**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/633

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| **PRODUCT** | ARTESUN R 30 mg INJECTION | | REF. NO: NDQA201511556 |
| **DATE RECEIVED:** 12.11.2015 | **LABEL CLAIM:** | Each box contains 1 vial of Artesunate for injection, 1 ampoule of sodium bicarbonate injection and 1 ampoule of sodium chloride injection. | |
| **BATCH NO.:** Powder ZA140219 NaHCO3 T140303 Nacl LN140307 | **PRESENTATION:** | Off-white free flowing powder for intramuscular and intravenous administration, contained in a clear colourless glass vial fitted with a grey rubber closure, aluminum band and a green coloured plastic flip off cap, packed along with Sodium chloride in a 2.5 mL clear colourless glass ampoule and Sodium Bicarbonate in 0.5 mL glass ampoule in a unit box. | |
| **MGF. DATE:** Powder Jan. 2014 NaHCO3 Mar. 2014 Nacl Mar. 2014 | **MANUFACTURER:** | GUILIN Pharmaceutical Co. Ltd. | |
| **EXP. DATE:**  Powder Jan. 2017 NaHCO3 Mar. 2018 Nacl Mar. 2017 | **ADDRESS:** | No.43 Qilidian Road, Guilin, Guangxi, CHINA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| KEN/KSM/AS/27/8/1/14/15 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, 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 vial deviate by more than 10% from mean vial content weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | BP 2016 Page 1119 | 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** |
| **Assay** | HPLC:Titration | :Int. Ph. 5th Edition 2015 | Artesunate 90.0% - 110.0% Sodium Bicarbonate 94.0% - 110.0% Sodium Chloride 95.0% - 105.0% | 97.7% (RSD=1.3%, n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC:Titration | :Int. Ph. 5th Edition 2015 | Artesunate 90.0% - 110.0% Sodium Bicarbonate 94.0% - 110.0% Sodium Chloride 95.0% - 105.0% | 102.1% n=3 | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC:Titration | :Int. Ph. 5th Edition 2015 | Artesunate 90.0% - 110.0% Sodium Bicarbonate 94.0% - 110.0% Sodium Chloride 95.0% - 105.0% | 99.0% (RSD=0.9%, n=3) | **COMPLIES:COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** | pH | B.P. 2016 Vol V App V L. | - | 3.94 | **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 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:06-05-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-17-2016 |