**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-17/106

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| **PRODUCT** | ARTECOSPE(R) TABLETS | | **REF. NO: NDQD201603781** |
| **DATE RECEIVED:** 04-03-2016 | **LABEL CLAIM:** | Each tablet contains: Artesunate 50 mg Ph.Int.; Each tablet contains: Sulfadoxine 500 mg, Pyrimethamine 25 mg USP | |
| **BATCH NO.:** LS141001 | **PRESENTATION:** | Off white coloured, round shaped, flat faced co-packed tablets consisting of Sulfadoxine/Pyrimethamine which are single scored on one face and embossed 'S' and 'P' on alternate sides of the score and 'SP' on the other and Artesunate is single scored on one face and embossed 'AS' and '50' on alternate sides of the score and 'AS 50' on the other, packed in a bister strip of 4 tablets and 25 such strips in a unit box. | |
| **MFG. DATE:** 16-Sep-2014 | **MANUFACTURER:** | GUILIN Pharmaceuticals Co., Ltd. | |
| **EXP. DATE:**  15-Sep-2016 | **ADDRESS:** | No.43 Qilidian Road, Guilin 541004, Guangxi, CHINA. | |
| **CLIENT REF NO:** | **CLIENT:** | WHO - SOMALIA, WHO-SOMALIA liaison Office, Nairobi, KENYA | |
|  | **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 the mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of the component peak in the assay sample preparation correspond to that in the assay standard preparation | Super-imposable peak at RT 13.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | Artesunate Average = 93% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 93 - 94% (RSD=0.6%, n=6) |  |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Artesunate 98.9% (RSD=2.0%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | DR. L. KARANJA | .......................................................... | DATE: 22-08-2016 |
| **ANALYST:** | DR. H. KWENA | .......................................................... | DATE: 22-08-2016 |
| **ANALYST:** | DR. E. MBAE | .......................................................... | DATE: 22-08-2016 |
| **DIRECTOR:** | DR. H. K. CHEPKWONY | .......................................................... | DATE: 22-08-2016 |