**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/93

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | TENOFOVIR DISOPROXIL FUMARATE TABLETS 300 mg | | **REF. NO: NDQD201607041** |
| **DATE RECEIVED:** 26.07.2016 | **LABEL CLAIM:** | Each film coated tablet contains; 300 mg of Tenofovir Disoproxil Fumarate, which is equivalent to 245 mg of Tenofovir Disoproxil. | |
| **BATCH NO.:** TJ3015002-B | **PRESENTATION:** | Off - white coloured, ovoid shaped, biconvex faced tablets embossed 'I' on one face and '36' on the other, packed in a white plastic multidose container fitted with a child proof cap carrying 30 tablets in a unit box. | |
| **MFG. DATE:** Oct .2015 | **MANUFACTURER:** | AUROBINDO Pharma Limited. | |
| **EXP. DATE:**  Sep. 2017 | **ADDRESS:** | Unit III, Survey No. 313, Bachupally Village, Quthubullapur Mandal, Ranga Reddy District, (A.P.)., 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 | B.P. 2016 Vol .V App XII C | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Authorised USP Pending Monograph | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 6.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | Authorised USP Pending Monograph | No tablet less than 85% (n=6) | Average = 97%, Range | **COMPLIES** |
| **Dissolution** |  |  |  | 96 - 99% (RSD=1.2%; n=6) |  |
| **Assay** | HPLC | Authorised USP Pending Monograph | 90.0 - 110.0% | 100.3% (RSD=1.0%; n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | DR.E. MUTUA | .......................................................... | DATE: 13-09-2016 |
| **ANALYST:** | DR .S. MUTERU | .......................................................... | DATE: 13-09-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-21-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-22-2016 |