**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | TENOFOVIR DISOPROXIL FUMARATE/ LAMIVUDINE/ EFAVIRENZ TABLETS 300 mg/300 mg/ 600 mg | | REF. NO: NDQD201508095 |
| **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 multi-dose 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 | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | B.P. 2012 Vol. V App XII C | < 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 3.6, 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 85.0% [n=6] :No tablet less than 85.0% [n=6]:No tablet less than 80.0% [n=6] | Tenofovir disoproxil fumarate 108.8% (RSD = 0.2%; n = 6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In - House Method | No tablet less than 85.0% [n=6] :No tablet less than 85.0% [n=6]:No tablet less than 80.0% [n=6] | Lamivudine 96.4% (RSD = 0.3%; n = 6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In - House Method | No tablet less than 85.0% [n=6] :No tablet less than 85.0% [n=6]:No tablet less than 80.0% [n=6] | Efavirenz 94.3% (RSD = 0.5%; n = 6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In - House Method | 90.0 - 110.0% | Tenofovir disoproxil fumarate 105.0% (RSD = 0.9%; n = 9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In - House Method | 90.0 - 110.0% | Lamivudine 110.0% (RSD = 1.4%; n = 6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In - House Method | 90.0 - 110.0% | Efavirenz 99.6% (RSD = 0.9%; 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:26-10- |
| REVIEWER: | DR. E. MBAE |  | DATE: |
| ANALYST: | NICHOLAS MWAURA |  | DATE:11-25-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:12-02-2015 |