**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/456

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| **PRODUCT** | LAMIVUDINE 300 mg and TENOFOVIR DISOPROXIL FUMARATE 300 mg TABLETS | | REF. NO: NDQB201602758 |
| **DATE RECEIVED:** 18.02.2016 | **LABEL CLAIM:** | Each film coated tablet contains Tenofovir Disoproxil Fumarate 300 mg equivalent to Tenofovir Disoproxil 245 mg & Lamivudine USP 300 mg. | |
| **BATCH NO.:** ELC4515A | **PRESENTATION:** | White coloured, caplet shaped, biconvex faced tablets, embossed 'CL 71' on one face and plain on the other, packed in a white plastic multi-dose container carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Dec. 2015 | **MANUFACTURER:** | MACLEODS Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Nov. 2017 | **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**

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| **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 standard preparation | Super-imposable peaks at RT 4.2 and 16.4 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 85.0% [n=6] | Lamivudine 98.0% (RSD=1.7%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 85.0% [n=6] | Tenofovir DF 94.2% (RSD=3.6%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0 % | Lamivudine 100.6% (RSD=0.2%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0 % | Tenofovir DF 95.1% (RSD=0.2%; n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. S. MWANGI |  | DATE:01-03-2016 |
| REVIEWER: | DR. M. KWENA |  | DATE:09-03-2016 |
| REVIEWER: | ERNEST MBAE |  | DATE:03-21-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:03-21-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-29-2016 |