**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | LONART-DS TABLETS | | REF. NO: NDQD201508182 |
| **DATE RECEIVED:** 24.08.2015 | **LABEL CLAIM:** | Each film coated tablet contains; Artemether 80 mg, Lumefantrine 480 mg,Excipients q.s. | |
| **BATCH NO.:** LD-594 | **PRESENTATION:** | Yellow coloured, circular shaped, flat faced, bevel edged tablets,single scored on one face and embossed 'BG' on the other, packed in blister strip of 12 tablets and 30 such strips packed in a box. | |
| **MGF. DATE:** Jun. 2014 | **MANUFACTURER:** | BLISS GVS Pharma Ltd. | |
| **EXP. DATE:** May 2016 | **ADDRESS:** | Factory: 10, Dewan Udyog Nagar , Aliyali, Palghar, Maharashtra-401404, Regd. Off.: 102, HYDE Park, Saki Vihar Road, Andheri (E), Mumbai-400 072, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy Board Of Sierra Leone, Central Medical Stores, Free Town, SIERRA LEONE | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Uniformity of Content, 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 Peak in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peak at RT 3.8, 5.6 -/+ 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 67.6% (RSD = 5.4%; 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 90.6% (RSD = 1.6%; 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 91.6% (RSD = 7.5%; n = 6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted InÃ¢â‚¬â€œhouse Method | 95.0 - 105.0% | Artemether 101.1% (RSD = 1.5%; n = 9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted InÃ¢â‚¬â€œhouse Method | 95.0 - 105.0% | Lumefantrine 99.4% (RSD = 0.9%; 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:01-19-2016 |