**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-17/107

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| **PRODUCT** | ARTECOSPE(R) TABLETS | | **REF. NO: NDQD201603782** |
| **DATE RECEIVED:** 04-03-2016 | **LABEL CLAIM:** | Each tablet contains: Artesunate 100 mg Ph. Int.; Each tablet contains: Sulfadoxine 500 mg, Pyrimethamine 25 mg USP | |
| **BATCH NO.:** LS141005 | **PRESENTATION:** | Off white coloured, round shaped, flat faced co-packed tablets consisting of Sulfadoxine/Pyrimethamine tablets which are single scored and embossed 'S' and 'P' on alternate sides of the score on one face and 'SP' on the other and Artesunate tablets which are single scored and embossed 'AS' and '100' on alternate sides of the score on one face and 'AS 100' on the other, co-packed in a blister strip of 3 Sulfadoxine/Pyrimethamine tablets and 6 artesunate tablets and 25 such strips in a unit box. | |
| **MFG. DATE:** 18.Aug.2014 | **MANUFACTURER:** | GUILIN Pharmaceutical Co., Ltd. | |
| **EXP. DATE:**  27.Aug.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 corresponds 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 = 91% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 91-93% (RSD=0.9%, n=6) |  |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Artesunate 95.70% (RSD=1.5%, n=6) | **COMPLIES** |

**CONCLUSION:** the product complies with specification for the tests performed.

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