**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/430

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| **PRODUCT** | EFAVIRENZ TABLETS 200 mg | | REF. NO: NDQD201508149 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film-coated tablet contains: Efavirenz USP 200 mg. | |
| **BATCH NO.:** 7219709 | **PRESENTATION:** | Beige coloured, circular shaped, biconvex faced tablets, double scored on one face and plain on the other, packed in a white plastic multidose container carrying 90 tablets in a unit box. | |
| **MGF. DATE:** Aug. 2013 | **MANUFACTURER:** | STRIDES Arcolab Limited. | |
| **EXP. DATE:**  Jul. 2016 | **ADDRESS:** | S-No. 36/7, Suragajakkanahalli, Indlavadi Cross, Anekal Taluk, Bangalore ÃƒÂ¢Ã¢â€šÂ¬Ã¢â‚¬Å“ 562 106, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme P. O. Box 19361, Nairobi, KENYA | |
| EFV/06/11.03.2015/00098 | **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 2012 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean 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 | 90.0 - 110.0% | 99.7% (RSD=0.7%; n=9) | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | No tablet less than 80.0% (n=6) | 102.0% (RSD=0.7%; n=6) | **COMPLIES** |

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

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| ANALYST: | MR. M. SANGALE |  | DATE:29-02-2016 |
| ANALYST: | DR. S. MUTERU |  | DATE:02-03-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:03-08-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-09-2016 |