**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | ABACAVIR SULFATE / LAMIVUDINE TABLETS 60 mg /30 mg | | REF. NO: NDQD201508141 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Abacavir Sulfate USP equivalent to Abacavir 60 mg and Lamivudine USP 30 mg. | |
| **BATCH NO.:** 3022056 | **PRESENTATION:** | Orange coloured, circular shaped tablets, single scored on one face and embossed 'M 26' on the opposite, unscored face. Packed in a white coloured plastic multi-dose container carrying 60 tablets. | |
| **MGF. DATE:** Jan. 2014 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:** Dec. 2015 | **ADDRESS:** | F-4 & F-12, MIDC, Malegaon, Sinnar, Nashik - 422 113, Maharashtra, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme P.O. BOX 19361 Nairobi | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | B.P. 2012 Vol .V App XII C | NMT 2 tablets deviate by more than 7.5% from mean 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 preparations |  | **COMPLIES** |
| **Identification** | HPLC | Adopted In House Method | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparations | Super-imposable peaks at RT 2.5 and 11.0 +/- 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In House Method | No tablet less than 80% (n=6) | Abacavir 105.5% (RSD=2.2%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In House Method | No tablet less than 80% (n=6) | Lamivudine 95.9% (RSD=3.4%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In House Method | 95.0% - 105.0% | Abacavir 100.0% (RSD=1.8%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In House Method | 95.0% - 105.0% | Lamivudine 102.8%, (RSD=1.0%, n=6) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:01-10-2015 |
| ANALYST: | DR. E. TANUI |  | DATE:26-10-2015 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:11-04-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:11-06-2015 |