**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/829

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | NEVIRAPINE 200 mg TABLETS USP | | **REF. NO: NDQD201606989** |
| **DATE RECEIVED:** 02.06.2016 | **LABEL CLAIM:** | Each tablet contains: Nevirapine USP 200 mg. | |
| **BATCH NO.:** G44449 | **PRESENTATION:** | White coloured, elliptical shaped, biconvex faced tablets, single scored on one face and embossed 'N' on the other, packed in a white plastic multi-dose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Apr. 2014 | **MANUFACTURER:** | CIPLA Ltd. | |
| **EXP. DATE:**  Mar. 2017 | **ADDRESS:** | Verna Industrial Estate, Goa 403 722, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme, P. O. Box 19361 - 00202, Nairobi, KENYA. | |
|  | **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 | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 4540 | RT of the component peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 4.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 4540 | No tablet less than 80% [n=6] | 100.7% (RSD=2.4%, n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 4540 | 90.0 - 110.0% | 101.5% (RSD=1.1%, n=6) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | DR. E. MUTUA | .......................................................... | DATE: 17-06-2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 23-06-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 06-28-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-18-2016 |