**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/292

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| **PRODUCT** | LAMIVUDINE / NEVIRAPINE / ZIDOVUDINE DISPERSIBLE TABLETS 30 mg/50 mg/60 mg | | **REF. NO: NDQB201610189** |
| **DATE RECEIVED:** 25.10.2016 | **LABEL CLAIM:** | Each dispersible tablets contains: Lamivudine USP 30 mg, Nevirapine USP 50 mg and Zidovudine USP 60 mg. | |
| **BATCH NO.:** 3032431 | **PRESENTATION:** | Cream coloured, circular shaped, bevel edged tablets, single scored and embossed â€˜M09â€™ on one side of the score on one face but plain on the other, packed in a white multidose plastic container of 60 tablets in a printed box. | |
| **MFG. DATE:** Nov. 2014 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Oct. 2019 | **ADDRESS:** | Plot No. 11,12 & 13 Indore SEZ, Pharma Zone, Phase-II, Sector-III, Pithampur - 454775, Dist.-Dhar (MP), INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P. O. Box 47715 - 00100, Nairobi, KENYA. | |
| 3TC/NVP/AZT/12/10/2016/200 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Disintegration, 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 | NMT 2 tablets deviate by more than 5% from mean weight | **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** |
| **Disintegration** | Disintegration | BP 2016 Vol. V App. XII A | No tablet disintegrates in more than 3 mins | All tablets disintegrated within 3 minutes [n=6] | **COMPLIES** |
| **Assay** | HPLC | Adopted In-house Method | 90.0 - 110.0% | Lamivudine 100.1% (RSD=1.8%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Nevirapine 103.9% (RSD=1.4%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Zidovudine 100.0% (RSD=1.9%; n=9) | **COMPLIES** |

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

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| **ANALYST:** | SARAH MWANGI | .......................................................... | DATE: 10-26-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 25-11-2016 |
| **ANALYST:** | NICHOLAS MWAURA | .......................................................... | DATE: 11-25-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-29-2016 |