**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/709

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| **PRODUCT** | TENOFOVIR DISOPROXIL FUMARATE/ LAMIVUDINE/ EFAVIRENZ TABLETS 300 mg/300 mg/600 mg | | REF. NO: NDQB201603817 |
| **DATE RECEIVED:** 31.03.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Tenofovir disoproxil fumarate 300 mg, Lamivudine USP 300 mg, Efavirenz USP 600 mg. | |
| **BATCH NO.:** 3048732 | **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:** Dec. 2015 | **MANUFACTURER:** | MYLAN Laboratories Ltd. | |
| **EXP. DATE:**  Nov. 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** |
| **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 sample preparation correspond to those in the standard preparation | Super-imposable peaks at RT 5.5, 15.1, 21.9 -/+ 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] No tablet less than 85%[n=6] | Efavirenz 98.3% (RSD=0.40%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80%[n=6] No tablet less than 85%[n=6] | Lamivudine 100.4% (RSD=3.4%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80%[n=6] No tablet less than 85%[n=6] | Tenofovir Disoproxil Fumarate 96.9% (RSD=0.5%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Efavirenz 97.1% (RSD=0.4%; n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Lamivudine 98.1% (RSD=0.5%; n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Tenofovir Disoproxil Fumarate 96.1% (RSD=0.8%; n=9) | **COMPLIES:COMPLIES:COMPLIES** |

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

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| ANALYST: | MR. M. SANGALE |  | DATE:08-06-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:08-06-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:06-08-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-13-2016 |