**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/184

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| **PRODUCT** | TENOFOVIR DISOPROXIL FUMARATE/ LAMIVUDINE/ EFAVIRENZ TABLETS 300 mg/300 mg /600 mg | | **REF. NO: NDQB201607005** |
| **DATE RECEIVED:** 05.07.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Tenofovir disoproxil fumarate 300 mg, Lamivudine USP 300 mg and Efavirenz USP 600 mg. | |
| **BATCH NO.:** 3044528 | **PRESENTATION:** | Off white coloured, caplet-shaped, biconvex faced tablets, embossed 'M 152' on one face and plain on the other, 30 tablets packed in a white plastic multi-dose container in a printed box. | |
| **MFG. DATE:** Sep. 2015 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Aug. 2017 | **ADDRESS:** | F-4 & F-12, MIDC, Malegaon, Sinnar, Nashik â€“ 422 113, Maharashtra, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P. O. Box 47715 - 00100, Nairobi, KENYA. | |
| TDF/3TC/EFV/07/06/2016/151 | **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 4.7, 16.2 and 25.4 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** |  | Adopted In-House Method | No tablet less than 80%[n=6] No tablet less than 85%[n=6] | Efavirenz Average = 97% Range | **COMPLIES** |
| **Dissolution** | HPLC |  |  | 95 - 99% (RSD=1.7%; n=6) |  |
| **Dissolution** |  |  |  | Lamivudine Average |  |
| **Dissolution** |  |  |  | = 97% Range |  |
| **Dissolution** |  |  |  | 93 - 101% (RSD=4.2%; n=6) |  |
| **Dissolution** |  |  |  | Tenofovir Disoproxil Fumarate Average = 94% Range |  |
| **Dissolution** |  |  |  | 89 - 99% (RSD=5.3%; n=6) |  |
| **Assay** |  | Adopted In-House Method | 90.0 - 110.0% | Efavirenz 91.1% (RSD=0.3%; n=6) | **COMPLIES** |
| **Assay** | HPLC |  |  | Lamivudine 100.8% (RSD=1.0; n=9) |  |
| **Assay** |  |  |  | Tenofovir Disoproxil Fumarate 94.2% (RSD=1.0%; n=9) |  |

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

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| **ANALYST:** | DR.. S. MWANGI | .......................................................... | DATE: 13-10-2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 13-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-14-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-18-2016 |