**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/634

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| **PRODUCT** | ARTESUN INJECTION 60 mg | | REF. NO: NDQA201511508 |
| **DATE RECEIVED:** 02.11.2015 | **LABEL CLAIM:** | Each box contains 1 vial of Artesunate for injection and 1 ampoule of 5% sodium bicarbonate. | |
| **BATCH NO.:** Powder: ZA130301 NaHCO3: T121206 | **PRESENTATION:** | Off-white crystalline powder for intramuscular and intravenous administration, contained in a clear colourless glass vial fitted with a grey rubber closure, aluminum band and a blue coloured plastic flip off cap, packed along with Sodium Bicarbonate in 1 mL glass ampoule in a unit box. | |
| **MGF. DATE:** Powder: Jan. 2013 NaHCO3: Dec. 2012 | **MANUFACTURER:** | GUILIN Pharmaceuticals Co. Ltd. | |
| **EXP. DATE:**  Powder Jan. 2016NaHCO3 Dec. 2016 | **ADDRESS:** | No. 17 Shanghai Road, Guilin, Guangxi, CHINA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| KEN/AS/KAJ/01/09/2014/002 | **TEST(S) REQUESTED:** | Uniformity of Weight, Sterility, Identification, Bacterial Endotoxin, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | NMT 2 vials deviate by more than 10% from mean vial content weight | None Deviates | **COMPLIES** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App XVI A | Powder and diluent No microbial growth | No Microbial growth Powder and diluent | **COMPLIES** |
| **Identification** | HPLC | Int. Ph. 5th Edition 2015 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 5.1 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | Int. Ph. 5th Edition 2015 | Artesunate NMT 2.5EU/mg :Sodium Bicarconate NMT 1.0EU/mL | 8.3 x 10-5 EU/mg | **COMPLIES:COMPLIES** |
| **Bacterial Endotoxin** | LAL | Int. Ph. 5th Edition 2015 | Artesunate NMT 2.5EU/mg :Sodium Bicarconate NMT 1.0EU/mL | 5.4 x 10-4 EU/mL | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:Titration | Int. Ph. 5th Edition 2015:Int. Ph. 5th Edition 2015 | Artesunate 90.0 % - 110.0% Sodium Bicarbonate 94.0% - 106.0% | 92.4% (RSD=0.9%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:Titration | Int. Ph. 5th Edition 2015:Int. Ph. 5th Edition 2015 | Artesunate 90.0 % - 110.0% Sodium Bicarbonate 94.0% - 106.0% | 102.1% (RSD=0.0%, n=3) | **COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** |  | B.P. 2016 Vol. V App V L | - | 3.80 | **COMPLIES** |

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

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| ANALYST: | MR. E. NGAMAU |  | DATE:09-02-2016 |
| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:20-04-2016 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:06-05-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-17-2016 |