**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/235

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| **PRODUCT** | LAMIVUDINE/NEVIRAPINE/ZIDOVUDINE TABLETS 150 mg/200 mg/300 mg | | **REF. NO: NDQD2016061042** |
| **DATE RECEIVED:** 03-06-2016 | **LABEL CLAIM:** | Each film coated tablet contains: Lamivudine USP 150 mg, Nevirapine USP 200 mg and Zidovudine USP 300 mg. | |
| **BATCH NO.:** 3033345 | **PRESENTATION:** | Sky blue coloured, caplet shaped, biconvex-faced, film coated tablets, embossed 'M104' on one face and plain on the other. Packed in a white coloured, plastic, multi-dose container carrying 60 tablets in a unit box. | |
| **MFG. DATE:** Dec. 2014 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Nov. 2019 | **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. | |
| AZT/3TC/NVP/02/10.03.2016/0246 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, 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 peak at RT 3.0, 7.2 and 4.2 -/+ 10% min present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No Tablet Less Than 80% [n=6] | Lamivudine Average | **COMPLIES** |
| **Dissolution** |  |  |  | 103% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 100% - 106% (RSD=2.0%; n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Nevirapine Average |  |
| **Dissolution** |  |  |  | 99% Range |  |
| **Dissolution** |  |  |  | 98 - 101% (RSD=1.1%; n=6) |  |
| **Dissolution** |  |  |  | Zidovudine Average |  |
| **Dissolution** |  |  |  | 92% Range |  |
| **Dissolution** |  |  |  | 90 - 93% (RSD=1.5%; n=6) |  |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Lamivudine 93.9% (RSD=1.1%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Nevirapine 106.6% (RSD=1.1%; n=6) | **COMPLIES** |
| **Assay** |  |  |  | Zidovudine 101.1% (RSD=1.2%; n=9) | **COMPLIES** |

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

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| **ANALYST:** | DR. E. MUTUA | .......................................................... | DATE: 06-07-2016 |
| **ANALYST:** | DR. N. MWAURA | .......................................................... | DATE: 08-08-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 11-09-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-15-2016 |