**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/290

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | LOPINAVIR / RITONAVIR TABLETS 200 mg / 50 mg | | **REF. NO: NDQB201610185** |
| **DATE RECEIVED:** 25.10.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Lopinavir 200 mg and Ritonavir USP 50 mg. | |
| **BATCH NO.:** 3051700 | **PRESENTATION:** | Beige coloured, caplet shaped, bevel edged tablets, imprinted™ on one face and plain on the other, packed in a white, plastic multi-dose container of 120 tablets in a printed box. | |
| **MFG. DATE:** Mar. 2016 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Feb. 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. | |
| LPV/11/10/2016/190 | **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 Pg 4131 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 11.5 & 10.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Pg 4131 | No tablet less than 85.0% | Lopinavir 99.6% (Range | **COMPLIES** |
| **Dissolution** |  |  |  | 95% - 106%) (RSD= 4.7%; n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Ritonavir 93.7% (Range |  |
| **Dissolution** |  |  |  | 89 - 99%) (RSD=4.7%; n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 Pg 4131 | 90.0 - 110.0% | Lopinavir 108.1% (RSD=0.3%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Ritonavir 100.6% (RSD=0.8%; n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | SARAH MWANGI | .......................................................... | DATE: 10-26-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 24-10-2016 |
| **ANALYST:** | NICHOLAS MWAURA | .......................................................... | DATE: 11-25-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-29-2016 |