**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | ABACAVIR SULFATE & LAMIVUDINE TABLETS | | REF. NO: NDQD201508123 |
| **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.:** 8029470 | **PRESENTATION:** | Beige 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 carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Oct.2014 | **MANUFACTURER:** | MYLAN Laboratories Ltd. | |
| **EXP. DATE:** Sep.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 Nairobi | |
|  | **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 2012 Vol.V App XII C | NMT 2 tablets deviate by more than 7.5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC:HPLC | Adopted In-House Method | RT of the major peaks in the assay sample preparation correspond to that in the assay standard preparations | Super-imposable peak at RT 2.5 and 11.0+/-10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC:HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] | Abacavir =105.8%, RSD=3.4%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC | Adopted In-House Method | No tablet less than 80.0% [n=6] | Lamivudine 98.8%, (RSD=6.1%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | Adopted In-House Method | 95.0%-105.0% | Abacavir 103.2%, (RSD=1.4%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | Adopted In-House Method | 95.0%-105.0% | Lamivudine =101.8%, RSD=1.0%, n=9) | **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 |
| REVIEWER: | DR. E. TANUI |  | DATE:16-10-2015 |
| ANALYST: | SERAH MUTERU |  | DATE:11-10-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:11-20-2015 |