**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/228

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| **PRODUCT** | ARTESUN 60 MG FOR INJECTION I.M./I.V. | | **REF. NO: NDQB201611202** |
| **DATE RECEIVED:** 2016-11-01 | **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: ZA150714 Diluent 1: T150709 Diluent 2: LN150170 | **PRESENTATION:** | White crystalline powder for injection packed in a clear colourless glass vial with a blue coloured flip-off cap contained in a plastic blister rack supplied together with Sodium Bicarbonate for Injection in a transparent 1 mL glass ampoule and Sodium Chloride for Injection in a transparent 5 mL glass ampoule in a unit box. | |
| **MFG. DATE:** Powder: 06/06/2015 Diluent 1: 20/07/2015 Diluent 2: 14/07/2015 | **MANUFACTURER:** | GUILIN Pharmaceuticals Co., Ltd. | |
| **EXP. DATE:**  Powder: 05/06/2018 Diluent 1: 19/07/2019 Diluent 2: 13/07/2018 | **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:** | Uniformity of Weight, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | Not more than 2 vials deviate by more than 10% from the mean vial content weight | None deviates | **COMPLIES** |
| **Assay** | HPLC | Ph. Int., 5th Edition, 2015 | 90.0 - 110.0% | Artesunate 97.3% (RSD=0.7%; n=9) | **COMPLIES** |
| **Assay** | Titration | Ph. Int., 5th Edition, 2015 | 90.0 - 110.0% | Sodium Bicarbonate 100.8% (RSD=0.0%; n=3) | **COMPLIES** |
| **Assay** |  |  |  | Sodium Chloride 99.5% (RSD=1.2%; n=3) | **COMPLIES** |

**CONCLUSION:**

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| **ANALYST:** | KENNEDY RUTTO | .......................................................... | DATE: 11-04-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 08/11/2016 |
| **ANALYST:** | EMMANUEL TANUI | .......................................................... | DATE: 11-08-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-10-2016 |