**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/109

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| **PRODUCT** | NEVIMUNE ORAL SUSPENSION | | **REF. NO: NDQD2016061009** |
| **DATE RECEIVED:** 2016-06-03 | **LABEL CLAIM:** | Each 5 mL contains Nevirapine (as hemihydrate) USP 50 mg. | |
| **BATCH NO.:** IA50434 | **PRESENTATION:** | Off white coloured suspension for oral administration contained in an amber coloured 100 mL plastic bottle packed along with a clear 5 mL graduated plastic measuring cup and a 2 mL graduated plastic syringe with a dust cap and a cannula in a unit box | |
| **MFG. DATE:** Apr 2015 | **MANUFACTURER:** | Cipla Ltd. | |
| **EXP. DATE:**  Mar 2017 | **ADDRESS:** | Plot 9 & 10, Indore SEZ, Pithampur, M.P. - 454 775, INDIA | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme, P. O. Box 19361 - 00202, Nairobi, KENYA. | |
| NVP/10/07.03.2016/0032 | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Identification** | HPLC | USP 38 NF 33 Page 4538 | RT of the Major Peak in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peak at RT 3.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 4538 | 90.0 - 110.0 % | 99.0% (RSD = 0.9%, n=9) | **COMPLIES** |
| **Microbial Load** | Plate Count | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL | TAMC < 10 CFU/mL | **COMPLIES** |
| **Microbial Load** |  |  | Total Combined Yeasts/ Moulds Count (TYMC) NMT 20 CFU/mL | TYMC < 10 CFU/mL |  |

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

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| **ANALYST:** | FRANCIS NAULA | .......................................................... | DATE: 06-21-2016 |
| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 07-01-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 07-11-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 07-21-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-27-2016 |