**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/683

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| **PRODUCT** | LAMIVUDINE 300 mg and TENOFOVIR DISOPROXIL FUMARATE 300 mg TABLETS | | REF. NO: NDQB201603803 |
| **DATE RECEIVED:** 15.03.2016 | **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.:** BLD154A | **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 multidose plastic container carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Feb. 2015 | **MANUFACTURER:** | MACLEODS Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Jan. 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 ÃƒÂ¢Ã¢â€šÂ¬Ã¢â‚¬Å“ 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 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** | HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | Lamivudine 99.0% (RSD=0.9%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | Tenofovir Disoproxil Fumarate 96.1% (RSD=0.8% n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0% - 110.0% | Lamivudine 98.3% (RSD=0.8%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0% - 110.0% | Tenofovir Disoproxil Fumarate 94.8% (RSD=0.6%, n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | MR. M. SANGALE |  | DATE:18-05-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:26-05-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:05-31-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-08-2016 |