**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | FANTEM ORAL SUSPENSION | | REF. NO: NDQD201508178 |
| **DATE RECEIVED:** 24.08.2015 | **LABEL CLAIM:** | Each 60 mL suspension after reconstitution contains: Artemether 180mg, Lumefantrine 1080mg & Excipients q.s. | |
| **BATCH NO.:** M140291 | **PRESENTATION:** | Yellow powder for reconstitution into suspension for oral administration, contained in a 60 mL transparent plastic bottle, packed packed along with a 22 mL transparent measuring cap in a unit box. | |
| **MGF. DATE:** Mar. 2014 | **MANUFACTURER:** | The MADRAS Pharmaceuticals. | |
| **EXP. DATE:** Feb. 2016 | **ADDRESS:** | 137-B, Old Mahabalipuram Road, Karapakkam, Chennai - 600 096. INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy Board Of Sierra Leone, Central Medical Stores, Free Town, SIERRA LEONE | |
| PVG/GFM/KEN-PRI/12/3/15 | **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 2013 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 5.4 & 5.6 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | Adopted In-house Method | 90.0 - 110.0% | Lumefantrine 99.6% (RSD = 1.7%; n = 9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-house Method | 90.0 - 110.0% | Artemether 104.0% (RSD = 0.6%; n = 9) | **COMPLIES: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 |