**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/409

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| **PRODUCT** | ARTESUN(R) 60 mg INJECTION | | REF. NO: NDQA201512643 |
| **DATE RECEIVED:** 21.12.2015 | **LABEL CLAIM:** | Each box contains 1 vial of 60 mg artesunate powder, 1 ampoule of 1 mL sodium bicarbonate 50 mg/mL solution and 1 ampoule of 5 mL Sodium Chloride 9 mg/mL solution. | |
| **BATCH NO.:** Powder;ZA141027; Diluets;T141009,LN141108 | **PRESENTATION:** | White powder for reconstitution into injection solution for intravenous or intramuscular administration, contained in a clear colourless glass vial with a blue flip off cap and aluminium band, packed along with a clear colourless solution of sodium bicarbonate in a 1 mL clear 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. | |
| **MGF. DATE:** Powder 25.Sep.2014, Diluents 29.Oct.2014, 07.Nov.2014 | **MANUFACTURER:** | GUILIN Pharmaceuticals Co. Ltd. | |
| **EXP. DATE:**  Powder 24.Sep.2017Diluents 28.Oct.2018, 06.Nov 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 | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Sterility, Identification, Bacterial Endotoxin, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol .V App XII C | < 2 vial contents deviate by more than 10% from mean vial contents weight | 2 Deviate (-13% & -11%) | **COMPLIES** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V Appendix XVI A | No Microbial Growth | Powder and Diluents; No Microbial Growth | **COMPLIES** |
| **Identification** | HPLC | Ph. Int. 5th Edition 2015 (Online Version) | RT of the major peak in the sample preparation corresponds to that in the standard preparation | Super-imposable peak at RT 11.4 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | Ph. Int. 5th Edition 2015 (Online Version) | NMT 2.5 EU/mg | Artesunate 2.2\*10-4 EU/mg | **COMPLIES** |
| **Assay** | HPLC | Ph. Int. 5th Edition 2015 (Online Version):BP 2016 Vol. III Page 1117:BP 2016 Vol. III Page 1119 | Artesunate 90.0 - 110.0%; Sodium Bicarbonate 94.0 - 106.0% Sodium Chloride 95.0 - 105.0% | 94.6% (RSD=0.2%; n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Ph. Int. 5th Edition 2015 (Online Version):BP 2016 Vol. III Page 1117:BP 2016 Vol. III Page 1119 | Artesunate 90.0 - 110.0%; Sodium Bicarbonate 94.0 - 106.0% Sodium Chloride 95.0 - 105.0% | 102.2% (RSD=1.6%; n=3) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Ph. Int. 5th Edition 2015 (Online Version):BP 2016 Vol. III Page 1117:BP 2016 Vol. III Page 1119 | Artesunate 90.0 - 110.0%; Sodium Bicarbonate 94.0 - 106.0% Sodium Chloride 95.0 - 105.0% | 100.7% (RSD=0.5%, n=3) | **COMPLIES:COMPLIES:COMPLIES** |

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

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| ANALYST: | MR. E. NGAMAU |  | DATE:null |
| ANALYST: | DR. J. CHEPCHUMBA |  | DATE: |
| REVIEWER: | DR. E. MBAE |  | DATE: |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-02-2016 |