**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/92

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| **PRODUCT** | NEVIRAPINE TABLETS USP 200 mg | | **REF. NO: NDQB201607023** |
| **DATE RECEIVED:** 14-07-2016 | **LABEL CLAIM:** | Each Tablet contains: Nevirapine USP 200 mg. | |
| **BATCH NO.:** 3050513 | **PRESENTATION:** | White coloured, caplet shaped, biconvex faced tablets, single scored on both faces and embossed 'M' and '107' on alternate sides of the score on one face, 60 tablets packed in a white plastic multidose container in a unit box. | |
| **MFG. 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** |
| **Uniformity of Weight** | Tablets | BP 2016 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from the 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 that in the assay standard preparation | Super-imposable peak at RT 5.9 -/+ 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] | Average = 101.0% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 93.0 - 106.0% (RSD=5.0%, n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 4540 | 90.0 - 110.0 % | 95.5% (RSD=0.5%, n=9) | **COMPLIES** |

**CONCLUSION:** The sample complies with the specifications of the tests performed.

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| **ANALYST:** | DR. S. MWANGI | .......................................................... | DATE: 12-08-2016 |
| **ANALYST** | DR. E. TANUI | .......................................................... | DATE: 21-09-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-21-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-22-2016 |