**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/725

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| **PRODUCT** | LAMIVUDINE 300 mg and TENOFOVIR DISOPROXIL FUMARATE 300 mg TABLETS | | REF. NO: NDQB201603813 |
| **DATE RECEIVED:** 31.03.2016 | **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.:** BLD1559A | **PRESENTATION:** | Off white coloured, caplet-shaped, biconvex faced tablets, embossed 'CL 71' on one face and plain on the other face, packed in a white plastic multidose container carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Apr. 2015 | **MANUFACTURER:** | MACLEODS Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Mar. 2017 | **ADDRESS:** | Village Theda, P.O. Lodhimajra, Tehsil Baddi, Dist. Solan, Himachal Pradesh, India - 174 101. 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** |
| **Identification** |  | 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 2.9 and 6.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** |  | Adopted In-House Method | No tablet less than 80% [n=6] | lamivudine 99.5% (RSD=0.6%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** |  | Adopted In-House Method | No tablet less than 80% [n=6] | Tenofovir Disoproxil Fumarate 94.2% (RSD=0.8%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** |  | Adopted In-House Method | 90.0% - 110.0% | lamivudine 99.7% (RSD=1.4%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** |  | Adopted In-House Method | 90.0% - 110.0% | Tenofovir Disoproxil Fumarate 93.2% (RSD=0.6%, n=9) | **COMPLIES:COMPLIES** |
| **Uniformity of Weight** |  | BP 2016 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |

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

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| ANALYST: | DR. E. MUTUA |  | DATE:18-05-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:18-05-20166 |
| ANALYST: | EMMANUEL TANUI |  | DATE:06-09-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-16-2016 |