**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/37

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| **PRODUCT** | NEVIRAPINE TABLETS USP 200 mg | | **REF. NO: NDQB201605958** |
| **DATE RECEIVED:** 2016-05-19 | **LABEL CLAIM:** | Each tablet contains: Nevirapine USP 200 mg. | |
| **BATCH NO.:** 3050364 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex tablets, single scored on both faces and alternatively embossed â€˜Mâ€™ and '107' on either side of the score on one face, 60 tablets packed in a plastic multidose container in a printed 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** | Weight | B.P. 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 Vol. 3 Page 4540 | RT of the component peak in the assay sample preparation correspond to that in the assay standard preparation | Super-imposable peak at RT 8.4 ± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Vol. 3 Page 4540 | No Tablet Less Than 75% [n=6] | Average 97%, Range 94% - 99%, (RSD=2.0%, n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Vol. 3 Page 4540 | 90.0 - 110.0% | Average 104.8% (RSD=0.4%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | ERIC MUTUA | .......................................................... | DATE: 05-27-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 07-18-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 08-02-2016 |