**CERTIFICATE OF ANALYSIS**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | LAMIVUDINE/ NEVIRAPINE/ZIDOVUDINE TABLETS 150 mg /200 mg/300 mg | | REF. NO: NDQD201508157 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Lamivudine USP 150 mg, Nevirapine USP 200 mg and Zidovudine USP 300 mg. | |
| **BATCH NO.:** 3024058 | **PRESENTATION:** | Sky blue coloured, film-coated caplets embossed with 'M104' on one face, packed in a white, plastic, multi-dose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Mar. 2014 | **MANUFACTURER:** | MYLAN Laboratories Ltd. | |
| **EXP. DATE:** Mar. 2019 | **ADDRESS:** | H-12 & H-13, MIDC, Waluj, Aurangabad - 431136, Maharashtra, 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 | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | B.P. 2012 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC:HPLC:HPLC | Adopted In-House Method | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 2.8, 3.7 and 5.2 Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC:HPLC:HPLC | Adopted In-House Method | No tablet less than 80% (n=6) | Lamivudine | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC:HPLC | Adopted In-House Method | No tablet less than 80% (n=6) | 98.3% (RSD = 0.8%; n = 6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC:HPLC | Adopted In-House Method | No tablet less than 80% (n=6) | Nevirapine | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC:HPLC | Adopted In-House Method | No tablet less than 80% (n=6) | 100.4% (RSD = 2.4%; n = 6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC:HPLC | Adopted In-House Method | No tablet less than 80% (n=6) | Zidovudine | **COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:HPLC:HPLC | Adopted In-House Method | No tablet less than 80% (n=6) | 98.4% (RSD = 2.3%; n = 6) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC:HPLC | Adopted In-House Method | 90.0 - 110.0% | Lamivudine | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC:HPLC | Adopted In-House Method | 90.0 - 110.0% | 97.9% (RSD = 0.7%; n = 9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC:HPLC | Adopted In-House Method | 90.0 - 110.0% | Nevirapine | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC:HPLC | Adopted In-House Method | 90.0 - 110.0% | 98.7% (RSD = 1.2%; n = 9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC:HPLC | Adopted In-House Method | 90.0 - 110.0% | Zidovudine | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC:HPLC | Adopted In-House Method | 90.0 - 110.0% | 97.1% (RSD = 0.9%; n = 9) | **COMPLIES:COMPLIES:COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | DR. E. MUTUA |  | DATE:01-10-2015 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:04-10-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:11-02-2015 |