**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/185

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | LAMIVUDINE 300 mg and TENOFOVIR DISOPROXIL FUMARATE 300 mg TABLETS | | **REF. NO: NDQB201607003** |
| **DATE RECEIVED:** 05.07.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Tenofovir Disoproxil Fumarate 300 mg equivalent to Tenofovir Disoproxil 245 mg and Lamivudine USP 300 mg. | |
| **BATCH NO.:** ELC4675A | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, embossed 'CL 71' on one face and plain on the other, 30 tablets packed in a white plastic multidose container in a printed box. | |
| **MFG. DATE:** Apr. 2016 | **MANUFACTURER:** | MACLEODS Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Mar. 2018 | **ADDRESS:** | Plot No. 25-27, Survey No. 366, Premier Ind. Estate, Kachigam, Daman - 396 210 (U.T.) Off.: Atlanta Arcade, Marol Church Road, Andheri (E), Mumbai - 400 059, 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 peaks at RT 4.7 and 16.2 -/+ 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] | Lamivudine Average = 100% Range | **COMPLIES** |
| **Dissolution** | HPLC |  |  | 100 - 101% (RSD=0.5%; n=6) |  |
| **Dissolution** |  |  |  | Tenofovir Disoproxil Fumarate Average = 96% Range |  |
| **Dissolution** |  |  |  | 95 - 97% ( RSD=1.0%; n=6) |  |
| **Assay** |  | Adopted In-House Method | 90.0 - 110.0% | Lamivudine 101.5% (RSD=1.7%; n=9) | **COMPLIES** |
| **Assay** | HPLC |  |  | Tenofovir Disoproxil Fumarate 92.9% (RSD=1.3%; n=6) |  |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | DR. S. MWANGI | .......................................................... | DATE: 13.10.2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 13.10.2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-14-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-18-2016 |