**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/95

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| **PRODUCT** | NEVIRAPINE TABLETS USP 200 mg | | **REF. NO: NDQB201607002** |
| **DATE RECEIVED:** 05.07.2016 | **LABEL CLAIM:** | Each tablet contains: Nevirapine USP 200 mg. | |
| **BATCH NO.:** 3039203 | **PRESENTATION:** | Off-white coloured, caplet shaped, biconvex faced tablets, single scored on both faces and embossed 'M and '107' on alternative sides of the score on one face, packed in a white plastic multidose container carrying 60 tablets in a unit box. | |
| **MFG. 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. | |
| NVP/09.06.2016/156 | **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 major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 4.6 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 4540 | Not less than 80.0% [n=6] | Average = 92%, Range | **COMPLIES** |
| **Dissolution** |  |  |  | 90 - 95% (RSD=2.6%, n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 4540 | 90.0 - 110.0% | 92.9% (RSD=0.2%; n=9) | **COMPLIES** |

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

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| **ANALYST:** | DR. J. CHEPCHUMBA | .......................................................... | DATE: 13-09-2016 |
| **ANALYST:** | DR. R. MANANI | .......................................................... | DATE: 13-09-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-21-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-22-2016 |