**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/405

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| **PRODUCT** | NEVIRAPINE TABLETS USP 200 mg | | REF. NO: NDQB201601701 |
| **DATE RECEIVED:** 26.01.2016 | **LABEL CLAIM:** | Each tablet contains Nevirapine USP 200 mg. | |
| **BATCH NO.:** 3039128 | **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:** Apr. 2015 | **MANUFACTURER:** | MYLAN Laboratories Ltd. | |
| **EXP. DATE:**  Mar. 2018 | **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** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean 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 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% [n=6] | 94.2% (RSD=1.5%; n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 4540 | 90.0 - 110.0% | 97.5% (RSD=0.6%, 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:29-02-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:03-01-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-02-2016 |