**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/701

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| **PRODUCT** | ANZAVIR-R TABLETS 300 mg/100 mg | | REF. NO: NDQB201604859 |
| **DATE RECEIVED:** 14.04.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Atazanavir (as sulfate) equivalent to Atazanavir 300 mg and Ritonavir USP 100 mg. | |
| **BATCH NO.:** 3048394 | **PRESENTATION:** | Bi-layered white to off-white coloured, caplet shaped, biconvex faced tablets, embossed 'M777'on white face and plain on the off-white face, packed in a white plastic multi-dose container carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Aug. 2015 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Jul. 2017 | **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 | |
|  | **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 | Manufacturer's 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 5.1 & 7.1 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | After 45 Minutes Atazanavir No Tablet Less than 50% Ritonavir No Tablet Less than 30% :After 90 Mins No Tablet Less than 80% [n=6] | Atazanavir 76.6% (RSD=15.3%, n=6) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | After 45 Minutes Atazanavir No Tablet Less than 50% Ritonavir No Tablet Less than 30% :After 90 Mins No Tablet Less than 80% [n=6] | Ritonavir 69.0% (RSD=14.3%, n=6) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | After 45 Minutes Atazanavir No Tablet Less than 50% Ritonavir No Tablet Less than 30% :After 90 Mins No Tablet Less than 80% [n=6] | Atazanavir 100.9% (RSD=4.6%, n=6) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | After 45 Minutes Atazanavir No Tablet Less than 50% Ritonavir No Tablet Less than 30% :After 90 Mins No Tablet Less than 80% [n=6] | Ritonavir 97.0% (RSD=5.9%, n=6) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | 95.0 -105.0% | Atazanavir 99.2% (RSD=0.8%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | 95.0 -105.0% | Ritonavir 100.2% (RSD=0.8%, n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. K. BOTA |  | DATE:20-05-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:06-06-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:06-07-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-10-2016 |