**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/120

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | TENOFOVIR DISOPROXIL FUMARATE/ LAMIVUDINE/ EFAVIRENZ TABLETS 300 mg/300 mg/600 mg | | **REF. NO: NDQB201607022** |
| **DATE RECEIVED:** 2016-07-14 | **LABEL CLAIM:** | Each film coated tablet contains Tenofovir Disoproxil Fumarate 300 mg, Lamivudine USP 300 mg & Efavirenz USP 600 mg tablets | |
| **BATCH NO.:** 3051330 | **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 plastic multi-dose container in a unit box. | |
| **MFG. DATE:** Feb 2016 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Jan 2018 | **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**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2012 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean 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 8.6,17.0 & 23.4 -/+ 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 = 93% Range | **COMPLIES** |
| **Dissolution** |  |  | No tablet less than 85% [n=6] | 92 - 93% (RSD=0.2%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Lamivudine Average = 106% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 106 - 107% (RSD=0.3%, n=6) |  |
| **Dissolution** |  |  |  | Tenofovir Disoproxil Fumarate Average = 97% Range |  |
| **Dissolution** |  |  |  | 96.6 - 97.2% (RSD=0.2%, n=6) |  |
| **Assay** | HPLC | Adopted In - house Method | 90.0 â€“ 110.0% | Efavirenz 98.3% (RSD=0.4%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Lamivudine 95.2% (RSD=1.0%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Tenofovir Disoproxil Fumarate 96.7% (RSD=1.59%, n=6) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | DR ERIC MUTUA | .......................................................... | DATE: 08-01-2016 |
| **ANALYST:** | DR MATHAYO KWENA | .......................................................... | DATE: 09-01-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-27-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-29-2016 |