**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/626

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| **PRODUCT** | ARTEFAN SUSPENSION | | REF. NO: NDQA201511464 |
| **DATE RECEIVED:** 02.11.2015 | **LABEL CLAIM:** | Each 60 mL suspension after reconstitution contains; Artemether Ph.Int. 180 mg, Lumefantrine 1080 mg. | |
| **BATCH NO.:** SB0074F | **PRESENTATION:** | Yellow fine granules for reconstitution into suspension for oral administration, contained in a 60 mL transparent plastic bottle, packed along with 15 mL transparent plastic measuring cap in a unit box. | |
| **MGF. DATE:** Jun.2014 | **MANUFACTURER:** | AJANTA Pharma Limited. | |
| **EXP. DATE:**  May 2017 | **ADDRESS:** | Ajanta House, Charkop, Kandivli (W), Mumbai 400 067, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| KEN/AL/NAI/12/09/2014/63 | **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 peak at RT 5.5 and 5.6 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | Adopted In-house Method | 90.0 - 110.0% | Artemether 93.6% (RSD=0.5%; n=9) Lumefantrine 82.9% (RSD=?????%; n=6) | **DOES NOT COMPLY** |
| **Acidity/Alkalinity** | pH | Adopted In-house Method | 3.0 - 5.0 | 4.2 | **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:05-10-2016 |