**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/411

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| **PRODUCT** | ABACAVIR SULFATE/ LAMIVUDINE TABLETS 60 mg/30 mg | | REF. NO: NDQB201601708 |
| **DATE RECEIVED:** 26.01.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Abacavir Sulfate USP equivalent to Abacavir 60 mg and Lamivudine USP 30 mg. | |
| **BATCH NO.:** 3035153 | **PRESENTATION:** | Peach coloured, circular shaped, biconvex faced tablets, single scored on one face and embossed 'M26' on the opposite, unscored face, packed in a white plastic multi-dose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Jan. 2015 | **MANUFACTURER:** | Mylan Laboratories Limited | |
| **EXP. DATE:**  Dec. 2016 | **ADDRESS:** | F-4 & F-12, MIDC, Malegaon, Sinnar, Nashik - 422 113, 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 7.5% 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 standard preparation | Super-imposable peaks at RT 4.2 and 7.1 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 85.0% [n=6] | Abacavir 99.5% (RSD=4.2%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 85.0% [n=6] | Lamividune 101.7% (RSD=4.8%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 95.0 - 105.0% | Abacavir 100.1% (RSD=1.0%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 95.0 - 105.0% | Lamividune 102.0% (RSD=0.9%; n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:19-02-2016 |
| ANALYST: | DR. S. MUTERU |  | DATE:29-02-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:03-02-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-04-2016 |