**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | ABACAVIR SULFATE/LAMIVUDINE TABLETS 60 mg/30 mg | | REF. NO: NDQD201508094 |
| **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.:** 3031838 | **PRESENTATION:** | Tan coloured, circular shaped, biconvex faced tablets, single scored on one face and embossed 'M26' on the other, packed in a white plastic, multi-dose container with child-proof cap, carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Oct.2014 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:** Sep.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 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. | Super-imposable peak at RT 2.5 and 11.0 +/- 10% min. present in both the sample and standard assay preparations. | **COMPLIES** |
| **Dissolution** | :HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] | Abacavir 105.9% (RSD = 2.6%, n = 6) | **COMPLIES:COMPLIES** |
| **Dissolution** | :HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] | Lamivudine 98.0% (RSD = 4.5%, n = 6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 95.0% - 105.0% |  | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 95.0% - 105.0% | Abacavir 100.5% (RSD=0.4%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 95.0% - 105.0% |  | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 95.0% - 105.0% | Lamividune 103.3% (RSD=0.5%, n=9) | **COMPLIES:COMPLIES** |

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

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| NULL | NULL |  | DATE:null |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:11-05-2015 |