**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/31

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| **PRODUCT** | LAMIVUDINE/NEVIRAPINE/ZIDOVUDINE TABLETS 150 mg/200 mg/300 mg | | **REF. NO: NDQB2016061161** |
| **DATE RECEIVED:** 2016-06-09 | **LABEL CLAIM:** | Each film coated tablets contains: Lamivudine USP 150 mg, Nevirapine USP 200 mg and Zidovudine USP 300 mg. | |
| **BATCH NO.:** 3036614 | **PRESENTATION:** | Blue coloured, caplet shaped, biconvex faced tablets, embossed "104" on one face and plain on the other, 60 tablets packed in a plastic multidose container in a printed box. | |
| **MFG. DATE:** Feb. 2015 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Jan. 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. | |
| AZT/3TC/NVP/23/05/2016/123 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | B.P. 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 3.0, 4.2 & 7.2 Â± 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 91%, Range 90% - 95%, (RSD=2.1%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Nevirapine Average 102%, Range 101.7% - 102.4%, (RSD=0.3%, n=6) |  |
| **Dissolution** |  |  |  | Zidovudine Average 90%, Range 89% - 94%, (RSD=1.9%, n=6) |  |
| **Assay** | HPLC | Adopted In - house Method | 90%-110% | Lamivudine 91.6%, (RSD=1.7%, n=6) | **COMPLIES** |
| **Assay** |  |  |  | Nevirapine 102.5%, (RSD=1.8%, n=7) |  |
| **Assay** |  |  |  | Zidovudine 94.7%, (RSD=2.0%, n=6) |  |

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

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| **ANALYST:** | ERIC MUTUA | .......................................................... | DATE: 07-01-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 07-18-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 07-26-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 08-02-2016 |