**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | ABACAVIR SULFATE & LAMIVUDINE TABLETS 60 mg/30 mg | | REF. NO: NDQD201508115 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Abacavir Sulfate equivalent to Abacavir 60 mg and Lamivudine U.S.P. 30 mg. | |
| **BATCH NO.:** 3031131 | **PRESENTATION:** | Pitch coloured, circular shaped tablets, single scored on one face and embossed M 26 on the other. Packed in a white coloured multi-dose container carrying 60 tablets. | |
| **MGF. DATE:** Sep.2014 | **MANUFACTURER:** | Mylan Laboratories Ltd | |
| **EXP. DATE:** Aug.2016 | **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 5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC:HPLC | In House Method | RT of the major peaks in the assay sample preparation correspond to those in the assay standard preparations | Super-imposable peaks at RT | **COMPLIES** |
| **Identification** | HPLC:HPLC | In House Method | RT of the major peaks in the assay sample preparation correspond to those in the assay standard preparations | 11.0 and 14.7 Ãƒâ€šÃ‚Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC:HPLC | In House Method | After 45 Mins | Abacavir 104.6% (RSD=2.8%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC | In House Method | After 45 Mins | Lamivudine 104.6% (RSD=2.8%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | In House Method | N/A | Abacavir 102.6% (RSD=1.1%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | In House Method | N/A | Lamivudine =103.2%, RSD=0.4%, n=6) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | JOYFRIDA CHEPCHUMBA |  | DATE:09-08-2015 |