**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/277

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | ARTESUN R 60 mg FOR I.M./I.V. INJECTION | | **REF. NO: NDQB201610177** |
| **DATE RECEIVED:** 2016-10-18 | **LABEL CLAIM:** | Each box contains 1 vial of 60 mg Artesunate powder for solution for injection, 1 ampoule of 1 mL sodium bicarbonate 50 mg/mL solution for injection and 1 ampoule of 5 mL sodium chloride 9 mg/mL solution for injection. | |
| **BATCH NO.:** Powder: ZA160121 Diluent 1: T160109 Diluent 2: LN160108 | **PRESENTATION:** | Off white crystalline powder for injection packed in a clear glass vial with a grey coloured closure and a blue coloured flip-off cap contained in a plastic blister pack supplied together one clear glass ampoule of 1 mL sodium bicarbonate and one clear glass ampoule of 5 mL sodium chloride packed in a unit box. | |
| **MFG. DATE:** Powder: 13/11/2015 Diluent 1: 15/01/2016 Diluent 2: 17/01/2016 | **MANUFACTURER:** | GUILIN Pharmaceutical Co. Ltd. | |
| **EXP. DATE:**  Powder: 12/11/2018 Diluent 1: 14/01/2020 Diluent 2: 16/01/2019 | **ADDRESS:** | No.43 Qilidian Road, Guilin 541004, Guangxi, CHINA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P. O. Box 47715 - 00100, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Sterility, Identification, Bacterial Endotoxin, Assay, Acidity/Alkalinity | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App. XVI A | No Microbial Growth | No Microbial Growth | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | Manufacturer's In-House Method | Powder; NMT 5.8 EU/mg | Powder 1.9x10-4 EU/mg | **COMPLIES** |
| **Bacterial Endotoxin** |  |  | Diluent 1 (NaHCO3; NMT 0.6 EU/mg | Diluent 1 1.1x10-6 EU/mg |  |
| **Bacterial Endotoxin** |  |  | Diluent 2 (NaCl); NMT 0.5 EU/mL | Diluent 2 2.6x10-6 EU/mL |  |
| **Identification** | HPLC | Manufacturer's In-House Method | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 9.4 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | BP 2016 Vol. V App XII C | 3.5 - 4.5 | 3.8 | **COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | 90.0 - 110.0% | Artesunate 98.9% (RSD=1.0%, n=9) | **COMPLIES** |
| **Assay** | Titration |  |  | Sodium Bicarbonate 101.6% (RSD=0.7%, n=3) | **COMPLIES** |
| **Assay** |  |  |  | Sodium Chloride 98.7% (RSD=1.1%, n=3) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 10-26-2016 |
| **ANALYST:** | DUNCAN OLUOCH | .......................................................... | DATE: 10-26-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 11-11-2016 |
| **ANALYST:** | EMMANUEL TANUI | .......................................................... | DATE: 11-11-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-22-2016 |