**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | Lamivudine 300 mg and Tenofovir Disoproxil Fumarate 300 mg Tablets | | REF. NO: NDQD201508128 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Tenofovir Disoproxil Fumarate 300 mg equivalent to Tenofovir Disoproxil 245 mg and Lamivudine USP 300 mg | |
| **BATCH NO.:** BLD1438A | **PRESENTATION:** | White coloured, caplet-shaped, biconvex faced tablets, embossed 'CL 71' on one face and plain on the other, packed in a white plastic multidose container carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Mar.2014 | **MANUFACTURER:** | MACLEODS Pharmaceuticals Ltd | |
| **EXP. DATE:** Feb.2016 | **ADDRESS:** | Village Theda,P.O. Lodhimajra, Tehsil Baddi,Dist. Solan, Himachal Pradesh, INDIA-174101. Off.:Atlanta Arcade,Marol Church Road, Andheri(E),Mumbai-400 059, 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 Major Peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT Value 3.5 and 8.0 Â± 10% min. present in the assay sample preparation | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 85.0% [n=6] | Lamivudine | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 85.0% [n=6] | 95.4% (RSD = 1.4% ; n = 6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 85.0% [n=6] | Tenofovir Disoproxil Fumarate | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 85.0% [n=6] | 94.8% (RSD = 1.4% ; n = 6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Lamivudine | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | 105.2% (RSD = 1.1% ; n = 6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Tenofovir Disoproxil Fumarate | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | 100.7% (RSD = 1.0% ; n = 6) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | MR. M. SANGALE |  | DATE:21-09-15 |
| REVIEWER: | DR. E. MBAE |  | DATE:23-11-15 |
| ANALYST: | ERNEST MBAE |  | DATE:12-08-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-14-2016 |