**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | ARTESUNATE & AMODIAQUINE TABLETS (50 mg/135 mg) | | REF. NO: NDQD201508210 |
| **DATE RECEIVED:** 24.08.2015 | **LABEL CLAIM:** | Each bilayer tablet contains: Artesunate Ph. Int 50 mg Amodiaquine Hydrochloride USP equivalent to Amodiaquine Base 135 mg. | |
| **BATCH NO.:** CYY104011 | **PRESENTATION:** | White and yellow coloured, bilayered, circular shaped, flat faced, bevel edged tablets, single scored on the white face and packed in an aluminium blister strip of 3 tablets in a unit box and 25 such boxes packed in a larger box. | |
| **MGF. DATE:** Feb. 2014 | **MANUFACTURER:** | IPCA Laboratories Ltd. | |
| **EXP. DATE:**  Jan. 2016 | **ADDRESS:** | Plot No.255/1, Athal Silvassa 396 230 (D&NH), Regd.Off.:48,Kandivli Ind. Estate, Mumbai 400 067, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy Board Of Sierra Leone, Central Medical Stores, Free Town, SIERRA LEONE | |
| PVG/GFM/FT/Pub/17/3/15 | **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. V App XII C | NMT 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 preparations correspond to those in the assay standard preparations | Super-imposable peaks 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 87.6% (RSD =0.7%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-house Method | No tablet less than 80% [n=6] | Artesunate 96.9% (RSD =0.7%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-house Method | 90.0 - 110.0% | Amodiaquine 108.5% (RSD= 1.4%, n=7) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-house Method | 90.0 - 110.0% | Artesunate 97.9% (RSD=1.3%, n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | MR. M. SANGALE |  | DATE:06-01-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:06-01-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:01-11-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:02-11-2016 |