**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | 0 | | REF. NO: NDQD201508107 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each 5 ml contains: Nevirapine USP (as Nevirapine hemihydrate) 50 mg | |
| **BATCH NO.:** NR0513048-A | **PRESENTATION:** | White coloured suspension for oral administration contained in a 100 mL white coloured plastic bottle fitted with a child proof cap packed along with a syringe in a unit box. | |
| **MGF. DATE:** May2013 | **MANUFACTURER:** | Aurobindo Pharma LImited | |
| **EXP. DATE:** Apr.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/07/10.3.2015/00103 | **TEST(S) REQUESTED:** | pH, Microbial Load, Identification, Assay | |

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **pH** | Acidity/Alkalinity | USP 38 NF 33 Vol 3 Page 4538-4539 | 4.5 - 6.5 | 5.5 | **COMPLIES** |
| **Microbial Load** | Plate count | In - House Method | Total Aerobic Microbial Count < 200 (CU)/ mL :Total Combined Yeasts /Moulds Count < 20 (CFU)/ mL | TAMC< 200 CFU/ mL | **COMPLIES:COMPLIES** |
| **Microbial Load** | Plate count | In - House Method | Total Aerobic Microbial Count < 200 (CU)/ mL :Total Combined Yeasts /Moulds Count < 20 (CFU)/ mL | TYMC< 20 CFU/ mL | **COMPLIES:COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Vol 3 Page 4538-4539 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super- imposable peak at 8.2 Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Vol 3 Page 4538-4539 | 90-110 | 103.5% RSD=0.4%,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: | SERAH MUTERU |  | DATE:10-05-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:10-07-2015 |