**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/83

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| **PRODUCT** | EFAVIRENZ TABLETS 600 mg | | **REF. NO: NDQB201607052** |
| **DATE RECEIVED:** 2016-07-28 | **LABEL CLAIM:** | Each film coated tablet contains Efavirenz 600 mg. | |
| **BATCH NO.:** BEA8634A | **PRESENTATION:** | Beige coloured, caplet shaped, biconvex faced tablets embossed 'ML 12' on one face and plain on the other, 30 tablets packed in a white plastic multidose container in a unit box. | |
| **MFG. DATE:** May 2016 | **MANUFACTURER:** | MACLEODS Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Apr 2019 | **ADDRESS:** | Village Theda, PO Lodhimajra, Tehsil Baddi, Dist. Solan, Himachal Pradesh, 174101, Off.: Atlanta Arcade, Marol Church Road, Andheri (E), Mumbai - 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** | Tablets | BP 2012 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean weight | None deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Pg 3270 | RT of the component peak in the assay sample preparation corresponds to that in the assay standard peparation | Super-imposable peak at RT 8.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Pg 3270 | No tablet less than 85 | Average = 104% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 93 - 110% (RSD=5.9%, n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 Pg 3270 | 92.0 - 108.0 % | 99.9%, (RSD=0.4%, n=9,) | **COMPLIES** |

**CONCLUSION:**

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| **ANALYST:** | SARAH MWANGI | .......................................................... | DATE: 08-01-2016 |
| **ANALYST:** |  | .......................................................... | DATE: 08-26-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 08-29-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-07-2016 |