**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/191

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| **PRODUCT** | ANZAVIR - R TABLETS 300 mg/100 mg | | **REF. NO: NDQB201607050** |
| **DATE RECEIVED:** 28-07-2016 | **LABEL CLAIM:** | Each film coated tablet contains: Atazanavir (as Sulfate) equivalent to Atazanavir 300 mg and Ritonavir USP 100 mg. | |
| **BATCH NO.:** 3054731 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, embossed 'M777' on one face and plain on the other, 30 tablets packed in a white coloured plastic multi-dose container in a printed box. | |
| **MFG. DATE:** Apr. 2016 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Mar. 2018 | **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 | B.P. 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 Major Peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 4.8 & 5.6 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In - house Method | Atazanavir No tablet less than 80% (n = 6) | Average = 93% Range | **COMPLIES** |
| **Dissolution** |  |  | Ritonavir No tablet less than 75% after 90 minutes (n = 6) | 91 - 96% (RSD=2.5%, n=6) |  |
| **Dissolution** |  |  | Ritonavir No tablet less than 85% after 150 minutes (n = 6) | Average = 97%, Range |  |
| **Dissolution** |  |  |  | 90 - 107%, (RSD=5.6%, n=6) |  |
| **Dissolution** |  |  |  | Average = 99% Range |  |
| **Dissolution** |  |  |  | 94 - 106%, (RSD=5.4%, n=6) |  |
| **Assay** | HPLC | Adopted In - house Method | 90.0 - 110.0% | Atazanavir 96.5% (RSD=1.7%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Ritonavir 103.6% (RSD=1.5%, n=9) |  |

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

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| **ANALYST:** | SARAH MWANGI | .......................................................... | DATE: 08-01-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 26-09-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-26-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-18-2016 |