**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/650

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| **PRODUCT** | LAMIVUDINE TABLETS 150 mg | | REF. NO: NDQB201603828 |
| **DATE RECEIVED:** 31.03.2016 | **LABEL CLAIM:** | Each film coated tablet contains:Lamivudine USP 150 mg. | |
| **BATCH NO.:** ELC9502A | **PRESENTATION:** | Off white coloured, caplet-shaped, biconvex faced tablets, single scored on one face and embossed 'ML 1' on the other face, packed in a white plastic multi-dose container carrying 60 tablets in a unit box. | |
| **MGF. 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 | |
|  | **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 the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 3.4 -/+ 10% min for Lamivudine present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80% [n=6] | 99.0% (RSD=1.3%, n=6) | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0% - 110.0% | 95.2% (RSD=1.0%, n=9) | **COMPLIES** |

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

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| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:09-05-2016 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:16-05-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:05-23-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-30-2016 |