**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**

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| **PRODUCT** | ARTESUNATE AMODIAQUINE WINTHROPÃ‚Â® 50 mg/135 mg TABLETS | | REF. NO: NDQD201508225 |
| **DATE RECEIVED:** 24.08.2015 | **LABEL CLAIM:** | Artesunate 50.00 mg, Amodiaquine base 135.00 mg (as hydrochloride) 176.32 mg)and Excipients q.s.p. 1 tablet. | |
| **BATCH NO.:** 3MA026 | **PRESENTATION:** | White and yellow coloured bi-layered tablets, circular shaped with a score line, engraved 'AS' on either side of the score on one face one and '25' on the other, packed in a blister strip of 3 tablets and 25 such strips in a unit box. | |
| **MGF. DATE:** Nov. 2013 | **MANUFACTURER:** | MAPHAR. | |
| **EXP. DATE:**  Jan. 2016 | **ADDRESS:** | Casablanca, MOROCCO. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy Board Of Sierra Leone, Central Medical Stores, Free Town, SIERRA LEONE | |
| PVG/GFM/KEN-PUB/9/3/15 | **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 | < 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of the component Peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peak at RT 2.0 & 8.2 -/+ 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] | Amodiaquine Hcl 109.9%, (RSD=1.0%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No Tablet Less than 80%[n=6] | Artesunate 98.4% (RSD=0.2% n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 93.0 - 107.0% 90.0 - 110.0% | Amodiaquine Hcl 105.3% (RSD=1.1%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 93.0 - 107.0% 90.0 - 110.0% | Artesunate 97.8% (RSD=0.75%, n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | MR. M. SANGALE |  | DATE:07-01-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:07-01-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:01-11-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:02-25-2016 |