**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/429

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | LAMIVUDINE 300 mg AND TENOFOVIR DISOPROXIL FUMARATE 300 mg TABLETS | | REF. NO: NDQB201601697 |
| **DATE RECEIVED:** 26.01.2016 | **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.:** BLD1520A | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, embossed 'CL 71' on one face and plain on the other, packed in a white plastic multidose container carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Mar. 2015 | **MANUFACTURER:** | MACLEODS Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Feb. 2017 | **ADDRESS:** | Village Theda, P.O. Lodhimajra, Tehsil Baddi, Dist. Solan, Himachal Pradesh, India - 174101 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 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 4.8 and 15.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% (n=6) | Lamivudine 98.5% (RSD=2.2%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% (n=6) | Tenofovir Disoproxil Fumarate 94.7% (RSD=4.6%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Lamivudine 93.9% (RSD=0.3%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Tenofovir Disoproxil Fumarate 96.3% (RSD=0.6%; n=9) | **COMPLIES:COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | DR. L. KARANJA |  | DATE:29-02-2016 |
| ANALYST: | DR. E. TANUI |  | DATE:03-03-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-09-2016 |