**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/827

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| **PRODUCT** | NEVIRAPINE TABLETS USP 200 mg | | **REF. NO: NDQD201606987** |
| **DATE RECEIVED:** 02.06.2016 | **LABEL CLAIM:** | Each tablet contains: 200 mg of Nevirapine USP. | |
| **BATCH NO.:** E140644 | **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, packed in a white plastic multidose 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 - 00202, Nairobi, KENYA. | |
| NVP/02/10.03.2016/0235 | **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 | 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** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 4540 | No tablet less than 80% [n=6] | 83% (RSD=2.0%, n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 4540 | 90.0 - 110.0% | 100.3% (RSD=0.9%, n=9) | **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 |