**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/98

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | LAMIVUDINE TABLETS 150 mg | | **REF. NO: NDQB201607008** |
| **DATE RECEIVED:** 2016-07-05 | **LABEL CLAIM:** | Each film coated tablet contains: Lamivudine USP 150 mg. | |
| **BATCH NO.:** ELC9505A | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, embossed 'ML 1" on one face and single scored on the other, packed in a plastic container of 60 tablets in a unit box. | |
| **MFG. DATE:** Jun. 2015 | **MANUFACTURER:** | MACLEODS Pharmaceuticals Ltd. | |
| **EXP. DATE:**  May 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/09/06/2016/157 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 | BP 2016 Volume III page 753 | RT of the Major Peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 6.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | BP 2016 Volume III page 753 | No Tablet Less Than 80% | Average = 95%, Range | **COMPLIES** |
| **Dissolution** |  |  |  | 94 - 97% (RSD=1.4%, n=6) |  |
| **Assay** | HPLC | BP 2016 Volume III page 753 | 95.0 - 105.0% | 96.7%, ( RSD=1.5%, n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | JOYFRIDA CHEPCHUMBA | .......................................................... | DATE: 07-12-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 22-09-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-22-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-26-2016 |