**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/314

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| **PRODUCT** | NEVIRAPINE TABLETS USP 200 MG | | **REF. NO: NDQB201609130** |
| **DATE RECEIVED:** 2016-09-29 | **LABEL CLAIM:** | Each tablet contains: Nevirapine USP 200 mg. | |
| **BATCH NO.:** 3050441 | **PRESENTATION:** | Off white coloured, eliptically shaped,biconvex shaped tablets, single scored on both faces and embossed 'M' and '107' on either side of the score on one face, packed in a white coloured, multi-dose container carrying 60 tablets. | |
| **MFG. DATE:** Feb. 2016 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Jan. 2019 | **ADDRESS:** | H-12 & H-13, MIDC, Waluj, Aurangabad - 431136, Maharashtra, Maharashtra, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P. O. Box 47715 - 00100, Nairobi, KENYA. | |
| NVP/20/09/2016/160 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPENDIA** | **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 major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 11.7 -/+ 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% | 95.2% (Range | **COMPLIES** |
| **Dissolution** |  |  |  | 94 - 96%) (RSD = 0.9%; n = 6) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 4540 | 90.0 - 110.0% | 96.0% (RSD = 1.9%; n = 9) | **COMPLIES** |

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

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| **ANALYST:** | MS. S. KARIUKI | .......................................................... | DATE: 10-03-2016 |
| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 11-14-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 11-29-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-29-2016 |