**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | BI-CORTEMÃ‚Â® SUSPENSION | | REF. NO: NDQD201508174 |
| **DATE RECEIVED:** 24.08.2015 | **LABEL CLAIM:** | Each 60 mL suspension after reconstition contains: Artemether 180 mg, Lumefantrine 1080 mg & Excipients q.s. | |
| **BATCH NO.:** 140407 | **PRESENTATION:** | Yellow powder for reconstitution into suspension for oral administration, contained in a 60 mL translucent plastic bottle, packed packed along with 30 mL transparent plastic measuring cap in a unit box. | |
| **MGF. DATE:** Apr. 2014 | **MANUFACTURER:** | SINOCHEM Ningbo Ltd. | |
| **EXP. DATE:** Apr. 2017 | **ADDRESS:** | Ningbo, P.R. CHINA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy Board Of Sierra Leone, Central Medical Stores, Free Town, SIERRA LEONE | |
|  | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Plate Count | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) <200 CFU/mL Total Combined Yeasts /Moulds Count (TYMC) <20 CFU/mL | < 10 TAMC CFU Per mL < 10 TYMC CFU Per mL | **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 peaks at RT; 5.5 & 5.6 Â± 10% min. present in both the assay sample and standard preparations. | **COMPLIES** |
| **Assay** | HPLC | Adopted In-house Method | 90.0-110.0% | Artemether 103.5% (RSD = 0.9%; n=9) Lumefantrine 94.3% (RSD = 0.4%; n=6) | **COMPLIES** |
| **Acidity/Alkalinity** | pH | Adopted In-house Method | 3.0-5.0 | 4.9 | **COMPLIES** |

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

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| ANALYST: | MR. F. NAULA |  | DATE:21-12-2015 |
| ANALYST: | DR. E. MUTUA |  | DATE:21-12-2015 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:21-12-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:12-23-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-15-2016 |