**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/705

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| **PRODUCT** | ALUVIA TM 200 mg/50 mg TABLETS | | REF. NO: NDQB201603802 |
| **DATE RECEIVED:** 15.03.2016 | **LABEL CLAIM:** | Each film-coated tablet contains: Lopinavir 200 mg and Ritonavir 50 mg. | |
| **BATCH NO.:** 1045942 | **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. | |
| **MGF. DATE:** May 2015 | **MANUFACTURER:** | ABBOTT GmbH & Co. KG. | |
| **EXP. DATE:**  Apr. 2019 | **ADDRESS:** | Knollstrasse, Ludwigshafen, GERMANY. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P.O. Box 47715 - 00100, Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **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 | Adopted In-House Method | RT of the component peaks in assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 7.0 & 8.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | :S2: Average Not Less Than 80%; No Unit is less than 65% (n=12) |  | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | :S2: Average Not Less Than 80%; No Unit is less than 65% (n=12) |  | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | :S2: Average Not Less Than 80%; No Unit is less than 65% (n=12) | Lopinavir 98.4% (RSD=6.5% ; n=12) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | :S2: Average Not Less Than 80%; No Unit is less than 65% (n=12) | Ritonavir 94.7% (RSD=6.8% ; n=12) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Lopinavir 103.7% (RSD=0.5% ; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Ritonavir 98.0% (RSD=0.7% ; n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. K. BOTA |  | DATE:12-05-2016 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:06-06-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:06-07-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:06-07-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-10-2016 |