**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/176

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| **PRODUCT** | ESTIVA 600 mg TABLETS | | **REF. NO: NDQB2016061157** |
| **DATE RECEIVED:** 09-06-2016 | **LABEL CLAIM:** | Each film-coated tablet contains Efavirenz 600mg. | |
| **BATCH NO.:** EFI16005 | **PRESENTATION:** | Beige coloured, caplet shaped, biconvex faced tablets, embossed '4' on one face and 'H' on the other, 30 Tablets packed in a white plastic multidose container in a unit box. | |
| **MFG. DATE:** Apr. 2016 | **MANUFACTURER:** | HETERO Labs Limited. | |
| **EXP. DATE:**  Mar. 2020 | **ADDRESS:** | Unit-V, TSIIC Formulation SEZ, Polepally Village, Jadcherla mandal, Mahaboobnagar Dist., Telangana, 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 | Adopted In-House Method | RT of the major 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 = 102% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 100 - 104% (RSD=1.5%; n=6) |  |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | 106.5% (RSD=1.60%; n=6) | **COMPLIES** |

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

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| **ANALYST:** | MR. M. SANGALE | .......................................................... | DATE: 07-01-2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 07-20-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-13-2016 |