**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/89

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| **PRODUCT** | ABACAVIR SULFATE TABLETS USP 300 mg | | **REF. NO: NDQD201606985** |
| **DATE RECEIVED:** 02.06.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Abacavir Sulfate USP equivalent to Abacavir 300 mg. | |
| **BATCH NO.:** 3033483 | **PRESENTATION:** | Peach coloured, caplet shaped, biconvex faced tablets, embossed 'M110' on one face but plain on the other, packed in a white coloured, plastic multi-dose container carrying 60 tablets in a unit box. | |
| **MFG. DATE:** Dec. 2014 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Nov. 2017 | **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 - 00202, Nairobi, KENYA. | |
| ABC/09/07.03.2016/0018 | **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 | USP 38 NF 33 Page 1997 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 13.9 +/- 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 1997 | No tablet less than 85% [n=6] | Average = 99% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 93 - 106% (RSD=4.7%, n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 1997 | 90.0% - 110.0% | 97.5% (RSD=1.7%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | MR. M. ONGAS | .......................................................... | DATE: 24-06-2016 |
| **ANALYST:** | DR. G. WANG'ANG'A | .......................................................... | DATE: 29-06-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 08-23-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-22-2016 |