**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/1

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| **PRODUCT** | GSUNATE INJECTION | | **REF. NO: NDQD201508199** |
| **DATE RECEIVED:** 24.08.2015 | **LABEL CLAIM:** | Each vial contains: Artesunate 60 mg. The combi pack contains 1 mL ampoule of Sodium Bicarbonate Injection BP 5% w/v and 5 mL ampoule of Sodium Chloride Injection BP 0.9 % w/v. | |
| **BATCH NO.:** Injection: BI14012L Diluents: B007, B005 | **PRESENTATION:** | Off-white coloured powder for reconstitution into injection solution for intravenous or intramuscular administration, contained in a clear colourless glass vial with a blue flip off cap, packed along with a clear colourless solution of sodium chloride in a 5 mL clear colourless glass ampoule and a clear colourless solution of sodium bicarbonate in a 1 mL clear glass ampoule on a plastic rack in a unit box. | |
| **MGF. DATE:** Injection: Jul. 2014 Diluents: Jul. 2014 | **MANUFACTURER:** | Bliss GVS Pharma Ltd. | |
| **EXP. DATE:**  Injection: Jun. 2016 Diluents: Jun. 2017 | **ADDRESS:** | At: Plot N0. 73 to 76, Silver Industrial Estate, Bhimpore, Daman 396 210 (UT) INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy Board Of Sierra Leone, Central Medical Stores, Free Town, SIERRA LEONE | |
| PVG/GFM/FT-PRI/11/03/15 | **TEST(S) REQUESTED:** | Sterility, Identification, Bacterial Endotoxin, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Bacterial Endotoxin** | LAL | Int. Ph. Online Edition | Artesunate NMT 2.5 IU/mg | 2.3\*10-5 IU/mg | **COMPLIES** |
| **Bacterial Endotoxin** |  | USP 38 NF 33 Page 5309 | Sodium Bicarbonate NMT 5 EU/mEq | 1.7\*10-5 EU/mEq | **COMPLIES** |
| **Bacterial Endotoxin** |  | USP 38 NF 33 Page 5314 | Sodium Chloride NMT 0.5 EU/mL | 2.0\*10-6 EU/mL | **COMPLIES** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App. XVI A | No microbial growth | No Microbial growth | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of the component peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 7.2 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | Artesunate 90.0 - 110.0 % |  |  |
| **Assay** | Titration | BP 2016 Vol. III Page 1117 | Sodium Chloride 95.0 - 105.0% | 98.2% (RSD=0.4%, n=5) |  |
| **Assay** |  |  | Sodium Bicarbonate 94.0 - 106.0% | NaCl |  |
| **Assay** |  |  |  | 101.2% (RSD=0.75%, n=3) |  |
| **Assay** |  |  |  |  |  |
| **Assay** |  |  |  |  |  |
| **Assay** |  |  |  | 101.1% (RSD=0.00%, n=3) |  |
| **Assay** |  |  |  |  |  |

**CONCLUSION:** The sample complies with the specifications for the tests performed.

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| **ANALYST:** | MR. E. NGAMAU | .......................................................... | DATE: 09-11-2015 |
| **ANALYST:** | MR. M. SANGALE | .......................................................... | DATE: 09-30-2015 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 01-27-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 02-12-2016 |
| **ANALYST:** | MATTHEW KWENA | .......................................................... | DATE: 07-04-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-22-2016 |