**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/414

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| **PRODUCT** | ABACAVIR TABLETS USP 300 mg | | REF. NO: NDQB201602729 |
| **DATE RECEIVED:** 02.02.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Abacavir Sulfate USP equivalent to Abacavir 300 mg. | |
| **BATCH NO.:** 3033446 | **PRESENTATION:** | Peach coloured, caplet shaped, biconvex faced tablets, embossed 'M110' on one face and plain on the other, packed in a white plastic multi-dose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Dec. 2014 | **MANUFACTURER:** | Mylan Laboratories Ltd | |
| **EXP. DATE:**  Nov. 2017 | **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 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of the major peak in the assay sample preparation corresponds to those in the standard preparation | Super-imposable peak at RT 7.1 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | U.S.P 38 NF 33 Page 1997 | No tablet less than 85.0% [n=6] | 102.5% (RSD=2.4%; n=6) | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 95.0 - 105.0% | 97.0% (RSD=2.0%; n=6) | **COMPLIES** |

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

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| ANALYST: | JOYFRIDA CHEPCHUMBA |  | DATE:19-02-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:29-02-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:03-02-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-04-2016 |