**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/525

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| **PRODUCT** | ANZAVIR-R TABLETS 300 mg/ 100 mg | | REF. NO: NDQB201601710 |
| **DATE RECEIVED:** 26.01.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Atazanavir (as sulfate) equivalent to Atazanavir 300 mg and Ritonavir USP 100 mg. | |
| **BATCH NO.:** 3038779 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, embossed 'M777'on one face and plain on the other, packed in a white plastic multi-dose container carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Mar 2015 | **MANUFACTURER:** | MYLAN Laboratories Ltd. | |
| **EXP. DATE:**  Feb 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 | Adopted In-House Method | RT of the Component peaks in assay sample preparation correspond to those in the assay standard preparation | Super-imposable peak at RT 8.6 and 13.2 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | After 45 Mins Ritonavir No Tablet Less than 30% Atazanavir No Tablet Less than 50% [n=6]:After 90 Mins No Tablet Less than 80% [n=6] | Ritonavir 60% (RSD=9.3%, n=6) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | After 45 Mins Ritonavir No Tablet Less than 30% Atazanavir No Tablet Less than 50% [n=6]:After 90 Mins No Tablet Less than 80% [n=6] | Atazanavir 87% (RSD=12.5%, n=6) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | After 45 Mins Ritonavir No Tablet Less than 30% Atazanavir No Tablet Less than 50% [n=6]:After 90 Mins No Tablet Less than 80% [n=6] | Ritonavir 95% (RSD=9.1%, n=6) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | After 45 Mins Ritonavir No Tablet Less than 30% Atazanavir No Tablet Less than 50% [n=6]:After 90 Mins No Tablet Less than 80% [n=6] | Atazanavir 98% (RSD=4.9%, n=6) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Ritonavir 101.9% (RSD=1.1%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | Atazanavir 100.2% (RSD=1.6%; n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. K. BOTA |  | DATE:04-04-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:07-04-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:04-12-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-19-2016 |