**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/726

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| **PRODUCT** | NEVIRAPINE TABLETS USP 200 mg | | REF. NO: NDQB201605925 |
| **DATE RECEIVED:** 12.05.2016 | **LABEL CLAIM:** | Each tablet contains 200 mg of Nevirapine USP. | |
| **BATCH NO.:** E160371 | **PRESENTATION:** | 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:** Mar. 2016 | **MANUFACTURER:** | HETERO Labs Limited. | |
| **EXP. DATE:**  Feb. 2021 | **ADDRESS:** | 22-110, I.D.A., Jeedimetla, Hyderabad - 500 055, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P.O. Box 47715 - 00100, Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Identification** |  | Adopted In-House Method | RT of the component peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 6.7 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** |  | Adopted In-House Method | No tablet less than 80% [n=6] | 99.0% (RSD=1.9%, n=6) | **COMPLIES** |
| **Assay** |  | Adopted In-House Method | 90% - 110% | 95.7% (RSD=0.5%, n=9) | **COMPLIES** |
| **Uniformity of Weight** |  | BP 2016 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |

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

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| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:23-05-2016 |
| ANALYST: | DR. N. MWAURA |  | DATE:08-06-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:06-14-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:06-14-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-16-2016 |