**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/84

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| **PRODUCT** | LOPINAVIR and RITONAVIR TABLETS 200 mg/ 50 mg | | **REF. NO: NDQD2016061023** |
| **DATE RECEIVED:** 03.06.2016 | **LABEL CLAIM:** | Each film coated tablet contains Lopinavir 200 mg and Ritonavir USP 50 mg. | |
| **BATCH NO.:** 3046712 | **PRESENTATION:** | Beige coloured, caplet shaped, biconvex faced tablets, embossed 'M124' on one face and plain on the other, packed in a white plastic multidose container carrying 120 tablets in a unit box. | |
| **MFG. DATE:** Nov. 2015 | **MANUFACTURER:** | MYLAN Laboratories Limited. | |
| **EXP. DATE:**  Oct. 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. | |
| LPV/R/02/09.03.2016/0135 | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | Ph. Int. 5th Edition | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Ph. Int. 5th Edition | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 5.2 and 7.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Ph. Int. 5th Edition | No tablet less than 80% [n=6] | Lopinavir Average = 102% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 97 - 104% (RSD=2.5%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Ritonavir Average = 104% Range |  |
| **Dissolution** |  |  |  | 100 - 106% (RSD=2.2%, n=6) |  |
| **Assay** | HPLC | Ph. Int. 5th Edition | 90.0 - 110.0% | Lopinavir 107.2% (RSD=1.1%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Ritonavir 108.9% (RSD=0.8%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | MR. M. ONGAS | .......................................................... | DATE: 18-06-2016 |
| **ANALYST:** | DR. G. WANG'ANG'A | .......................................................... | DATE: 29-06-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 08-23-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-22-2016 |