**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | ARTESUNATE TABLETS 50 mg + AMODIAQUINE TABLETS 150 mg | | REF. NO: NDQD201508230 |
| **DATE RECEIVED:** 24.08.2015 | **LABEL CLAIM:** | Each white tablet contains: Artesunate 50 mg & Each yellow tablet contains: Amodiaquine 150 mg | |
| **BATCH NO.:** 130106 | **PRESENTATION:** | Off white coloured, circular shaped, biconvex faced tablets, plain on both faces and yellow coloured, caplet shaped, biconvex faced tablets, single scored on one face and plain on the other, copacked in blister strip of 3 tablets each and 25 such blisters in a unit box. | |
| **MGF. DATE:** Jan.2013 | **MANUFACTURER:** | GEN ILAC A.S. | |
| **EXP. DATE:** Jan.2016 | **ADDRESS:** | TURKEY | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy Board Of Sierra Leone, Central Medical Stores, Free Town, SIERRA LEONE | |
| PVG/GFM/PL-PRI/05/03/15 | **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 IV App. XII C | Not more than 2 tablets deviate by more than 5% of the 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 Standard preparation. | Super-imposable peaks at RT 2.0 & 8.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC: | Adopted In-house Method | After 30 Mins No tablet is less than 80% | Amodiaquine HCl 85.3% (RSD = 2.2%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC: | Adopted In-house Method | After 30 Mins No tablet is less than 80% | Artesunate 83.4% (RSD = 0.5%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC: | Adopted In-house Method | 90.0 - 110.0% | Amodiaquine HCl 99.1% (RSD = 1.2%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC: | Adopted In-house Method | 90.0 - 110.0% | Artesunate 99.1% (RSD = 0.8%; n =9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | MICHAEL SANGALE |  | DATE:06-01-2016 |
| REVIEWER: | DR. WANG'ANG'A |  | DATE:06-01-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:01-11-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-26-2016 |