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|------------------------|---|
| 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. | 1906030 |
| Batch size | 1000sets |
| Mfg. Date | 2019.06 |
| Inspection Date | 2019.06 |
| Exp. Date | 2022.05 |
| 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 | 25.85 |
| b. Monobasic Sodium Phosphate (NaH ₂ PO ₄ •H ₂ O) | 2.11 - 2.33 | 2.27 |
| c. Total citrate | 19.16 - 21.18 | 20.19 |
| d. Sodium (Na ⁺) | 6.21 - 6.86 | 6.80 |
| SAGM Solution | | |
| a. Dextrose (C ₆ H ₁₂ O ₆ •H ₂ O) | 8.55 - 9.45 | 9.13 |
| b. Mannitol (C ₆ H ₁₄ O ₆) | 4.99 - 5.51 | 5.23 |
| c. Sodium Chloride | 8.33 - 9.21 | 8.87 |
| d. Adenine (C ₅ H ₅ N ₅) | 0.161 - 0.178 | 0.168 |

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 |

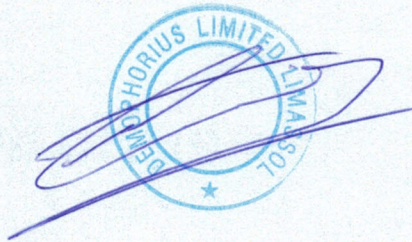
| SAGM Solution | Acceptance limit | Assay result |
|------------------------|---|--------------|
| a. Description | A clear colourless, odourless solution | Passed |
| b. pH | 5.0-6.5 | 5.5 |
| c. Clarity & impurity | Clear and without impurity | Passed |
| d. Particulate matter | $\geq 10\mu\text{m}:\leq 25 /\text{ml}; \geq 25\mu\text{m}:\leq 3 /\text{ml}$ | Passed |
| e. Volume | 100ml (No less than the labeled volume) | Passed |
| f. Bacterial endotoxin | <5.56EU/mL | Passed |
| g. Sterile | 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 |

Comments: Complies Product released.

Date: 2019.07.12



196 Archbishop Makarios III Av. DEMOPHORIOUS
Limassol 3030, Cyprus F-SOP0760029-02COM

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|---------------|----------------------|-----------|---------|
| Name | SINGLE-USE BLOOD BAG | Mfg. date | 2019.06 |
| Specification | OQS-450SSFW | Exp. date | 2022.05 |
| Lot | 1906030 | | |

Control result of sterilization process parameters

| | | |
|---------------------------|-------------------|---|
| Sterilization No. | M1906247 M1906248 | |
| F0 value of sterilization | ≥ 15 | non-compliance <input type="checkbox"/> |
| sterilization temperature | 118°C | non-compliance <input type="checkbox"/> |
| sterilization time | 1800 | non-compliance <input type="checkbox"/> |

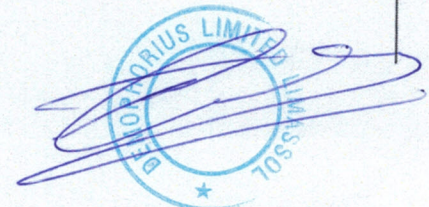
Result of microbiological control

| Testing Item | Criteria | Testing Results |
|--------------------------------|--|----------------------|
| Initial contaminating bacteria | $<1 \times 10^2$ cfu/unit | 7 |
| 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

info@demophorius.com

T +357 25 749 896 | F +357 25 749 907



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