**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/649

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| **PRODUCT** | NEVIRAPINE TABLETS USP 200 mg | | REF. NO: NDQB201603805 |
| **DATE RECEIVED:** 15.03.2016 | **LABEL CLAIM:** | Each tablet contains: Nevirapine USP 200mg. | |
| **BATCH NO.:** 3038941 | **PRESENTATION:** | Off-white coloured, caplet shaped, biconvex faced tablets, single scored on both faces and embossed 'M' and '107' on either side of the score on one face, packed in a white plastic multidose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Apr. 2015 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **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 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 4.3 -/+ 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] | 96.0% (RSD=1.2%, n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 4540 | 90.0% - 110.0% | 94.7% (RSD=0.9%, n=9) | **COMPLIES** |

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

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| ANALYST: | MR. M. SANGALE |  | DATE:17-05-2016 |
| ANALYST: | DR. N. MWAURA |  | DATE:19-05-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:05-25-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-30-2016 |