**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/584

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| **PRODUCT** | ASAQ ARTESUNATE AMODIAQUINE WINTHROPÃ‚Â® 25 mg/67.5 mg TABLETS | | REF. NO: NDQD201508227 |
| **DATE RECEIVED:** 24.08.2015 | **LABEL CLAIM:** | Each fixed dose combination contains: Artesunate 25.00 mg & Amodiaquine base 67.50 mg (as hydrochloride 88.16 mg) and Excipients q.s.p. | |
| **BATCH NO.:** 3MA025 | **PRESENTATION:** | Off white and yellow coloured bi-layered, circular shaped tablets, single scored and embossed 'A' & 'S' on either side of the score on the off white coloured face and embossed "25" on the other, packed in a blister strip of 3 tablets in a unit box and 25 such strips in a unit box. | |
| **MGF. DATE:** Aug. 2013 | **MANUFACTURER:** | MAPHAR. | |
| **EXP. DATE:**  Jul. 2016 | **ADDRESS:** | Maphar, Km 10, route cotiere 111, Zenata Ain Sebaa - Casablanca, MOROCCO. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy Board Of Sierra Leone, Central Medical Stores, Free Town, SIERRA LEONE | |
| PVG/FGM/FT -pub/20/3/15 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | B.P. 2016 Vol. IV App XII C | < 2 tablets deviate by more than 7.5% 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 106.9% (RSD=0.9%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-house Method | No tablet less than 80% (n=6) | Artesunate 100.3% (RSD=0.5%, n=9 | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-house Method | 90.0 - 110.0% | Amodiaquine Hcl 90.1%, (RSD=1.8%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-house Method | 90.0 - 110.0% | Artesunate 99.8% (RSD=0.5%, n=6) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. E. MUTUA |  | DATE:09-02-2016 |
| ANALYST: | DR.G. WANG'ANG'A |  | DATE:09-02-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-10-2016 |