**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/672

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| **PRODUCT** | TENOFOVIR DISOPROXIL FUMARATE/ LAMIVUDINE/ EFAVIRENZ TABLETS 300 mg/300 mg /600 mg | | **REF. NO: NDQB201604870** |
| **DATE RECEIVED:** 19.04.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Tenofovir disoproxil fumarate 300 mg, Lamivudine USP 300 mg and Efavirenz USP 600 mg. | |
| **BATCH NO.:** 3045249 | **PRESENTATION:** | Off white coloured, caplet-shaped, biconvex faced tablets, embossed 'M 152' on one face and plain on the other, packed in a white plastic multidose container carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Sep. 2015 | **MANUFACTURER:** | MYLAN Laboratories Ltd. | |
| **EXP. DATE:**  Aug. 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 | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **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 5.4, 15.1 and 21.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | Lamivudine and Tenofovir disoproxil fumarate No tablet less than 85% (n=6); Efavirenz No tablet less than 80% (n=6) | Lamivudine 100.0% (RSD=9.5%; n=12) | **COMPLIES** |
| **Dissolution** |  |  |  | Tenofovir disoproxil fumarate 95.0% (RSD=8.4%; n=12) | **COMPLIES** |
| **Dissolution** |  |  |  | Efavirenz 96.0% (RSD=8.3%; n=12) | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0% - 110.0% | Lamivudine 98.6% (RSD=1.7%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Tenofovir disoproxil fumarate 95.3% (RSD=0.5%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Efavirenz 94.8% (RSD=1.2%; n=9) | **COMPLIES** |
| **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** |

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

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| **ANALYST:** | MR. M. SANGALE | .......................................................... | DATE: 11-05-2016 |
| **ANALYST:** | DR. N. MWAURA | .......................................................... | DATE: 26-05-2016 |
| **ANALYST:** | EMMANUEL TANUI | .......................................................... | DATE: 05-30-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 05-31-2016 |