**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/46

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| **PRODUCT** | KALETRA ORAL SOLUTION | | **REF. NO: NDQD2016061147** |
| **DATE RECEIVED:** 03.06.2016 | **LABEL CLAIM:** | Each 1 mL contains 80 mg Lopinavir and 20 mg Ritonavir. | |
| **BATCH NO.:** 6054811 | **PRESENTATION:** | Straw coloured solution for oral administration, contained in a 60 mL amber coloured plastic bottle fitted with a child proof cap, 5 bottles packed along with 5 plastic 5 mL graduated dispensing syringes in a unit box. | |
| **MFG. DATE:** Jun. 2015 | **MANUFACTURER:** | AbbVie (Pty) Ltd | |
| **EXP. DATE:**  May 2017 | **ADDRESS:** | Abbott Place, 219 Golf Club Terrace, Constantia Kloof, 1709, SOUTH AFRICA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme, P. O. Box 19361 - 00202, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Plate count | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL | < < 10 CFU / mL | **COMPLIES** |
| **Microbial Load** |  |  | Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/mL | < 10 CFU / mL |  |
| **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; 5.2 and 7.6 ± 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 105.9% (RSD = 0.3%, n =9) | **COMPLIES** |
| **Assay** |  |  |  | Ritonavir 106.8% (RSD = 0.3%, n =9) |  |

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

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| **ANALYST:** | MR. F. NAULA | .......................................................... | DATE: 06-10-2016 |
| **ANALYST:** | MR. M. ONGAS | .......................................................... | DATE: 06-10-2016 |
| **ANALYST:** | DR. G. WANG'ANG'A | .......................................................... | DATE: 06-30-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 08-02-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 08-04-2016 |