**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/617

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| **PRODUCT** | ARTESUN-PLUSÃ‚Â® TABLETS | | REF. NO: NDQD201508219 |
| **DATE RECEIVED:** 24.08.2015 | **LABEL CLAIM:** | Composition; Artesunate; 50.00 mg, Amodiaquine base 135.00 mg (in the form of Amodiaquine hydrochloride 176.32 mg)and Excipients q.s.p.: 1 tablet. | |
| **BATCH NO.:** SH140304 | **PRESENTATION:** | Off white and yellow coloured, bi-layered, circular shaped tablets, embossed '50' on the off white face and plain on the other , packed in an aluminium blister strip of 3 tablets in a unit box and 20 such boxes in a larger box. | |
| **MGF. DATE:** 22. Mar. 2014 | **MANUFACTURER:** | GUILIN Pharmaceuticals Co., Ltd. | |
| **EXP. DATE:**  21. Mar. 2016 | **ADDRESS:** | Add. No. 43 Qilidian Road, Guilin 541004, Guangxi, CHINA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy Board Of Sierra Leone, Central Medical Stores, Free Town, SIERRA LEONE | |
| PVG/GFM/FT-PUB/24/03/15 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of the major peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 2.0 and 8.5 Ãƒâ€šÃ‚Â± 10% min. present in both the assay sample preparation and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | Amodiaquine HCl 79.5% (RSD = 1.5%; n =6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | Artesunate 103.7% (RSD = 0.3%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Amodiaquine HCl 95.0% (RSD = 1.0%; n =9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Artesunate 100.8% (RSD = 0.0%; n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. E. MUTUA |  | DATE:04-02-2016 |
| ANALYST: | DR. M. KWENA |  | DATE:04-02-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:02-05-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-10-2016 |