**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/621

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| **PRODUCT** | NEVIMUNE ORAL SUSPENSION | | REF. NO: NDQB201601674 |
| **DATE RECEIVED:** 26.01.2016 | **LABEL CLAIM:** | Each 5 mL contains: Nevirapine (as hemihydrate) USP 50 mg. | |
| **BATCH NO.:** IA50426 | **PRESENTATION:** | White coloured suspension for oral administration contained in a 100 mL amber coloured plastic bottle packed along with a 2 mL syringe with a dust cap, a plastic dispenser and a 10 mL plastic measuring cap in a unit box. | |
| **MGF. DATE:** Apr. 2015 | **MANUFACTURER:** | CIPLA Ltd. | |
| **EXP. DATE:**  Mar. 2017 | **ADDRESS:** | Plot No. 9 & 10, Indore SEZ, Pithampur, M.P.-454 775, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P.O. Box 47715 - 00100, Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Microbial Load | BP 2016 vol. V App. XVI B | Total Aerobic Microbial Count < 200 (CU)/ mL :Total Combined Yeasts /Moulds Count < 20 (CFU)/ mL | < 10 CFU/ mL | **COMPLIES:COMPLIES** |
| **Microbial Load** | Microbial Load | BP 2016 vol. V App. XVI B | Total Aerobic Microbial Count < 200 (CU)/ mL :Total Combined Yeasts /Moulds Count < 20 (CFU)/ mL | < 10 CFU/ mL | **COMPLIES:COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 4538 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super- imposable peak at 32.0 Ã‚Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 4538 | 90.0 - 110.0% | 96.1% (RSD=0.4%, n=9) | **COMPLIES** |
| **Acidity/Alkalinity** | pH | BP 2016 Vol. V App. VL | - | 5.9 | **COMPLIES** |

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

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|  |  |  | DATE: |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-10-2016 |