

# CERTIFICATE OF ANALYSIS

DEMOPHORUS  
.COM

196 Archbishop Makarios III Av.  
Limassol 3030, Cyprus

Version: 01

demophorius

Report No. CP1905010  
HEALTHCARE

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.
Batch No.	1905009
Batch size	2000sets
Mfg. Date	2019.05
Inspection Date	2019.05.10
Exp. Date	2022.04
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 <sub>6</sub> H <sub>12</sub> O <sub>6</sub> •H <sub>2</sub> O)	24.22 - 26.78	25.93
b. Monobasic Sodium Phosphate (NaH <sub>2</sub> PO <sub>4</sub> •H <sub>2</sub> O)	2.11 - 2.33	2.27
c. Total citrate	19.16 - 21.18	19.67
d. Sodium (Na <sup>+</sup> )	6.21 <sub>1</sub> - 6.86	6.30
SAGM Solution	Acceptance limit	Assay result
a. Dextrose (C <sub>6</sub> H <sub>12</sub> O <sub>6</sub> •H <sub>2</sub> O)	8.55 - 9.45	9.04
b. Mannitol (C <sub>6</sub> H <sub>14</sub> O <sub>6</sub> )	4.99 - 5.51	5.17
c. Sodium Chloride	8.33 - 9.21	8.91
d. Adenine (C <sub>5</sub> H <sub>5</sub> N <sub>5</sub> )	0.161 - 0.178	0.176

## 2. OTHER TESTS OR REQUIREMENTS

CPD Solution	Acceptance limit	Assay result
a. Description	A clear colourless, odorless solution	Passed
b. pH	5.0-6.0	5.6
c. Chloride	<0.0035%	Passed
d. Clarity & impurity	Clear and without impurities	Passed
e. Particulate matter	≥ 10 μm: ≤ 6000/container ; ≥ 25 μm: ≤ 1000/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

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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. Ba	$< 5.56 \text{EU/mL}$	Passed
g. Ste	No contamination found	Passed

### 3. OTHER QC SPECIFICATION AND INSPECTION RESULT

- |   |          |
|---|----------|
| 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 |

