**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/2

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | ARTESUN 60 mg FOR INJECTION | | **REF. NO: NDQD201508198** |
| **DATE RECEIVED:** 24.08.2015 | **LABEL CLAIM:** | Each vial contains: Artesunate 60 mg. The combi pack contains 1 mL ampoule of Sodium Bicarbonate Injection 5%. | |
| **BATCH NO.:** Injection ZA140311 Diluent T140306 | **PRESENTATION:** | White powder for reconstitution into injection solution for intravenous or intramuscular administration, contained in a clear colourless glass vial with a blue flip off cap and aluminium band, packed along with a clear colourless solution of 5% Sodium Bicarbonate in a 1 mL clear glass ampuole on a plastic rack in a unit box and 5 such boxes in a unit box. | |
| **MGF. DATE:** Feb.2016 | **MANUFACTURER:** | GUILIN Pharmaceuticals Co. Ltd. | |
| **EXP. DATE:**  Powder Feb 2017 Diluent Mar 2018 | **ADDRESS:** | No.43 Qilidian Road, Guilin 541004, Guangxi, CHINA | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy Board Of Sierra Leone, Central Medical Stores, Free Town, SIERRA LEONE | |
| PVG/GEM/FT/PUB/30/03/15 | **TEST(S) REQUESTED:** | Sterility, Identification, Bacterial Endotoxin, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App. XVI A | No Microbial Growth | No Microbial Growth | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | Int. Ph. Online Edition | Artesunate NMT 2.5 IU/mg | 3.5\*10-5 EU/mg | **COMPLIES** |
| **Bacterial Endotoxin** |  | USP 38 NF 33 Page 5309 | Sodium Bicarbonate NMT 5 EU/mEq | 2.2\*10-5 EU/mEq | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's In-House Method | RT of the major peak in the asasy 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 | AManufacturer's In-House Method | Artesunate 90.0 - 110.0 % |  | **COMPLIES** |
| **Assay** | Titration | BP 2016 Vol. III Page 1117 | Sodium Bicarbonate 94.0 - 106.0% | 97.6 % (RSD=0.3%, n=4) |  |
| **Assay** |  |  |  | 101.12% (RSD=0.00%, n=3) | **COMPLIES** |
| **Assay** |  |  |  |  |  |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | MR. E. NGAMAU | .......................................................... | DATE: 10-02-2016 |
| **ANALYST:** | MR. M. SANGALE | .......................................................... | DATE: 10-02-2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 10-02-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 02-12-2016 |
| **ANALYST:** | MATTHEW KWENA | .......................................................... | DATE: 07-04-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-22-2016 |