**CERTIFICATE OF ANALYSIS**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | LAMIVUDINE 300 mg and TENOFOVIR DISOPROXIL FUMARATE 300 mg TABLETS | | REF. NO: NDQD201508105 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Lamivudine USP 300 mg and Tenofovir disoproxil fumarate 300 mg equivalent to tenofovir disoproxil 245 mg. | |
| **BATCH NO.:** LTSA14017-B | **PRESENTATION:** | Blue coloured, caplet-shaped, biconvex faced tablets, embossed 'J' on one face and '27' on the other, packed in a white plastic multi-dose container with a child proof cap carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Apr. 2014 | **MANUFACTURER:** | AUROBINDO Pharma Limited | |
| **EXP. DATE:** Mar. 2016 | **ADDRESS:** | Unit-VII, SEZ, APIIC, Plot. No. S1, S.Nos: 411, 425, 434, 435 & 458, Green Industrial Park, Polepally Village, Jedcherla Mandal, Mahaboobnagar District,Andhra Pradesh, 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 | B.P. 2012 Vol. V App XII C | < 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | 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 | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | 3.5 and 8.0 +/- 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 85.0% [n=6] | Tenofovir Disoproxil Fumarate 85.4% (RSD=0.5%; n = 6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 85.0% [n=6] | Lamivudine 88.8% (RSD=0.5%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Tenofovir Disoproxil Fumarate 96.1% (RSD=1.7%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Lamivudine 103.5% (RSD=1.7%; n=9) | **COMPLIES:COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | MR. M. SANGALE |  | DATE:26-10-2015 |
| REVIEWER: | DR. E. MBAE |  | DATE:17-11-2015 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:11-20-2015 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:11-20-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:11-25-2015 |