**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/690

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| **PRODUCT** | TENOFOVIR DISOPROXIL FUMARATE and LAMIVUDINE TABLETS 300 mg/300 mg | | REF. NO: NDQB201605922 |
| **DATE RECEIVED:** 12.05.2016 | **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.:** E160438 | **PRESENTATION:** | Light blue coloured, caplet-shaped, biconvex faced tablets, embossed '129' on one face and 'H' on the other, packed in a white plastic multidose container carrying 30 tablts in a unit box. | |
| **MGF. DATE:** Mar. 2016 | **MANUFACTURER:** | HETERO Labs Limited. | |
| **EXP. DATE:**  Feb. 2018 | **ADDRESS:** | 22 - 110, I.D.A., Jeedimetla, Hyderabad - 500 055, 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 99.9% (RSD=0.4%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | Tenofovir Disoproxil Fumarate 98.3% (RSD=0.3% n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0% - 110.0% | Lamivudine 100.5% (RSD=0.6%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0% - 110.0% | Tenofovir Disoproxil Fumarate 97.0% (RSD=0.7%, n=9) | **COMPLIES: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:26-05-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:05-31-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-08-2016 |