**CERTIFICATE OF ANALYSIS**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | EFAVIRENZ 200MG TABLETS | | REF. NO: NDQD201508104 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film-coated tablet contains Efavirenz USP 200mg | |
| **BATCH NO.:** 7220422 | **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:** Dec.2013 | **MANUFACTURER:** | STRIDES Arcolab Limited. | |
| **EXP. DATE:** Nov.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**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App. XII C | < 2 tablets deviate by more than 5% from mean tablet weight | < 2 tablets deviate by more than 5% from mean tablet weight | **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 Value | **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 | 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% [n=6] | 96.1% (RSD = 0.4%; n = 6) | **COMPLIES** |
| **Assay** | HPLC | Adopted In - House Method | 90.0 - 110.0% | 99.3% (RSD = 0.7%; n = 9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| 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 |