**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/320

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | LAMIVUDINE TABLETS 150 mg | | **REF. NO: NDQD201606999** |
| **DATE RECEIVED:** 02-06-2016 | **LABEL CLAIM:** | Each film coated tablet contains: Lamivudine USP 150mg. | |
| **BATCH NO.:** ELC9503A | **PRESENTATION:** | Off-white coloured, caplet shaped, biconvex faced tablets, single scored on one face and embossed 'ML 1" on the other, 60 such tablets packed a in a white plastic multidose container in a printed 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.) INDIA | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme, P. O. Box 19361 - 00202, Nairobi, KENYA. | |
| 3TC/09/15.03.2016/0294 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | Not More Than 2 tablets deviate by more than 5% from mean weight | None deviates | **COMPLIES** |
| **Identification** | HPLC | BP 2016 Vol. III Page 753 | Retention Time 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 Page 753 | No tablet less than 80% | Average | **COMPLIES** |
| **Dissolution** |  |  |  | 94% (Range |  |
| **Dissolution** |  |  |  | 93 - 94%) (RSD=0.4%; n=6) |  |
| **Assay** | HPLC | BP 2016 Vol. III Page 753 | 95.0 - 105.0% | 101.0% (RSD=1.3%; n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | JOYFRIDA CHEPCHUMBA | .......................................................... | DATE: 07-01-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-11-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 12-02-2016 |