**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/708

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| **PRODUCT** | EFAVIRENZ, LAMIVUDINE and TENOFOVIR DISOPROXIL FUMARATE TABLETS 600 mg/300 mg/300 mg | | REF. NO: NDQB201605893 |
| **DATE RECEIVED:** 05.05.2016 | **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 fumarate. | |
| **BATCH NO.:** E160203 | **PRESENTATION:** | Straw coloured, caplet-shaped, biconvex faced tablets, embossed '127' on one face and 'I' on the other, packed in a white plastic multidose container with a child proof closure carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Feb. 2016 | **MANUFACTURER:** | HETERO Labs Limited. | |
| **EXP. DATE:**  Jan. 2018 | **ADDRESS:** | 22 - 110, I.D.A., Jeedimetla, Hyderabad - 500 055, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P.O. Box 47715 - 00100, Nairobi, KENYA | |
|  | **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 | 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 sample preparation correspond to those in the standard preparation | Super-imposable peak at RT 5.5, 15.1, 21.9 -/+ 10% min.for present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | No tablet less than 80%[n=6] No tablet less than 85%[n=6] | Efavirenz 97.7% (RSD=0.8%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | No tablet less than 80%[n=6] No tablet less than 85%[n=6] | Lamivudine 100.0%; (RSD=0.8%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | No tablet less than 80%[n=6] No tablet less than 85%[n=6] | Tenofovir Disoproxil Fumarate 98.6% (RSD=1.0%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | 90.0 - 110.0% | Efavirenz 98.2% (RSD=0.4%; n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | 90.0 - 110.0% | Lamivudine 101.7% (RSD=0.4%; n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | 90.0 - 110.0% | Tenofovir Disoproxil Fumarate 100.1% (RSD=0.6%; n=9) | **COMPLIES:COMPLIES:COMPLIES** |

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

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| ANALYST: | MR. M. SANGALE |  | DATE:08-06-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:08-06-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:06-08-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-13-2016 |