**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/302

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| **PRODUCT** | ARTESUN 60 mg INJECTION I.M./I.V. | | **REF. NO: NDQA201511485** |
| **DATE RECEIVED:** 02-11-2015 | **LABEL CLAIM:** | Each box contains 1 vial of Artesunate 60 mg for injection, 1 ampoule of sodium bicarbonate 50 mg/mL injection and 1 ampoule of sodium chloride 9 mg/mL injection. | |
| **BATCH NO.:** Powder: ZA140127 Diluent 1: T131211 Diluent 2 LN140108 | **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 bicarbonate in a 1 mL clear colourless glass ampoule and a clear colourless solution of sodium chloride in a 5 mL clear glass ampoule on a plastic rack in a unit box. | |
| **MFG. DATE:** Powder 04/01/2014 Diluent 1: 31/12/2013 Diluent 2: 28/01/2014 | **MANUFACTURER:** | GUILIN Pharmaceuticals Co. Ltd. | |
| **EXP. DATE:**  Powder: 03/01/2017 Diluent 1: 30/12/2017 Diluent 2: 27/01/2017 | **ADDRESS:** | No.43 Qilidian Road, Guilin 541004, Guangxi, CHINA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board, P. O. Box 27663 - 00506 Nairobi, KENYA. | |
| KEN/AS/KER/9/9/14/19 | **TEST(S) REQUESTED:** | Identification, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Identification** | HPLC | Adopted In-House Method | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation. | Artesunate Super-imposable peak at RT 13.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Artesunate 99.6% (RSD= 0.5%; n=4) | **COMPLIES** |
| **Assay** | Titration |  |  | Sodium bicarbonate 101.1% (RSD= -; n=3) | **COMPLIES** |
| **Assay** |  |  |  | Sodium chloride 98.2% (RSD= -; n=3) | **COMPLIES** |

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

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| **NULL** | NULL | .......................................................... | DATE: null |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 06-07-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-29-2016 |