**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/42

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| **PRODUCT** | EFAVIRENZ TABLETS 600 mg | | **REF. NO: NDQB2016061158** |
| **DATE RECEIVED:** 2016-06-09 | **LABEL CLAIM:** | Each film coated tablet contains: Efavirenz 600 mg. | |
| **BATCH NO.:** HG6014005 - A | **PRESENTATION:** | Beige coloured, caplet shaped, biconvex faced tablets, embossed on one face and '37' on the other, 30 tablets packed in a plastic multidose container in a printed box. | |
| **MFG. 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. | |
| EFV/24/05/2016/126 | **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 | Adopted In - house Method | RT of the component peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 7.8 ± 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] | Average 96%, Range 91% - 97%, (RSD=2.4%, n=6) | **COMPLIES** |
| **Assay** | HPLC | Adopted In - house Method | 90.0 - 110.0% | 98.4% (RSD=1.5%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | MICHAEL SANGALE | .......................................................... | DATE: 07-01-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 07-18-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 07-26-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 08-02-2016 |