**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/94

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | NEVIRAPINE TABLETS USP 200 mg | | **REF. NO: NDQB201607001** |
| **DATE RECEIVED:** 05.07.2016 | **LABEL CLAIM:** | Each tablet contains: Nevirapine USP 200 mg. | |
| **BATCH NO.:** 3050548 | **PRESENTATION:** | Off-white coloured, caplet shaped, biconvex faced tablets, single scored on both faces and embossed 'M and '107' on alternate sides of the score on one face, packed in a white plastic multidose container carrying 60 tablets in a unit box. | |
| **MFG. DATE:** Feb. 2016 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Jan. 2019 | **ADDRESS:** | H-12 & H-13, MIDC, Waluj, Aurangabad - 431136, Maharashtra, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P.O. Box 47715 - 00100, 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 major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 4.6 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 4540 | Not less than 80.0% [n=6] | Range | **COMPLIES** |
| **Dissolution** |  |  |  | 91 - 94% (Average = 92% RSD=1.3%; n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 4540 | 90.0 - 110.0% | 93.5% (RSD=1.1%, n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | DR. J. CHEPCHUMBA | .......................................................... | DATE: 13-09-2016 |
| **ANALYST:** | DR. R. MANANI | .......................................................... | DATE: 13-09-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-21-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-22-2016 |