**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/291

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| **PRODUCT** | LAMIVUDINE / ZIDOVIDNE TABLETS USP 150 mg/300 mg | | **REF. NO: NDQB201609138** |
| **DATE RECEIVED:** 29.09.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Lamivudine USP 150 mg and Zidovudine USP 300 mg. | |
| **BATCH NO.:** 3038927 | **PRESENTATION:** | White coloured, caplet shaped, biconvex faced tablets, single scored and embossed â€˜Mâ€™ and '2' on either side of the score on one face and â€˜Lâ€™ and 'Z' on either side of the score on the opposite face, packed in a white, plastic multi-dose container of 60 tablets in a printed box. | |
| **MFG. DATE:** Apr. 2015 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Mar. 2019 | **ADDRESS:** | F-4 & F-12, MIDC, Malegaon, Sinnar, Nashik - 422 113, Maharashtra, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P. O. Box 47715 - 00100, Nairobi, KENYA. | |
| 3TC/AZT/19/09/2016/156 | **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 | RT 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% | Lamivudine 96.0% (Range | **COMPLIES** |
| **Dissolution** |  |  |  | 95.9 - 96.3%) (RSD=0.3%; n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Zidovudine 97.0%, (Range |  |
| **Dissolution** |  |  |  | 95 - 98%) (RSD=1.1%; n=6) |  |
| **Assay** | HPLC | Adopted In-house Method | 90.0 - 110.0% | Lamivudine 99.2% (RSD=0.8%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Zidovudine 98.9% (RSD=0.9%; n=9) | **COMPLIES** |

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

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| **ANALYST:** | KENNEDY RUTTO | .......................................................... | DATE: 10-03-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 25-11-2016 |
| **ANALYST:** | NICHOLAS MWAURA | .......................................................... | DATE: 11-25-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-29-2016 |