**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/432

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| **PRODUCT** | TENOFOVIR DISOPROXIL FUMARATE/ LAMIVUDINE/ EFAVIRENZ TABLETS 300 mg /300 mg/ 600 mg | | REF. NO: NDQD201508154 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Tenofovir disoproxil fumarate 300 mg, Lamivudine USP 300 mg, Efavirenz USP 600 mg. | |
| **BATCH NO.:** 3030183 | **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:** Aug. 2014 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Jul. 2016 | **ADDRESS:** | F-4 & F-12, MIDC, Malegaon, Sinnar, Nashik - 422 113, Maharashtra, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme P. O. Box 19361, Nairobi, KENYA | |
| TDF/3TC/EFV/01/16.03.2015/00295 | **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 3.5, 7.9 and 11.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% (n=6) | Efavirenz 96.2% (RSD=5.5%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% (n=6) | Lamivudine 99.5% (RSD=0.3%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% (n=6) | Tenofovir disoproxil fumarate 100.4% (RSD=0.3%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Efavirenz 99.8% (RSD=1.6%; n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Lamivudine 107.9% (RSD=1.8%, n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Tenofovir disoproxil fumarate 103.8% (RSD=1.9%; n=9) | **COMPLIES:COMPLIES:COMPLIES** |

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

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| ANALYST: | MR. D. MOENGA |  | DATE:21-10-2015 |
| ANALYST: | MR. M. SANGALE |  | DATE:29-02-2016 |
| ANALYST: | DR. S. MUTERU |  | DATE:02-03-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:03-08-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-09-2016 |