**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | LAMIVUDINE and TENOFOVIR DISOPROXIL FUMARATE TABLETS 300 mg/ 300 mg | | REF. NO: NDQD201508119 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each tablet contains 300 mg of Lamivudine USP and 300 mg of Tenofovir disoproxil fumarate, which is equivalent to 245 mg of Tenofovir disoproxil | |
| **BATCH NO.:** E140989 | **PRESENTATION:** | Pale blue coloured, caplet-shaped, biconvex faced tablets, embossed '129' on one face and 'H' on the other, packed in a white plastic multi-dose container carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Jun. 2014 | **MANUFACTURER:** | HETERO Labs Limited. | |
| **EXP. DATE:** May. 2016 | **ADDRESS:** | 22-110, I.D.A., Jeedimetla, Hyderabad-500 055, 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 | B.P. 2012 Vol .V App XII C | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of the component peaks in the assay sample preparation corresponds to those in the assay standard preparation | Super-imposable peak at RT 3.6 and 7.9 +/- 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 85% | Tenofovir Disoproxil Fumarate 98.5% (RSD= 1.2%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 85% | Lamivudine 98.6% (RSD=1.2%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0% 110.0% [n=6] | Tenofovir Disoproxil Fumarate 100.9% (RSD =1.4%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0% 110.0% [n=6] | Lamivudine 108.4% (RSD=1.6%; n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | MR. S. SANGALE |  | DATE:21-10-2015 |
| REVIEWER: | DR. E. MBAE |  | DATE:17-11-2015 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:11-19-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:11-25-2015 |