**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2015-16/XYZ

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| **PRODUCT** | EFAVIRENZ TABLETS 600 mg | | REF. NO: NDQD201508153 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film-coated tablet contains Efavirenz USP 600 mg | |
| **BATCH NO.:** 7218652 | **PRESENTATION:** | Beige coloured, caplet shaped, biconvex faced tablets, plain on both faces, packed in a white plastic multi-dose container carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Apr. 2013 | **MANUFACTURER:** | STRIDES Arcolab Limited. | |
| **EXP. DATE:** Mar. 2016 | **ADDRESS:** | S-No. 36/7, Suragajakkanahalli, Indlavadi Cross, Anekal Taluk, Bangalore - 562 106, 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** | Weight | B.P. 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 RT 11.3 +/- 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] | 90.9% (RSD = 1.7%; n = 6) | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | 101.4% (RSD = 0.8%; 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:16-11-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:12-02-2015 |