**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/96

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| **PRODUCT** | LAMIVUDINE TABLETS 150 mg | | **REF. NO: NDQB2016061148** |
| **DATE RECEIVED:** 2016-06-09 | **LABEL CLAIM:** |  | |
| **BATCH NO.:** ELC9503A | **PRESENTATION:** | White coloured, caplet shaped, biconvex faced tablets, single scored on one face and embossed ' ML 1' on the other. Packed in a white plastic multi dose container carrying 60 tablets in a unit box. | |
| **MFG. DATE:** May 2015 | **MANUFACTURER:** | Macleods Pharmaceuticals Ltd | |
| **EXP. DATE:**  Apr 2018 | **ADDRESS:** | Plot No. 25-27, Survey No. 366, Premier Ind. Estate, Kachigam, Daman - 396 210 (U.T.) Off.: Atlanta Arcade, Marol Church Road, Andheri (E), Mumbai - 400 059 INDIA | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P.O. Box 47715 - 00100, Nairobi, Kenya. | |
| 3TC/24/05/2016/134 | **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 weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | BP 2016 Vol III Pg 753 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 6.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | BP 2016 Vol III Pg 753 | No tablet less than 80% | Average = 92% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 90 - 93% (RSD=1.3%, n=6) |  |
| **Assay** | HPLC | BP 2016 Vol III Pg 753 | 95.0-105.0% | 99.9% (RSD=1.2%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | DR. KWENA | .......................................................... | DATE: 07-01-2016 |
| **ANALYST:** | DR. SERAH MUTERU | .......................................................... | DATE: 08-12-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-22-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-22-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-22-2016 |