**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2016-17/XYZ

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| **PRODUCT** | EFAVIRENZ TABLETS 600 mg | | REF. NO: NDQD201508093 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film-coated tablet contains Efavirenz USP 600 mg | |
| **BATCH NO.:** BEH406A | **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. | |
| **MGF. DATE:** Mar.2014 | **MANUFACTURER:** | MACLEODS Pharmaceuticals Ltd. | |
| **EXP. DATE:** Feb.2016 | **ADDRESS:** | Village Theda, P.O. Lodhimajra, Tehsil Baddi, District Solan, Himachal Pradesh,- 174 101 , Off.: Atlanta Arcade, Marol Church Road, Andheri (E), Mumbai - 400 059, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme P.O. BOX 19361 Nairobi | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** |  | BP 2012 Vol. V App. XII C | < 2 tablets deviate by more than 5% from 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 11.3 Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In - House Method | No tablet less than 80.0% [n=6] | 85.8% (RSD = 0.8% ; n = 6) | **COMPLIES** |
| **Assay** | HPLC | Adopted In - House Method | 90.0%-110.0% | 99.2% RSD = 0.9% ; n = 9) | **COMPLIES** |

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

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| ANALYST: | MR. M. SANGALE |  | DATE:21-10-2015 |
| REVIEWER: | DR. E. MBAE |  | DATE:25-11-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:12-08-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-14-2016 |