**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/657

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| **PRODUCT** | LAMIVUDINE/NEVIRAPINE/ZIDOVUDINE TABLETS 150 mg/200 mg/300 mg | | REF. NO: NDQB201603821 |
| **DATE RECEIVED:** 31.03.2016 | **LABEL CLAIM:** | Each film-coated tablet contains: Lamivudine USP 150 mg, Nevirapine USP 200 mg and Zidovudine USP 300 mg. | |
| **BATCH NO.:** 3035569 | **PRESENTATION:** | Sky blue coloured, caplet shaped, biconvex faced, film coated tablets, embossed 'M104' on one face and plain on the other face, packed in a white plastic multi-dose container carrying 60 tablets in a unit box. | |
| **MGF. 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 | |
|  | **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 3.4, 4.7 and 8.2 -/+ 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 100.0% (RSD=1.9%, n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | Nevirapine 95.0% (RSD=2.6%, n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | Zidovudine 97.0% (RSD=1.3%, n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0% - 110.0% | Lamivudine 96.8% (RSD=1.9%, n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0% - 110.0% | Nevirapine 92.7% (RSD=1.9%, n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0% - 110.0% | Zidovudine 93.5% (RSD=1.4%, n=9) | **COMPLIES:COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:09-05-2016 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:16-05-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:05-23-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-30-2016 |