**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/455

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| **PRODUCT** | LAMIVUDINE/NEVIRAPINE/ZIDOVUDINE TABLETS 150 mg/ 200 mg/ 300 mg | | REF. NO: NDQB201601685 |
| **DATE RECEIVED:** 2016-01-26 | **LABEL CLAIM:** | Each film coated tablet contains Lamivudine USP 150 mg, Nevirapine USP 200 mg and Zidovudine USP 300 mg. | |
| **BATCH NO.:** 3032332 | **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. | |
| **MGF. DATE:** Nov 2014 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Oct 2017 | **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 | |
| DOLDOL DISTRICT HOSPITAL Sample 28 | **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 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, 4.3 and 7.1-/+ 10% min present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] | lamivudine 106.6% (RSD=3.0%, n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] | Nevirapine 102.4% (RSD=3.3%, n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] | Zidovudine 103.3% (RSD=2.1%, n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Lamivudine 105.6% (RSD=1.3%, n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Nevirapine 105.3 (RSD=1.9%) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Zidovudine 106.3% (RSD=0.6%, n=9) | **COMPLIES:COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. E. MUTUA |  | DATE:29-02-2016 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:14-03-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:03-18-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-29-2016 |