**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | BI-CORTEM TABLETS | | REF. NO: NDQD201508191 |
| **DATE RECEIVED:** 24.08.2015 | **LABEL CLAIM:** | Each tablet contains; Artemether 20 mg,Lumefantrine 120 mg. | |
| **BATCH NO.:** 140351 | **PRESENTATION:** | Yellow coloured circular shaped, biconvex faced tablets, plain on both faces, packed in blister strip of 6 tablets and 2 such strips in a unit box. | |
| **MGF. DATE:** Mar. 2014 | **MANUFACTURER:** | SINOCHEM Ningbo Ltd. | |
| **EXP. DATE:** Mar. 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:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2012 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean 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 assay standard preparation | Super-imposable peak at RT 3.8, 6.8 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC:UV | Adopted In-house Method:Adopted In-house Method | After 1 hour run No tablet less than 50.0%[n=6] After 3 hours run No tablet less than 70.0% [n=6] After 45 min run No tablet less than 65.0% [n=6] | Artemether 61.9% (RSD = 3.2%, n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:UV | Adopted In-house Method:Adopted In-house Method | After 1 hour run No tablet less than 50.0%[n=6] After 3 hours run No tablet less than 70.0% [n=6] After 45 min run No tablet less than 65.0% [n=6] | Artemether 80.7% (RSD = 2.7%, n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:UV | Adopted In-house Method:Adopted In-house Method | After 1 hour run No tablet less than 50.0%[n=6] After 3 hours run No tablet less than 70.0% [n=6] After 45 min run No tablet less than 65.0% [n=6] | Lumefantrine 98.9% (RSD = 3.6%, n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-house Method | 95.0 - 105.0% | Artemether 98.7% (RSD = 1.4%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-house Method | 95.0 - 105.0% | Lumefantrine 104.3% (RSD = 1.7%, n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:29-12-2015 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:29-12-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:01-06-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-20-2016 |