**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/322

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| **PRODUCT** | ANZAVIR-R TABLETS 300 mg/ 100 mg | | **REF. NO: NDQB201609136** |
| **DATE RECEIVED:** 29.09.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Atanazavir (as sulfate) equivalent to Atazanavir 300 mg and Ritonavir 100 mg. | |
| **BATCH NO.:** 3044452 | **PRESENTATION:** | White coloured, caplet shaped, biconvex faced tablets, embossed â€˜M777â€™ on one face and plain on the opposite face, packed in a white, plastic multi-dose container of 30 tablets contained in a printed box. | |
| **MFG. 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. | |
| ATV/23-09-2016/181 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **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 | Manufacturer's In-House Method | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 6.6 and 8.4 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | After 45 Minutes No tablet less than 50.0% | After 45 Minutes Atazanavir 76.5% Range 76% - 77% (RSD=0.4%; n=6) Ritonavir 53.4% Range 53% - 54% (RSD=0.6%, n=6) | **COMPLIES** |
| **Dissolution** |  |  | After 90 Minutes No tablet less than 80.0% | After 90 Minutes Atazanavir 94.0% (Range | **COMPLIES** |
| **Dissolution** |  |  |  | 93 - 95%) (RSD=1.3%; n=6) Ritonavir 97.3% (Range |  |
| **Dissolution** |  |  |  | 96 - 98%) (RSD=0.7%; n=6) |  |
| **Assay** | HPLC | Manufacturer's In-House Method | 95.0 - 105.0% | Atazanavir 96.2% (RSD=1.8%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Ritonavir 99.2% (RSD=0.6%; n=9) | **COMPLIES** |

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

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| **ANALYST:** | SARAH KARIUKI | .......................................................... | DATE: 10-03-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 30-11-2016 |
| **ANALYST:** | NICHOLAS MWAURA | .......................................................... | DATE: 11-30-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 12-02-2016 |