**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | ANZAVIR-R TABLETS | | REF. NO: NDQD201508146 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film coated tablet contains:Atazanavir (as sulfate) equivalent to Atazanavir 300 mg Ritonavir USP 100 mg. | |
| **BATCH NO.:** 3025839 | **PRESENTATION:** | Bi-layered caplet shaped, biconvex faced, embossed with "M777" on one face of the tablet and plain on the other, packed in a white plastic multi-dose container, carrying 30 tablets in a unit box. | |
| **MGF. DATE:** Feb.2014 | **MANUFACTURER:** | MYLAN Laboratories Ltd. | |
| **EXP. DATE:** Jan.2016 | **ADDRESS:** | F-4 & F-12, MIDC,Malegaon, Sinnar, Nashik - 422 113, Maharashtra, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme P.O. BOX 19361 Nairobi | |
| ATV/08/11.03.2015/00131 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | B.P. 2012 Vol .V App XII C | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | :HPLC | Adopted In House Method | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peaks at RT | **COMPLIES** |
| **Identification** | :HPLC | Adopted In House Method | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | 8.2 and 11.1 Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | :HPLC | Adopted In House Method | No tablet less than 80.0% [n=6] | Atazanavir 90.7% (RSD = 6.1% ; n = 6) | **COMPLIES** |
| **Assay** | HPLC:HPLC | In House Method | 90.0-110.0 | Ritonavir 100.2% (RSD = 1.2% ; n = 9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | In House Method | 90.0-110.0 | Atazanavir 98.3% (RSD = 0.4% ; n = 9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | MR. D. MOENGA |  | DATE:30-09-2015 |
| ANALYST: | DR. G. WANG'ANGA |  | DATE:02-10-2015 |
| ANALYST: | SERAH MUTERU |  | DATE:10-14-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:10-14-2015 |