**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/197

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | LAMIVUDINE 150 mg & ZIDOVUDINE 300 mg TABLETS | | **REF. NO: NDQD201607040** |
| **DATE RECEIVED:** 26-07-2016 | **LABEL CLAIM:** | Each film coated tablet contains: Lamivudine USP 150 mg and Zidovudine USP 300 mg.. | |
| **BATCH NO.:** LZ1516013-A | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, embossed 'C60' on one face and plain on the other, 60 tablets packed in a white coloured plastic multi-dose container in a printed box. | |
| **MFG. DATE:** Jun. 2016 | **MANUFACTURER:** | AUROBINDO Pharma Limited. | |
| **EXP. DATE:**  May 2019 | **ADDRESS:** | Unit III, Survey No. 313 & 314, Bachupally Village, Quthulbullapur Mandal, Ranga Reddy District Telangana State, 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 the 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 peak at RT 2.8 & 3.6 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In - house Method | No Tablet Less Than 80% [n=6] | Lamivudine Average = 101% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 100 - 105%, (RSD=1.6%; n=6) |  |
| **Dissolution** |  |  |  | Zidovudine Average = 101% Range |  |
| **Dissolution** |  |  |  | 100 - 105% (RSD=1.8%; n=6) |  |
| **Assay** | HPLC | Adopted In - house Method | 90.0 - 110.0 % | Lamivudine 98.0% (RSD=1.4%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Zidovudine 98.5% (RSD=1.5%; n=9) |  |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | DR. S. MWANGI | .......................................................... | DATE: 08-01-2016 |
| **ANALYST:** | DR M. KWENA | .......................................................... | DATE: 08-26-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-18-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-19-2016 |