**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/175

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| **PRODUCT** | EFAVIRENZ TABLETS 600 mg | | **REF. NO: NDQB2016061156** |
| **DATE RECEIVED:** 09-06-2016 | **LABEL CLAIM:** | Each film coated tablet contains: Efavirenz USP 600 mg. | |
| **BATCH NO.:** BEA8616A | **PRESENTATION:** | Beige coloured, caplet shaped, biconvex faced tablets, embossed 'ML 12' on one face and plain on the other, 30 such tablets packed in a white plastic multidose container in a unit box. | |
| **MFG. DATE:** Apr. 2016 | **MANUFACTURER:** | MACLEODS Pharmaceuticals Ltd | |
| **EXP. DATE:**  Mar. 2019 | **ADDRESS:** | Village Theda, P.O. Lodhimajra,Tehsil Baddi, Dist. Solan, Himachal Pradesh, India - 174 101 , Off.: Atlanta Arcade, Marol Church Road, Andheri (E), Mumbai â€“ 400 059, 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** |  |  |  | 99 - 104% (RSD=1.7%; n=6) |  |
| **Assay** | HPLC | Adopted In-House Method | 90.0% - 110.0% | 108.2% (RSD=0.9%, 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 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 08-02-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-13-2016 |