**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/670

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | TENOFOVIR DISOPROXIL FUMARATE/ LAMIVUDINE/ EFAVIRENZ TABLETS 300 mg/300 mg /600 mg | | REF. NO: NDQB201604850 |
| **DATE RECEIVED:** 07.04.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Tenofovir disoproxil fumarate 300 mg, Lamivudine USP 300 mg and Efavirenz USP 600 mg. | |
| **BATCH NO.:** 8044434 | **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:** Dec. 2015 | **MANUFACTURER:** | MYLAN Laboratories Ltd. | |
| **EXP. DATE:**  Nov. 2017 | **ADDRESS:** | F-4 & F-12, MIDC, Malegaon, Sinnar, Nashik-422 113, 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**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 peak at RT 5.4, 15.1 and 21.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | Efavirenz No tablet less than 80.0% (n=6; Lamivudine and Tenofovir disoproxil fumarate No tablet less than 85% (n=6) | Lamivudine 96.0% (RSD=10.4%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | Efavirenz No tablet less than 80.0% (n=6; Lamivudine and Tenofovir disoproxil fumarate No tablet less than 85% (n=6) | Efavirenz 91.0% (RSD=9.4%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | Efavirenz No tablet less than 80.0% (n=6; Lamivudine and Tenofovir disoproxil fumarate No tablet less than 85% (n=6) | Tenofovir disoproxil fumarate 92.0% (RSD=10.2%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Lamivudine 97.2% (RSD=0.5%, n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Efavirenz 92.6% (RSD=2.0%; n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Tenofovir disoproxil fumarate 95.8% (RSD=0.5%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | DR. E. MUTUA |  | DATE:10-05-2016 |
| REVIEWER: | DR. N. MWAURA |  | DATE:23-05-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:05-30-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-31-2016 |