**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/798

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| **PRODUCT** | NEVIRAPINE TABLETS USP 200 mg | | REF. NO: NDQB201605957 |
| **DATE RECEIVED:** 19.05.2016 | **LABEL CLAIM:** | Each tablet contains Nevirapine USP 200 mg. | |
| **BATCH NO.:** 3050442 | **PRESENTATION:** | White coloured, elliptical shaped, biconvex faced tablets, single scored on both faces, and alternately embossed 'M' and '107' either half of the score on one face, packed in a white plastic multi-dose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Feb. 2016 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Jan. 2019 | **ADDRESS:** | H-12 & H-13, MIDC, Waluj, Aurangabad - 431136, Maharashtra, 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** |  | 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** |  | USP 38 NF 33 Page 4540 | No tablet less than 80% [n=6] | 97.1% (RSD=3.6%, n=6) | **COMPLIES** |
| **Assay** |  | USP 38 NF 33 Page 4540 | 90.0 - 110.0% | 94.1% (RSD=1.8%, n=6 | **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. E. MUTUTA |  | DATE:27-05-2016 |
| ANALYST: | DR. S. MUTERU |  | DATE:06-22-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:06-28-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-30-2016 |