**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/195

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| **PRODUCT** | TENOFOVIR DISOPROXIL FUMARATE/ LAMIVUDINE/ EFAVIRENZ TABLETS 300 mg/300 mg /600 mg | | **REF. NO: NDQB201607044** |
| **DATE RECEIVED:** 26-07-2016 | **LABEL CLAIM:** | Each film coated tablet contains Tenofovir Disoproxil Fumarate 300 mg, Lamivudine USP 300 mg and Efavirenz USP 600 mg. | |
| **BATCH NO.:** 3054810 | **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 coloured plastic multi-dose container in a printed box. | |
| **MFG. DATE:** Jun 2016 | **MANUFACTURER:** | MYLAN Laboratories Limited | |
| **EXP. DATE:**  May 2019 | **ADDRESS:** | H-12 & H-13, MIDC, Waluj, Aurangabad - 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 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 4.3,16.1 and 25.3 -/+ 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] | Efavirenz Average = 100% Range | **COMPLIES** |
| **Dissolution** |  |  | No tablet less than 85% [n=6] | 99 - 100% (RSD=0.3%, n=6) |  |
| **Dissolution** |  |  |  | Lamivudine Average = 104% Range |  |
| **Dissolution** |  |  |  | 103 - 104% (RSD=0.4%, n=6) |  |
| **Dissolution** |  |  |  | Tenofovir Disoproxil Fumarate Average = 97% Range |  |
| **Dissolution** |  |  |  | 96 - 97% (RSD=0.3%, n=6) |  |
| **Assay** | HPLC | Adopted In - house Method | 90.0-110.0% | Efavirenz 93.7% (RSD=1.5%, n=6) | **COMPLIES** |
| **Assay** |  |  |  | Lamivudine 98.2% (RSD=0.7%, n=6) |  |
| **Assay** |  |  |  | Tenofovir Disoproxil Fumarate 92.9% (RSD=0.7%, n=6) |  |

**CONCLUSION:**

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| **ANALYST:** | DR. S. MWANGI | .......................................................... | DATE: 08-01-2016 |
| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 10-03-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-14-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-18-2016 |