**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/236

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| **PRODUCT** | LAMIVUDINE/NEVIRAPINE/ZIDOVUDINE DISPERSIBLE TABLETS 30 mg/50 mg/60 mg | | **REF. NO: NDQD2016061065** |
| **DATE RECEIVED:** 03-06-2016 | **LABEL CLAIM:** | Each dispersible tablet contains: Lamivudine USP 30 mg, Nevirapine USP 50 mg and Zidovudine USP 60 mg. | |
| **BATCH NO.:** 3010274 | **PRESENTATION:** | Beige coloured, circular shaped, flat faced, bevel edged tablets, single scored one face and embossed 'M09' on one side of the score and plain on the other face. Packed in a white coloured, plastic, multi-dose container carrying 60 tablets in a unit box. | |
| **MFG. DATE:** Mar. 2013 | **MANUFACTURER:** | Mylan Laboratories Ltd | |
| **EXP. DATE:**  Feb. 2017 | **ADDRESS:** | F-4 & F-12, MIDC, Malegaon, Sinnar, Nashik-422 113, Maharashtra, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme, P. O. Box 19361 - 00202, Nairobi, KENYA. | |
| A2T/3TC/NUP/09/15.03.2016/0273 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Friability, Disintegration, 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 the mean tablet 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 3.2, 4.2 and 9.5 -/+ 10% min present in both the assay sample and standard preparations | **COMPLIES** |
| **Disintegration** | Disintegration | Adopted In-House Method | All Tablets disintegrate within 3 minutes [n=6] | All Tablets disintegrated in 1 minute | **COMPLIES** |
| **Friability** | Friability | BP 2016 Vol. V App. XVII G | NMT 1.0% | 1.2% | **DOES NOT COMPLY** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Lamivudine 95.0% (RSD=1.9%; n=7) | **COMPLIES** |
| **Assay** |  |  |  | Nevirapine 95.7% (RSD=1.6%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Zidovudine 90.6% (RSD=0.5%; n=7) | **COMPLIES** |

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

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| **ANALYST:** | DR. E. MUTUA | .......................................................... | DATE: 15-07-2016 |
| **ANALYST:** | DR. N. MWAURA | .......................................................... | DATE: 27-08-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 11-09-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-15-2016 |