**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/431

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| **PRODUCT** | EFAVIRENZ, LAMIVUDINE and TENOFOVIR DISOPROXIL FUMARATE TABLETS 600 mg/ 300 mg/ 300 mg | | REF. NO: NDQD201508134 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film coated tablet contains 600 mg of Efavirenz USP, 300 mg of Lamivudine USP and 300 mg of Tenofovir Disoproxil Fumarate, which is equivalent to 245 mg of Tenofovir Disoproxil. | |
| **BATCH NO.:** E140433A | **PRESENTATION:** | Beige coloured, caplet-shaped, biconvex faced tablets, embossed '127' on one face and 'I' on the other, packed in a white plastic multidose container carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Mar. 2014 | **MANUFACTURER:** | HETERO Labs Limited. | |
| **EXP. DATE:**  Feb. 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, KENYA | |
| TDF/3TC/EFV/01/11.3.15/00083 | **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 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, 7.9 and 11.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% (n=6) | Efavirenz 99.7% (RSD=1.7%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% (n=6) | Lamivudine 104.7% (RSD=0.5%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% (n=6) | Tenofovir disoproxil fumarate 102.5% (RSD=0.4%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Efavirenz 99.6% (RSD=1.9%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Lamivudine 107.8% (RSD=1.9%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Tenofovir disoproxil fumarate 99.1% (RSD=1.9%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |

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

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| ANALYST: | MR. M. SANGALE |  | DATE:29-02-2016 |
| ANALYST: | DR. S. MUTERU |  | DATE:02-03-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:03-08-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-09-2016 |