**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/239

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| **PRODUCT** | ABACAVIR SULFATE/LAMIVUDINE TABLETS 60 mg/30 mg | | **REF. NO: NDQD2016061028** |
| **DATE RECEIVED:** 03-06-2016 | **LABEL CLAIM:** | Each film coated tablet contains: Abacavir Sulfate USP equivalent to Abacavir 60 mg, Lamivudine USP 30 mg. | |
| **BATCH NO.:** 3032097 | **PRESENTATION:** | Beige coloured, circular shaped, biconvex tablets, single scored on one face and embossed 'M26' on the other. Packed in a white coloured multi-dose container carrying 60 tablets. | |
| **MFG. DATE:** Nov. 2014 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Oct. 2016 | **ADDRESS:** | F-4 & F-12, MIDC, Malegaon, Sinnar, Nashik Ã¢â‚¬â€œ 422 113, Maharashtra, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme, P. O. Box 19361 - 00202, Nairobi, KENYA. | |
| ABC/3TC/03/11.03/2016/00107 | **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 peak at RT 9.0 and 2.4 -/+ 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] | Abacavir Average | **COMPLIES** |
| **Dissolution** |  |  |  | 90% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 88 - 91% (RSD=1.0%; n=6) |  |
| **Dissolution** |  |  |  | Lamivudine Average |  |
| **Dissolution** |  |  |  | 89% Range |  |
| **Dissolution** |  |  |  | 88 - 90% (RSD=0.8%; n=6) |  |
| **Assay** | HPLC | Adopted In-House Method | 95.0 Ã¢â‚¬â€œ 105.0% | Abacavir 99.0% (RSD=0.6%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Lamivudine 98.2% (RSD=0.4%; n=9) | **COMPLIES** |

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

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| **ANALYST:** | DR. E. MUTUA | .......................................................... | DATE: 21-07-2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 12-08-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 11-09-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-15-2016 |