**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/115

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| **PRODUCT** | ABACAVIR SULFATE / LAMIVUDINE DISPERSIBLE TABLETS 60 mg/ 30 mg | | **REF. NO: NDQB201607051** |
| **DATE RECEIVED:** 2016-07-28 | **LABEL CLAIM:** | Each tablet contains: Abacavir Sulfate USP equivalent to Abacavir 60 mg and Lamivudine USP 30 mg. | |
| **BATCH NO.:** 3054265 | **PRESENTATION:** | Off white coloured, circular shaped, flat faced, bevel edged tablets, embossed â€˜Mâ€™ on one face and single scored and embossed 'AL' and '7' on alternate sides of the score on the other face. 60 tablets packed in a white plastic multi-dose container in a printed box. | |
| **MFG. DATE:** May 2016 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Apr. 2018 | **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, Disintegration, 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 Major Peaks in the assay sample preparation corresponds to those in the assay standard preparation | Super-imposable peaks at RT 3.9, 13.6 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Disintegration** | Disintegration | Adopted In - house Method | All Tablets disintegrate within 3 minutes | All Tablets disintegrated within 1 minute | **COMPLIES** |
| **Assay** | HPLC | Adopted In - house Method | 95.0 - 105.0 % | Abacavir Sulphate 99.0% (RSD=1.6%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Lamivudine 96.9% (RSD=1.5%, n=9) |  |

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

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| **ANALYST:** | SARAH MWANGI | .......................................................... | DATE: 08-01-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 26-09-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-26-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-27-2016 |