**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/298

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| **PRODUCT** | LAMIVUDINE 150 mg & ZIDOVUDINE 300 mg TABLETS | | **REF. NO: NDQB201610191** |
| **DATE RECEIVED:** 25.10.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Lamivudine USP 150 mg and Zidovudine USP 300 mg. | |
| **BATCH NO.:** LZ1516016-A | **PRESENTATION:** | White coloured, caplet shaped, biconvex tablets, embossed â€˜C 60â€™ on one face and plain on the other; packed in a white multidose plastic container of 60 tablets 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, Quthubullapur Mandal, Ranga Reddy District (A.P), Telangana State, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P. O. Box 47715 - 00100, Nairobi, KENYA. | |
| 3TC/AZT/12/10/2016/193 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App. XII C | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted In-house Method | RTs of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 2.9 and 3.7 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-house Method | No tablet less than 80.0% | Lamivudine 102.2% (Range | **COMPLIES** |
| **Dissolution** |  |  |  | 100 - 107%) (RSD=2.4%; n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Zidovudine 100.9% (Range |  |
| **Dissolution** |  |  |  | 95 - 108%) (RSD=4.2%; n=6) |  |
| **Assay** | HPLC | Adopted In-house Method | 90.0 - 110.0% | Lamivudine 100.0% (RSD=1.5%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Zidovudine 101.4% (RSD=1.7%; n=9) | **COMPLIES** |

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

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| **ANALYST:** | SARAH MWANGI | .......................................................... | DATE: 10-26-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 25-11-2016 |
| **ANALYST:** | NICHOLAS MWAURA | .......................................................... | DATE: 11-25-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-29-2016 |