**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/127

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| **PRODUCT** | LAMIVUDINE/ZIDOVUDINE 150 mg/300 mg TABLETS | | **REF. NO: NDQB201607007** |
| **DATE RECEIVED:** 2016-07-05 | **LABEL CLAIM:** | Each film coated tablet contains: Lamivudine USP 150 mg and Zidovudine USP 300 mg. | |
| **BATCH NO.:** 3034819 | **PRESENTATION:** | Off-white coloured, caplet shaped, biconvex faced tablets, embossed 'M103' on one face and plain on the other. 60 such tablets packed in a white plastic multidose container with a child proof cap in a unit box. | |
| **MFG. DATE:** Jan. 2015 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Dec. 2018 | **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/07/06/2016/152 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **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 mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of major peaks in assay sample preparation correspond to those in assay standard preparations | Super-imposable peaks at RT 2.8 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 Average = 101% 100 - 102% (RSD=0.6%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Zidovudine Average = 99% Range |  |
| **Dissolution** |  |  |  | 97 - 100% (RSD=1.1%, n=6) |  |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Lamivudine 91.5% (RSD=1.4%, n=6) | **COMPLIES** |
| **Assay** |  |  |  | Zidovudine 93.3% (RSD=0.5%, n=6) |  |

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

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| **ANALYST:** | JOYFRIDA CHEPCHUMBA | .......................................................... | DATE: 07-12-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-27-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-29-2016 |