**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/116

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| **PRODUCT** | TENOFOVIR DISOPROXIL FUMARATE/LAMIVUDINE TABLETS 300 mg/300 mg | | **REF. NO: NDQB201607042** |
| **DATE RECEIVED:** 2016-07-26 | **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.:** EI60671 | **PRESENTATION:** | Sky blue coloured, caplet shaped, biconvex faced tablets, embossed '129' on one face and 'H on the other, 30 tablets packed in a white plastic multi-dose container in a unit box. | |
| **MFG. DATE:** Apr 2016 | **MANUFACTURER:** | HETERO Labs Limited | |
| **EXP. DATE:**  Mar 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 2012 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean 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 peak at RT 8.6 & 17.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In - house Method | No tablet less than 85% [n=6] | Lamivudine Average 108% Range 108 - 109% RSD=0.4%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Tenofovir Disoproxil Fumarate Average = 104% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 103.7 - 104.2 (RSD=0.2%, n=6) |  |
| **Assay** | HPLC | Adopted In - house Method | 90.0 - 110.0% | Lamivudine 98.8% (RSD=1.7%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Tenofovir Disoproxil Fumarate 94.3% (RSD=1.9%, n=6) | **COMPLIES** |

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

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| **ANALYST:** | DR ERIC MUTUA | .......................................................... | DATE: 08-01-2016 |
| **ANALYST:** | DR MATHAYO KWENA | .......................................................... | DATE: 09-01-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-27-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-29-2016 |