**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/418

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| **PRODUCT** | EFAVIRENZ 600 mg, LAMIVUDINE 300 mg AND TENOFOVIR DISOPROXIL FUMARATE 300 mg TABLETS | | REF. NO: NDQB201601681 |
| **DATE RECEIVED:** 26.01.2016 | **LABEL CLAIM:** | Each film-coated tablet contains: Efavirenz 600 mg, Lamivudine USP 300 mg, Tenofovir disoproxil fumarate 300 mg equivalent to Tenofovir disoproxil 245 mg. | |
| **BATCH NO.:** EISA15003-A | **PRESENTATION:** | Off white coloured, ovoid-shaped, biconvex faced tablets, embossed '91' on one face and 'I' on the other, packed in a white plastic multi-dose container carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Jan. 2015 | **MANUFACTURER:** | Aurobindo Pharma Limited. | |
| **EXP. DATE:**  Dec. 2016 | **ADDRESS:** | Unit-VII, SEZ, APIIC, Plot. No.S1, S.No's: 411, 425, 434, 435 & 458, Green Industrial Park, Polepally Village, Andhra Pradesh, 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** | Weigt | BP 2016 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean tablets 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, 16.4 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 80.0% (n=6) | Efavirenz 94.8% (RSD=0.7%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% (n=6) | Lamivudine 99.9% (RSD=0.6%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% (n=6) | Tenofovir disoproxil fumarate 91.7% (RSD=2.2%; n=6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0 % | Efavirenz 96.5% (RSD=0.7%; n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0 % | Lamivudine 102.0% (RSD=1.3%; n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0 % | Tenofovir disoproxil fumarate 90.7% (RSD=1.5%; n=9) | **COMPLIES:COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. S. MWANGI |  | DATE:29-02-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:02-03-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:03-03-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-07-2016 |