**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-2016/259

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| **PRODUCT** | GVITHER FORTE INJECTION | | REF. NO: NDQD201508196 |
| **DATE RECEIVED:** 24.08.2015 | **LABEL CLAIM:** | Each ampoule contains: Artemether 80mg/ml | |
| **BATCH NO.:** B1A13006 | **PRESENTATION:** | Clear, colourless solution for intramuscular administration contained in clear, colourless, 1 mL glass ampoule. Packed in a blister pack carrying 5 ampoules and 2 such rack in a unit box. | |
| **MGF. DATE:** Jul.2013 | **MANUFACTURER:** | Bliss GVS Pharma Ltd. | |
| **EXP. DATE:**  Jun.2016 | **ADDRESS:** | At:Plot No. 73 to 76, Silver Industrial Estate, Bhimpore, Daman -396 210(UT)Regd. Off.:102,Hydepark,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 | |
| PUG/FIFM/FT-PM/09/03/0115 | **TEST(S) REQUESTED:** | Sterility, Identification, Bacterial Endotoxin, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App. XVI A | No microbial growth | No microbial growth | **COMPLIES** |
| **Identification** | HPLC | Int. Ph. 5th Edition 2015 | RT of the Major Peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 9.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | Int. Ph. 5th Edition 2015 | NMT 4.37 EU/mg | 2.2\*10-4 EU/mg | **COMPLIES** |
| **Assay** | HPLC | Int. Ph. 5th Edition 2015 | 95-105 | 104.2% (RSD = 0.9% ; n = 9) | **COMPLIES** |

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

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| ANALYST: | MR. E. NGAMAU |  | DATE:09-02-2016 |
| ANALYST: | MR. M. SANGALE |  | DATE:09-02-2016 |
| ANALYST: | DR. M. KWENA |  | DATE:09-02-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:02-12-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-01-2016 |