**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/416

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| **PRODUCT** | NEVIRAPINE TABLETS USP 200 mg | | REF. NO: NDQB201601702 |
| **DATE RECEIVED:** 26.01.2016 | **LABEL CLAIM:** | Each tablet contains 200 mg of Nevirapine USP | |
| **BATCH NO.:** E141660 | **PRESENTATION:** | White coloured, caplet shaped, biconvex faced tablets, single scored on both faces and embossed 'H' on one face and '7' on the opposite face on either side of the score, packed in a white plastic multi-dose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Sep. 2014 | **MANUFACTURER:** | HETERO Labs Ltd. | |
| **EXP. DATE:**  Aug. 2018 | **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** |
| **Uniformity of Weight** | Weight | BP 2012 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 major peak in the assay sample preparation corresponds to those in the standard preparation | Super-imposable peak at RT 9.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 4540 | No tablet less than 80.0% [n=6] | 92.9% (RSD=1.7%; n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 4540 | 90.0 - 110.0% | 98.7% (RSD=0.4%; n=9) | **COMPLIES** |

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

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| ANALYST: | DR. E. MUTUA |  | DATE:19-02-2016 |
| ANALYST: | DR. E. TANUI |  | DATE:01-03-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:03-02-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-04-2016 |