**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/434

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| **PRODUCT** | LAMIVUDINE and TENOFOVIR DISOPROXIL FUMARATE TABLETS 300 mg/ 300 mg | | REF. NO: NDQB201601699 |
| **DATE RECEIVED:** 26.01.2016 | **LABEL CLAIM:** | Each film coated tablet contains Lamivudine USP 300 mg and Tenofovir Disoproxil Fumarate 300 mg equivalent to Tenofovir Disoproxil 245 mg. | |
| **BATCH NO.:** Y41495 | **PRESENTATION:** | Off white and peach coloured, bi-layered, caplet-shaped, biconvex faced tablets, embossed 'L T' on the peach coloured face and plain on the other, 30 tablets packed in a white plastic multi-dose container in a unit box. | |
| **MGF. DATE:** Jun. 2014 | **MANUFACTURER:** | CIPLA Ltd. | |
| **EXP. DATE:**  May 2016 | **ADDRESS:** | MIDC, Indl. Area, Kurkumbh, Dist. Pune 413 802, 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 tablets 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 106.6% (RSD=1.2%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% (n=6) | Tenofovir Disoproxil Fumarate 107.0% (RSD=1.4%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Lamivudine 96.2% (RSD=0.3%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Tenofovir Disoproxil Fumarate 100.5% (RSD=1.1%, n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR.L. KARANJA |  | DATE:29-02-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:08-03-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-15-2016 |