**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/4

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| **PRODUCT** | LAMIVUDINE 300 mg and TENOFOVIR DISOPROXIL FUMARATE 300 mg TABLETS | | **REF. NO: NDQB2016061150** |
| **DATE RECEIVED:** 09-06-2016 | **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.:** BLD1567A | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex tablets, imprinted â€˜CL 71â€™ on one face and plain on the other packed in a plastic multidose container of 30 tablets contained in a unit box. | |
| **MGF. DATE:** May 2015 | **MANUFACTURER:** | Macleods Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Apr 2017 | **ADDRESS:** | Village Theda, P. O. Lodhimajra, Tehsil Baddi, Dist. Solan, Himachal Pradesh, 174 101 INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority P.O. Box 47715 - 00100, Nairobi, KENYA. | |
| TDF/3TC/23/05/2016/124 | **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 Major Peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 3.0 & 5.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80% | Lamivudine Average = 83 % Range | **COMPLIES** |
| **Dissolution** |  |  |  | 82 % - 84% (RSD=1.2%, n=6) |  |
| **Dissolution** |  |  |  | Tenofovir Disoproxil Fumarate Average = 93% Range |  |
| **Dissolution** |  |  |  | 91% - 94% (RSD=1.1%, n=6) |  |
| **Assay** | HPLC | Adopted In-House Method | 90 - 110% | Lamivudine 93.2% (RSD=1.0%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Tenofovir Disoproxil Fumarate 92.8% (RSD=0.8%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 07-01-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 07-11-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 07-21-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-26-2016 |