**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/99

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| **PRODUCT** | NEVIMUNE ORAL SUSPENSION | | **REF. NO: NDQB201607009** |
| **DATE RECEIVED:** 2016-07-05 | **LABEL CLAIM:** | Each 5 mL contains Nevirapine (as hemihydrate) USP 50 mg. | |
| **BATCH NO.:** IA50850 | **PRESENTATION:** | White coloured suspension for oral administration contained in an amber coloured 100 mL plastic bottle packed along with a clear plastic pouch containing a plastic cannula, 2 mL syringe with a dust cap and a 10 mL graduated measuring cap and packed in a unit box. | |
| **MFG. DATE:** Jul. 2015 | **MANUFACTURER:** | CIPLA Ltd. | |
| **EXP. DATE:**  Jun. 2017 | **ADDRESS:** | Plot 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. | |
| NVP/09/06/2016/155 | **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 Counts (TAMC) NMT 200 CFU/mL | < 10 CFU/mL | **COMPLIES** |
| **Microbial Load** |  |  | Total Combined Teast/Moulds Counts (TYMC) NMT 20 CFU/mL | < 10 CFU/mL | **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 RT 5.6 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | - | - | 5.8 |  |
| **Assay** | HPLC | USP 38 NF 33 page 4538 | 90.0 - 110.0% | 101.4% (RSD=0.6%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | FRANCIS NAULA | .......................................................... | DATE: 07-08-2016 |
| **ANALYST:** | JOYFRIDA CHEPCHUMBA | .......................................................... | DATE: 07-12-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 22-09-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-22-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-26-2016 |