**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/832

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| **PRODUCT** | NEVIRAPINE TABLETS USP 200 mg | | **REF. NO: NDQD201606992** |
| **DATE RECEIVED:** 02.06.2016 | **LABEL CLAIM:** | Each tablet contains: 200 mg of Nevirapine USP. | |
| **BATCH NO.:** E140583 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, single scored on both faces and embossed 'H' on one face and '7' on the other on one side of the core, packed in a white plastic multidose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Mar. 2014 | **MANUFACTURER:** | HETERO Labs Limited. | |
| **EXP. DATE:** Feb. 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 - 00202, Nairobi, KENYA. | |
| NVP/11/10.03.2016/163 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 4540 | No tablet less than 80% [n=6] | 81.8% (RSD=0.8%, n=6) | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 4540 | RT of the component peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 4.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 4540 | 90.0 - 110.0% | 102.3% (RSD=0.7%, n=6) | **COMPLIES** |

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

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| **ANALYST:** | DR. E. MUTUA | .......................................................... | DATE: 17-06-2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 23-06-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 06-28-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-18-2016 |