**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/102

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| **PRODUCT** | ARTESUNATE SUPPOSITORIES 100 mg | | **REF. NO: NDQD2016061236** |
| **DATE RECEIVED:** 30.06.2016 | **LABEL CLAIM:** | Each rectal suppository contains: Artesunate Ph.. Int .100 mg. | |
| **BATCH NO.:** KB60177 | **PRESENTATION:** | Off white coloured elongated soft gelatin suppository, containing off white paste, packed in an aluminium blister strip of 2 suppositories in a unit box. | |
| **MFG. DATE:** Feb. 2016 | **MANUFACTURER:** | CIPLA Ltd. | |
| **EXP. DATE:**  Jan. 2018 | **ADDRESS:** | MIDC Kurkumbh, Dist. Pune 413 802, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | PHARMA SPECIALITIES Ltd P.O. Box 49146- 00100 GPO, Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Microbial Load, Identification, Disintegration, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | NMT 2 suppositories deviate by more than 5% from mean suppository weight | None Deviates | **COMPLIES** |
| **Microbial Load** | Plate Count | BP 2016 Vol. V App.XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL | < 10 CFU/mL | **COMPLIES** |
| **Microbial Load** |  |  | Total Combined Yeasts/ Moulds Count (TYMC) NMT 20 CFU/mL | < 10 CFU/mL |  |
| **Identification** |  | Manufacturer's In-House Method | RT of the major peak in the assay sample preparation correspond to that in the assay standard preparation |  | **COMPLIES** |
| **Identification** | HPLC |  |  | Super-imposable peak at RT 17.3 -/+ 10% min. present in both the assay sample and standard preparations |  |
| **Disintegration** |  | Manufacturer's In-House Method | All suppositories disintegrate eithin 30 Mins | All suppositories disintegrated within 08 mins | **COMPLIES** |
| **Assay** |  | Manufacturer's In-House Method | 95.0 - 105.0% |  | **COMPLIES** |
| **Assay** | HPLC |  |  | 95.4% (RSD=0.1%, n=6) |  |

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

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| **ANALYST:** | MR.F. NAULA | .......................................................... | DATE: 02-09-2016 |
| **ANALYST:** | DR. E. MUTUA/SARAH | .......................................................... | DATE: 02-09-2016 |
| **ANALYST:** | DR. N. MWAURA | .......................................................... | DATE: 02-09-2016 |
| **ANALYST:** | DR.E. MBAE | .......................................................... | DATE: 02-09-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-22-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-26-2016 |