**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/299

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| **PRODUCT** | LAMIVUDINE / NEVIRAPINE / ZIDOVUDINE TABLETS 150 mg/200 mg/300 mg | | **REF. NO: NDQB201609133** |
| **DATE RECEIVED:** 29.09.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Lamivudine USP 150 mg, Nevirapine USP 200 mg and Zidovudine USP 300 mg. | |
| **BATCH NO.:** 3035605 | **PRESENTATION:** | Blue coloured, caplet shaped, biconvex faced tablets, embossed â€˜M104â€™ on one face and plain on the other; packed in a white multidose plastic container of 60 tablets in a printed box. | |
| **MFG. DATE:** Feb. 2015 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Jan. 2018 | **ADDRESS:** | F-4 & F-12, MIDC, Malegaon, Sinnar, Nashik - 422 113, Maharashtra, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P. O. Box 47715 - 00100, Nairobi, KENYA. | |
| 3TC/NVP/AZT/19/09/2016/159 | **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 | Adopted In-house Method | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 2.9, 5.2 and 3.7 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-house Method | No tablet less than 80.0% | Lamivudine 99.0%, (Range | **COMPLIES** |
| **Dissolution** |  |  |  | 98 - 100%) (RSD=1.0%; n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Nevirapine 101.2% (Range | **COMPLIES** |
| **Dissolution** |  |  |  | 99 - 105%) (RSD=2.8%; n=6) |  |
| **Dissolution** |  |  |  | Zidovudine 99.7% (Range |  |
| **Dissolution** |  |  |  | 98 - 103%) (RSD=2.4%; n=6) |  |
| **Assay** | HPLC | Adopted In-house Method | 90.0 - 110.0% | Lamivudine 103.4% (RSD=0.7%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Nevirapine 103.5% (RSD=0.9%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Zidovudine 104.0% (RSD=1.9%; n=8) | **COMPLIES** |

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

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| **ANALYST:** | KENNEDY RUTTO | .......................................................... | DATE: 10-03-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 25-11-2016 |
| **ANALYST:** | NICHOLAS MWAURA | .......................................................... | DATE: 11-25-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-29-2016 |