**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/311

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | ABACAVIR TABLETS USP 300 MG | | **REF. NO: NDQB201609137** |
| **DATE RECEIVED:** 2016-09-29 | **LABEL CLAIM:** | Each film coated tablet contains: Abacavir Sulfate USP equivalent to Abacavir 300 mg. | |
| **BATCH NO.:** 3025951 | **PRESENTATION:** | Beige coloured, caplet shaped,biconvex faced tablets, embossed 'M 110' on one face and plain on the other, packed in a white coloured multi-dose container carrying 60 tablets. | |
| **MFG. DATE:** Apr. 2014 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Mar. 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. | |
| ABC/20-09-2016/178 | **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 | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 1997 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 22.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 1997 | No Tablet Less Than 85.0% | 100.8% (Range | **COMPLIES** |
| **Dissolution** |  |  |  | 100 - 101%) (RSD = 0.5%; n = 6) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 1997 | 90.0 - 110.0% | 98.6% (RSD = 0.9%; n = 9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | MS. S. KARIUKI | .......................................................... | DATE: 10-03-2016 |
| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 11-14-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 11-29-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-29-2016 |