**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | ABACAVIR TABLETS USP 300 mg | | REF. NO: NDQD201508158 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Abacavir Sulfate USP equivalent to Abacavir 300 mg. | |
| **BATCH NO.:** 3022169 | **PRESENTATION:** | Tan coloured, caplet shaped, film-coated tablets, embossed 'M110' on one face and packed in a white coloured, plastic multi-dose container carrying 60 tablets in a unit box. | |
| **MGF. DATE:** Jan. 2014 | **MANUFACTURER:** | MYLAN Laboratories Ltd. | |
| **EXP. DATE:** Dec. 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 | |
|  | **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 1997 | No tablet less than 85.0% (n=6) |  | **:COMPLIES::** |
| **Dissolution** | :UV | USP 38 NF 33 Vol 2 Page 1997 | No tablet less than 85.0% (n=6) | 99.6% (RSD=2.9%, n=6) | **:COMPLIES::** |
| **Dissolution** | :UV | USP 38 NF 33 Vol 2 Page 1997 | No tablet less than 85.0% (n=6) |  | **:COMPLIES::** |
| **Dissolution** | :UV | USP 38 NF 33 Vol 2 Page 1997 | 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% | 99.0% (RSD=0.9%, 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 |