**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2016-17/XYZ

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| **PRODUCT** | Tenofovir Disoproxil Fumarate/Lamivudine Tablets | | REF. NO: NDQD201508096 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Tenofovir disoproxil fumarate 300 mg & Lamivudine USP 300 mg. | |
| **BATCH NO.:** 3030545 | **PRESENTATION:** | White coloured, caplet-shaped, tablets, embossed 'M 112' on one face and plain on the other, packed in a white plastic multidose container carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Sep.2014 | **MANUFACTURER:** | MYLAN Laboratories Limited | |
| **EXP. DATE:** Aug.2016 | **ADDRESS:** | H-12 & H-13, MIDC, Waluj, Aurangabad - 431136, 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 2016 Vol. V App XII C | < 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 peaks at RT 3.5 and 8.0 +/- 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 85.0% [n=9] | Tenofovir Disoproxil Fumarate 98.8% (RSD 1.3% ; n = 6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 85.0% [n=9] | Lamivudine 100.3% (RSD = 1.4%; n = 6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0%-110% | Tenofovir Disoproxil Fumarate 96.4% (RSD = 0.6%; n = 6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0%-110% | Lamivudine 96.7% (RSD = 0.6%; n = 6) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | MR. M. SANGALE |  | DATE:21-09-2015 |
| REVIEWER: | DR.E.MBAE |  | DATE:20-11-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:12-08-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-14-2016 |