**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | NEVIRAPINE TABLETS, USP 200 mg | | REF. NO: NDQD201508147 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each tablet contains 200 mg of Nevirapine USP. | |
| **BATCH NO.:** E140643 | **PRESENTATION:** | White coloured, caplet shaped, biconvex faced, single scored on both faces tablets and embossed with 'H' and '7' on respective half-sided of each scored face, packed in a white multi-dose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Apr. 2014 | **MANUFACTURER:** | HETERO Labs Limited. | |
| **EXP. DATE:** Mar. 2018 | **ADDRESS:** | 22 - 110, I.D.A., Jeedimetla, Hyderabad - 500 055, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme P.O. BOX 19361 Nairobi | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | B.P. 2012 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of the main peak in the assay sample preparation correspond to that in the assay standard preparation | Super-imposable peak at RT 5.4 Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80% [n = 6] | 97.0% (RSD = 4.1%; n = 6) | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | 102.3% (RSD = 0.6%; n = 9) | **COMPLIES** |

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

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| ANALYST: | DR. E. MUTUA |  | DATE:01-10-2015 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:19-10-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:11-04-2015 |