**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/196

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| **PRODUCT** | EFAVIRENZ, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS 600 mg/ 300 mg/ 300 mg | | **REF. NO: NDQB201605976** |
| **DATE RECEIVED:** 26-05-2016 | **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 | |
| **BATCH NO.:** E160380 | **PRESENTATION:** | Light brown coloured, caplet shaped, biconvex faced tablets, embossed 'I' on one face and '127' on the other, 30 tablets packed in a white coloured plastic multi-dose container fitted with a childproof lid in a printed box. | |
| **MFG. DATE:** Mar 2016 | **MANUFACTURER:** | HETERO Labs Limited | |
| **EXP. DATE:**  Feb 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 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 4.3, 16.1 and 25.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In - house Method | No tablet less than 80% [n=6] | Efavirenz Average = 93%, Range | **COMPLIES** |
| **Dissolution** |  |  | No tablet less than 85% [n=6] | 92.8 - 91.3% (RSD=0.1%, n=6) |  |
| **Dissolution** |  |  |  | Lamivudine Average = 99% Range |  |
| **Dissolution** |  |  |  | 98.5 - 99.4% (RSD=0.3%, n=6) |  |
| **Dissolution** |  |  |  | Tenofovir Disoproxil Fumarate Average = 98% Range |  |
| **Dissolution** |  |  |  | 97.7 - 97.8% (RSD=0.04%, n=6) |  |
| **Assay** | HPLC | Adopted In - house Method | 90.0-110.0% | Efavirenz 93.7% (RSD=1.6%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Lamivudine 99.9% (RSD=0.3%, n=6) |  |
| **Assay** |  |  |  | Tenofovir Disoproxil Fumarate 99.4% (RSD=0.7%, n=6) |  |

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

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| **ANALYST:** | DR. S. MWANGI | .......................................................... | DATE: 05-27-2016 |
| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 10-03-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-14-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-18-2016 |