**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | ABACAVIR SULFATE TABLETS 300 mg | | REF. NO: NDQD201508144 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Abacavir Sulfate equivalent to Abacavir 300 mg. | |
| **BATCH NO.:** 3009581 | **PRESENTATION:** | Peach coloured, caplet shaped, film-coated tablets, embossed 'M110' on one face but plain on the other, packed in a white coloured, plastic multi-dose container with a child-proof cap carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Feb. 2013 | **MANUFACTURER:** | MYLAN Laboratories Ltd. | |
| **EXP. DATE:** Jan. 2016 | **ADDRESS:** | F-4 & F-12, MIDC, Malegaon, Sinnar, Nashik ÃƒÆ’Ã‚Â¢ÃƒÂ¢Ã¢â‚¬Å¡Ã‚Â¬ÃƒÂ¢Ã¢â€šÂ¬Ã…â€œ 422 113, Maharashtra, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme P.O. BOX 19361 Nairobi | |
|  | **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 peak 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 | 7.0 +/- 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP.38 NF 33 Vol 2 Page 1998 | No tablet less than 85.0% [n=6] |  | **::COMPLIES:** |
| **Dissolution** | UV | USP.38 NF 33 Vol 2 Page 1998 | No tablet less than 85.0% [n=6] | 97.4% (RSD=4.5%, n=6) | **::COMPLIES:** |
| **Dissolution** | UV | USP.38 NF 33 Vol 2 Page 1998 | No tablet less than 85.0% [n=6] |  | **::COMPLIES:** |
| **Dissolution** | UV | USP.38 NF 33 Vol 2 Page 1998 | No tablet less than 85.0% [n=6] |  | **::COMPLIES:** |
| **Assay** | HPLC | Adopted In-House Method | 95.0% - 105.0% |  | **:COMPLIES::** |
| **Assay** | HPLC | Adopted In-House Method | 95.0% - 105.0% | 103.3% (RSD=1.2%, n=9) | **:COMPLIES::** |
| **Assay** | HPLC | Adopted In-House Method | 95.0% - 105.0% |  | **:COMPLIES::** |
| **Assay** | HPLC | Adopted In-House Method | 95.0% - 105.0% |  | **:COMPLIES::** |

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

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|  |  |  | DATE: |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:11-05-2015 |