**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/44

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | TENOFOVIR DISOPROXIL FUMARATE/LAMIVUDINE/EFAVIRENZ TABLETS 300 mg/300 mg/600 mg | | **REF. NO: NDQB2016061162** |
| **DATE RECEIVED:** 2016-06-09 | **LABEL CLAIM:** | Each film coated tablet contains: Tenofovir Disoproxil Fumarate 300 mg, Lamivudine USP 300 mg & Efavirenz 600 mg tablets. | |
| **BATCH NO.:** 3045339 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, embossed on one face and plain on the other, 30 tablets packed in a plastic multidose container in a printed box. | |
| **MFG. DATE:** Sep. 2015 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Aug. 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. | |
| TDF/3TC/EFV/24/05/2016/132 | **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 the 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 2.2, 6.7 & 7.8 ± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In - house Method | No Tablet Less Than 85% [n=6] | Tenofovir Disoproxil Fumarate Average 91% Range 88% - 92% (RSD=1.6%, n=6) | **COMPLIES** |
| **Dissolution** |  |  | No Tablet Less Than 80% [n=6] | Lamivudine Average 90%, Range 89% - 90% (RSD=0.5%, n=6) |  |
| **Dissolution** |  |  |  | Efavirenz Average 93% Range 86% - 108% (RSD=8.6%, n=6) |  |
| **Assay** | HPLC | Adopted In - house Method | 90%-110% | Tenofovir Disoproxil Fumarate 92.1% (RSD=0.7%, n=6) | **COMPLIES** |
| **Assay** |  |  |  | Lamivudine 99.1%, (RSD=2.0%, n=9) |  |
| **Assay** |  |  |  | Efavirenz 93.4% (RSD=1.1%, n=9) |  |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | MICHAEL SANGALE | .......................................................... | DATE: 07-01-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 07-18-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 07-26-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 08-02-2016 |