**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/128

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| **PRODUCT** | LAMIVUDINE/NEVIRAPINE/ZIDOVUDINE 150 mg/200 mg/300 mg TABLETS | | **REF. NO: NDQB201607006** |
| **DATE RECEIVED:** 2016-07-05 | **LABEL CLAIM:** | Each film coated tablet contains: Lamivudine USP 150 mg, Nevirapine USP 200 mg and Zidovudine USP 300 mg. | |
| **BATCH NO.:** 3037355 | **PRESENTATION:** | Blue coloured, caplet shaped, biconvex faced tablets embossed 'M104' on one face plain on the other, 60 tablets packed in a white plastic multidose container in a unit box. | |
| **MFG. DATE:** Mar. 2015 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Feb. 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/07/06/2016/154 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BB 2016 Vol. V App. XII C | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of major peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 3.1, 5.0 and 10.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | Not Tablet less than 80% | Lamivudine Average = 100% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 95 - 103% (RSD=3.0%, n=6) |  |
| **Dissolution** |  |  |  | Nevirapine Average = 97%, Range |  |
| **Dissolution** |  |  |  | 94 - 100% (RSD=2.2%, n=6) |  |
| **Dissolution** |  |  |  | Zidovudine Average = 99% Range |  |
| **Dissolution** |  |  |  | 95 - 102% (RSD=2.5%, n=6) |  |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Lamivudine 100.3% (RSD=0.9%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Nevirapine 99.9% (RSD=0.4%, n=9) |  |
| **Assay** |  |  |  | Zidovudine 101.0% (RSD=0.4%, n=9) |  |

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

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| **ANALYST:** | JOYFRIDA CHEPCHUMBA | .......................................................... | DATE: 07-12-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-27-2016 |
| **REVIEWER** | DR. EMMANUEL TANUI | .......................................................... | DATE: 27-Sep-16 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-29-2016 |