**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/103

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| **PRODUCT** | LAMIVUDINE, NEVIRAPINE & ZIDOVUDINE DISPERSIBLE TABLETS 30 mg/50 mg/ 60 mg | | **REF. NO: NDQD2016061067** |
| **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.:** 3022273 | **PRESENTATION:** | Cream coloured, circular shaped, flat faced tablets, single scored and embossed 'M 0 9' one one side of the score on one face and plain on the other, packed in a white plastic multi-dose container carrying 60 tablets in a unit box. | |
| **MFG. DATE:** Jan. 2014 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Dec. 2018 | **ADDRESS:** | H-12 & H-13, MIDC, Waluj, Aurangabad - 431136, Maharashtra, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme, P. O. Box 19361 - 00202, Nairobi, KENYA. | |
| A2T/3TC/NVP/07/09.03.2016/0235 | **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 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, 5.0 and 12.7 -/+ 10% min . present in both the assay sample and standard preparations | **COMPLIES** |
| **Disintegration** | Disintegration | BP 2016 Vol. V App XII A | All tablets disintegrate within 3 min [n=6] | All tablets disintegrated within 1 min [n=6] | **COMPLIES** |
| **Friability** | Weight | BP 2016 Vol. V App XVII G | Percentage weigh loss NMT 1% | 0.2% | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Lamivudine 102.5% (RSD=0.7, n=9) | **COMPLIES** |
| **Assay** |  |  | Zidovudine 90.0 - 115.0 % | Nevirapine 92.5% (RSD=0.5, n=9) |  |
| **Assay** |  |  |  | 92.6% (RSD=1.3, n=9) |  |

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

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| **ANALYST:** | DR. E. MUTUA | .......................................................... | DATE: 01-09-2016 |
| **ANALYST:** | DR. N. MWAURA | .......................................................... | DATE: 01-09-2016 |
| **ANALYST** | DR.E. MBAE | .......................................................... | DATE: 01-09-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-22-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-26-2016 |