**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | KALETRAÃƒâ€šÃ‚Â® ORAL SOLUTION | | REF. NO: NDQD201509272 |
| **DATE RECEIVED:** 09.09.2015 | **LABEL CLAIM:** | Each 1 mL contains 80 mg Lopinavir and 20 mg Ritonavir. | |
| **BATCH NO.:** 6039095 | **PRESENTATION:** | Straw coloured solution for oral administration, contained in a 60 mL amber coloured plastic bottle fitted with a child proof cap. | |
| **MGF. DATE:** Oct. 2013 | **MANUFACTURER:** | ABBOTT Laboratories S.A (Pty) Ltd. | |
| **EXP. DATE:** Sep. 2015 | **ADDRESS:** | Abbott Place, Golf Club Terrace 219, Constantia Kloof, 1709, SOUTH AFRICA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme P.O. BOX 19361 Nairobi | |
| LPV/06/09.03.2015/00034 | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Plate Count Method | In- House Method | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/mL | Total Aerobic Microbial Count (TAMC) < 200 CFU/mL Total Combined Yeasts /Moulds Count (TYMC) < 20 CFU/mL | **COMPLIES** |
| **Identification** | :HPLC | Adopted Ph. Int. - 5th Edition 2015 (Online version) | RT of the Component Peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT | **COMPLIES** |
| **Identification** | :HPLC | Adopted Ph. Int. - 5th Edition 2015 (Online version) | RT of the Component Peaks in the assay sample preparation correspond to those in the assay standard preparation | 5.5, 7.2 Ãƒâ€šÃ‚Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | :HPLC | Adopted Ph. Int. - 5th Edition 2015 (Online version) | 90.0 - 110.0% | Lopinavir; 105.0% (RSD=0.3%, n=9) Ritonavir; 101.9% (RSD=0.2%, n=9) | **COMPLIES** |
| **Acidity/Alkalinity** | pH | B.P. 2012 Vol. V App VL | - | 4.9 | **COMPLIES** |

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

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| ANALYST: | MR. F. NAULA |  | DATE:10-09-2015 |
| ANALYST: | DR. L. KARANJA |  | DATE:23-09-2015 |
| REVIEWER: | DR. M . KWENA |  | DATE:01-10-2015 |
| ANALYST: | SERAH MUTERU |  | DATE:10-12-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:10-15-2015 |