**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/85

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | ALUVIA(TM) 200 mg /50 mg TABLETS | | **REF. NO: NDQD2016061024** |
| **DATE RECEIVED:** 03.06.2016 | **LABEL CLAIM:** | Each film-coated tablet contains: Lopinavir 200 mg and Ritonavir 50 mg. | |
| **BATCH NO.:** 485168D | **PRESENTATION:** | Brick red coloured, caplet shaped, biconvex faced tablets, embossed with the manufacturer's logo and 'AL' on one face and plain on the other, packed in a white plastic multidose container fitted with a child proof cap carrying 120 tablets. | |
| **MFG. DATE:** Aug. 2014 | **MANUFACTURER:** | ABBOTT GmbH & Co. KG. | |
| **EXP. DATE:**  Jul. 2018 | **ADDRESS:** | Knollstrasse, Ludwigshafen, GERMANY. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme, P. O. Box 19361 - 00202, Nairobi, KENYA. | |
| LPV/04/16.03.2016/0101 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | Ph. Int. 5th Edition | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Ph. Int. 5th Edition | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 5.2 and 7.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Ph. Int. 5th Edition | No tablet less than 80% (n=6) | Lopinavir Average = 99% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 98 - 100% (RSD=0.7%, n=6) |  |
| **Dissolution** |  |  |  | Ritonavir Average = 100% Range |  |
| **Dissolution** |  |  |  | 99 - 101% (RSD=0.6%, n=6) |  |
| **Assay** | HPLC | Ph. Int. 5th Edition | 90.0 - 110.0% | Lopinavir 94.8% (RSD=0.8%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Ritonavir 96.7% (RSD=0.8%, n=9 |  |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | MR. M. ONGAS | .......................................................... | DATE: 18-06-2016 |
| **ANALYST:** | DR. G. WANG'ANG'A | .......................................................... | DATE: 29-06-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 08-23-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-22-2016 |