		
a. Dextrose (C ₆ H ₁₂ O ₆ •H ₂ O)	8.55 - 9.45	9.07
b. Mannitol (C ₆ H ₁₄ O ₆)	4.99 - 5.51	5.20
c. Sodium Chloride	8.33 - 9.21	8.81
d. Adenine (C ₅ H ₅ N ₅)	0.161 - 0.178	0.169

2. OTHER TESTS OR REQUIREMENTS

CPD Solution	Acceptance limit	Assay result
a. Description	A clear colourless, odourless solution	Passed
b. pH	5.0-6.0	5.6
c. Chloride	<0.0035%	Passed
d. Clarity& impurity	Clear and without impurity	Passed
e. Particulate matter	≥10 μ m: ≤6000/container; ≥25 μ m: ≤600/container	Passed
f. Volume	63ml (No less than the labeled volume)	Passed
g. Bacterial endotoxins	<5.56EU/mL	Passed
h. Sterile	No contamination found	Passed

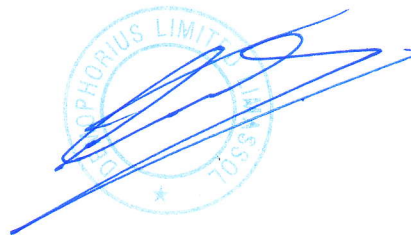
SAGM Solution	Acceptance limit	Assay result
a. Description	A clear colourless, odourless solution	Passed
b. pH	5.0-6.5	5.3
c. Clarity& impurity	Clear and without impurity	Passed
d. Particulate matter	$\geq 10\mu\text{m}:\leq 25 /\text{ml}; \geq 25\mu\text{m}:\leq 3 /\text{ml}$	Passed
e. Volume	100ml (No less than the labeled volume)	Passed
f. Bacterial endotoxin	$< 5.56\text{EU}/\text{mL}$	Passed
g. Sterile	No contamination found	Passed

3. OTHER QC SPECIFICATION AND INSPECTION RESULT

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|---|----------|
| 1) Chemical test for PVC material | - Passed |
| 2) Chemical test for other plastic material based on internal standards | - Passed |
| 3) Function test for PVC container according to ISO 3826 | - Passed |
| 4) Biological test (pyrogen test) according to ISO10993 | - Passed |
| 5) Biological test (acute toxicity test) according to ISO10993 | - Passed |
| 6) Microbiological test (sterility test) according to USP | - Passed |

Comments: Complies Product released.

Date: 2019.03.26



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Name	SINGLE-USE BLOOD BAG	Mfg. date	2019.03
Specification	OQS-450SSFW	Exp. date	2022.02
Lot	1903017		

Control result of sterilization process parameters		
Sterilization No.	M1903081	
F0 value of sterilization	≥ 15	Compliance <input checked="" type="checkbox"/> non-compliance <input type="checkbox"/>
sterilization temperature	118°C	Compliance <input checked="" type="checkbox"/> non-compliance <input type="checkbox"/>
sterilization time	1800	Compliance <input checked="" type="checkbox"/> non-compliance <input type="checkbox"/>
Result of microbiological control		
Testing Item	Criteria	Testing Results
Initial contaminating bacteria	$<1 \times 10^6$ cfu/unit	3
Bacterial Endotoxins	SOLUTION <5.56 EU/mL	<5.56 EU/mL
Sterility test	No growth of microbe (ATCC7953) LOT. <u>181211001</u>	No growth of microbe
Biological Indicator	Bacillus Stearothermophilus (ATCC7953) Remain purple after sterilization (-)	Remain purple

STERILIZATION CERTIFICATE