**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2016-17/

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| **PRODUCT** | LAMIVUDINE 150 mg & ZIDOVUDINE TABLETS 300 mg | | **REF. NO:** NDQD2016061039 |
| **DATE RECEIVED:** 03.06.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Lamivudine USP 150 mg and Zidovudine USP 300 mg. | |
| **BATCH NO.:** LZ1515037-A | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, embossed ΄C 60΄ on one face and plain on the other, packed in a white, plastic, multi-dose container carrying 60 tablets in a unit box. | |
| **MFG. DATE:** May. 2015 | **MANUFACTURER:** | AUROBINDO Pharma Limited. | |
| **EXP. DATE:** Apr. 2018 | **ADDRESS:** | Unit III, Survey No. 313,  Bachupally Village, Quthubullapur Mandal,  Ranga Reddy District (A.P.),  INDIA. | |
| **CLIENT REF NO:**  AZT/3TC/  09/07.03.2016/0015 | **CLIENT:** | National AIDS and STI Control Program,  P. O. Box 19361-00202, KNH, Nairobi,  KENYA. | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution and 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 | RT of component peaks in the sample assay preparation correspond to those in the standard assay preparation | Super-imposable peaks at  RT 2.8 and 4.2 ± 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**: 101%  Range: 101%  (RSD=0.2%; n=6) | **COMPLIES** |
| **Zidovudine**: 87%  Range: 87%  (RSD=0.1%; n=6) | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | **Lamivudine:** 98.5% (RSD=1.8%; n=8) | **COMPLIES** |
| **Zidovudine:** 93.7%  (RSD=1.5%; n=9) | **COMPLIES** |

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

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| **ANALYST:** | MR. K. RUTTO |  | DATE: | 22-05-2017 |
| **ANALYST:** | DR. N. MWAURA |  | DATE: | 22-05-2017 |
| **DIRECTOR:** | DR. H. K. CHEPKWONY |  | DATE: | 22-05-2017 |

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| **INVOICE** |

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| **INVOICE No: /16-17** | **Date: 22nd May 2017** |

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| **National AIDS and STI Control Program,** |
| **P.O. Box 19361 – 00202, KNH, Nairobi,** |
| **KENYA.** |

**Re: ANALYSIS OF LISTED PRODUCT**.

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| **PRODUCT:** | LAMIVUDINE 150 mg & ZIDOVUDINE 300 mg TABLETS |
| **BATCH NO:** | LZ1515037-A |
| **CERTIFICATE NO:** | CAN/2016-17/ |
| **LABORATORY REF NO:** | NDQD2016061039 |
| **CLIENT REF NO:** | AZT/3TC/09/07.03.2016/0015 |
| **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution and Assay. |

**COST OF ANALYSIS:**

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| **TEST** | **METHOD** | **COMPENDIA** | **COST (KShs)** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V | **2,040.00** |
| **Dissolution** | HPLC | Adopted In-House Method | **57,600.00** |
| **Identification and Assay** | HPLC | Adopted In-House Method | **52,630.00** |
|  | | **TOTAL COST** | **112,270.00** |
| **DISCOUNT 5%** | **(5,613.50)** |
| **AMOUNT PAYABLE** | **106,656.50** |

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| **DIRECTOR:** | DR. H. K. CHEPKWONY |  | **DATE:** | 22/05/2017 |