**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/186

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| **PRODUCT** | TENOFOVIR DISOPROXIL FUMARATE/ LAMIVUDINE/ EFAVIRENZ TABLETS 300 mg/300 mg /600 mg | | **REF. NO: NDQB201608083** |
| **DATE RECEIVED:** 23.08.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Tenofovir disoproxil fumarate 300 mg, Lamivudine USP 300 mg and Efavirenz USP 600 mg. | |
| **BATCH NO.:** 3056202 | **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:** Jul. 2016 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Jun. 2019 | **ADDRESS:** | H-12 & H-13, MIDC, Waluj, Aurangabad â€“ 431136, 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 2012 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 major 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 = 96% Range | **COMPLIES** |
| **Dissolution** | HPLC |  |  | 96 - 97% (RSD=0.3%; n=6) |  |
| **Dissolution** |  |  |  | Lamivudine Average = 101% Range |  |
| **Dissolution** |  |  |  | 101 - 102% (RSD=0.6%; n=6) |  |
| **Dissolution** |  |  |  | Tenofovir Disoproxil Fumarate Average = 97% Range |  |
| **Dissolution** |  |  |  | 96 - 99% (RSD=1.7%; n=6) |  |
| **Assay** |  | Adopted In-House Method | 90.0 - 110.0% | Efavirenz 95.6% (RSD=1.6%; n=9) | **COMPLIES** |
| **Assay** | HPLC |  |  | Lamivudine; 94.7% (RSD=1.1%; n=9) |  |
| **Assay** |  |  |  | Tenofovir Disoproxil Fumarate 97.5% (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:** | DR. E. MBAE | .......................................................... | DATE: 13-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-14-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-18-2016 |