**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | NEVIRAPINE ORAL SUSPENSION | | REF. NO: NDQD201508110 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each 5 ml contains: Nevirapine USP (as Nevirapine hemihydrate) 50 mg | |
| **BATCH NO.:** NR0513061-A | **PRESENTATION:** | White coloured suspension for oral administration contained in a 100 mL white coloured plastic bottle packed along with a syringe in a unit box. | |
| **MGF. DATE:** Jul.2013 | **MANUFACTURER:** | Aurobindo Pharma LImited. | |
| **EXP. DATE:** Jun.2016 | **ADDRESS:** | Unit III, Survey No. 313, Bachupally village, Quthubullapur Mandal, Ranga Reddy District (A.P.) INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme P.O. BOX 19361 Nairobi | |
| NVP/09/13.03.2015/354 | **TEST(S) REQUESTED:** | pH, Microbial Load, Identification, Assay | |

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **pH** | Acidity/Alkalinity | B.P. 2012 Vol .V App XII C | 4.5 - 6.5 | 5.4 | **COMPLIES** |
| **Microbial Load** | Plate Count Method | In House Method | Total Aerobic Microbial Count < 200 (CU)/ mL :Total Combined Yeasts /Moulds Count < 20 (CFU)/ mL | TAMC< 200 CFU/ mL | **COMPLIES** |
| **Microbial Load** | Plate Count Method | In House Method | Total Aerobic Microbial Count < 200 (CU)/ mL :Total Combined Yeasts /Moulds Count < 20 (CFU)/ mL | TCYMC< 200 CFU/ mL | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 2015 VOL 3 PG 4538-4539 | RT of the Component Peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT Value | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 2015 VOL 3 PG 4538-4539 | RT of the Component Peak in the assay sample preparation corresponds to that in the assay standard preparation | 8.2 Ã‚Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 2015 VOL 3 PG 4538-4539 | 90-110 | 98.3% RSD=0.8%,n=9,) | **COMPLIES** |

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

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| ANALYST: | MR. F. NAULA |  | DATE:08-12-2015 |
| ANALYST: | DR. L. KARANJA |  | DATE:09-08-2015 |
| ANALYST: | DR. E. MBAE |  | DATE:24-09-2015 |
| ANALYST: | DR. S. MUTERU |  | DATE:05-10-2015 |