**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | LOPINAVIR/ RITONAVIR 200 mg/50 mg TABLETS | | REF. NO: NDQD201508102 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film-coated tablet contains Lopinavir 200 mg, Ritonavir USP 50 mg | |
| **BATCH NO.:** 3019946 | **PRESENTATION:** | Light yellow coloured, caplet-shaped, biconvex faced tablets, embossed 'M124' on one face and plain on the other, packed in a white plastic multidose container with a child proof cap, containing 120 tablets in a unit box. | |
| **MGF. DATE:** Dec.2013 | **MANUFACTURER:** | Mylan Laboratories Ltd | |
| **EXP. DATE:** Nov.2015 | **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 | |
| LPV/10/13.03.2015/00161 | **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 | U.S.P. 38 NF 33 Vol3 Page 4131 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation |  | **COMPLIES** |
| **Identification** | :HPLC | U.S.P. 38 NF 33 Vol3 Page 4131 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peaks at RT 7.6 and 10.0 Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | :HPLC | IU.S.P. 38 NF 33 Vol3 Page 4131 | 90.0-110.0 | Lopinavir 107.0% (RSD = 1.9% ; n = 9) | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | IU.S.P. 38 NF 33 Vol3 Page 4131 | 90.0-110.0 | Ritonavir 100.8% (RSD = 2.0% ; n = 9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | MR. D. MOENGA |  | DATE:09-08-2015 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:01-10-2015 |
| ANALYST: | SERAH MUTERU |  | DATE:10-09-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:10-13-2015 |