**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/422

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| **PRODUCT** | TENOFOVIR DISOPROXIL FUMARATE/ LAMIVUDINE TABLETS 300 mg/300 mg | | REF. NO: NDQB201601698 |
| **DATE RECEIVED:** 26.01.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Tenofovir Disoproxil Fumarate 300 mg and Lamivudine USP 300 mg. | |
| **BATCH NO.:** 8034923 | **PRESENTATION:** | Off white coloured, ovoid shaped, biconvex faced tablets, embossed 'M112' on one face and plain on the other, packed in a white plastic multi-dose container carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Mar. 2015 | **MANUFACTURER:** | MYLAN Laboratories Limited | |
| **EXP. DATE:**  Feb. 2017 | **ADDRESS:** | H-12 & H-13, MIDC, Waluj, Aurangabad - 431136, Maharashtra, 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 4.0 and 10.1 -/+ 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 109.0% (RSD=0.5%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% (n=6) | Tenofovir Disoproxil Fumarate 104.9% (RSD=2.1%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Lamivudine 100.1% (RSD=2.0%; n=8) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Tenofovir Disoproxil Fumarate 95.2% (RSD=1.9%; n=7) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. S. MWANGI |  | DATE:29-02-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:02-03-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:03-03-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-07-2016 |