**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/599

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| **PRODUCT** | EFAVIRENZ TABLETS 600 mg | | REF. NO: NDQB201601695 |
| **DATE RECEIVED:** 26.01.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Efavirenz 600 mg. | |
| **BATCH NO.:** HG6014003-A | **PRESENTATION:** | Beige coloured, caplet shaped, biconvex faced tablets, embossed '37' on one face and 'D' on the other, packed in a white plastic multidose container carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Sep. 2014 | **MANUFACTURER:** | AUROBINDO Pharma Limited. | |
| **EXP. DATE:**  Aug. 2017 | **ADDRESS:** | Unit III, Survey No.313, Bachupally Village, Quthubullapur Mandal, Ranga Reddy District (A.P.), 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 the mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 3272 | RT of the component peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 3.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 3272 | No Tablet Less Than 80% [n=6] | 96.2% (RSD=3.3%, n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 3272 | 92.0 - 108.0% | 95.6% (RSD=1.2%, n=9) | **COMPLIES** |

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

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| ANALYST: | DR. K. BOTA |  | DATE:25-04-2016 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:06-05-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:05-10-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-10-2016 |