**CERTIFICATE OF ANALYSIS**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | KALETRAÂ® ORAL SOLUTION | | REF. NO: NDQD201509273 |
| **DATE RECEIVED:** 09.09.2015 | **LABEL CLAIM:** | Each 1 mL contains 80 mg Lopinavir and 20 mg Ritonavir. | |
| **BATCH NO.:** 6039098 | **PRESENTATION:** | Straw coloured solution for oral administration, contained in a 60 mL amber coloured plastic bottle with a child proof cap. | |
| **MGF. DATE:** Oct. 2013 | **MANUFACTURER:** | ABBOTT Laboratories S.A Pty Ltd. | |
| **EXP. DATE:** Sep.2015 | **ADDRESS:** | Abbott Place, 219 Golf Club Terrace/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/10/10.03.2015/00058 | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Microbial Load | 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 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 in the assay sample preparation correspond to those in the assay standard preparation | 5.5, 7.2 Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC:HPLC | Adopted Ph. Int. - 5th Edition 2015 (Online version) | 90.0 -110.0% | Lopinavir; 106.0% (RSD=0.1%, n=9) Ritonavir; 102.5% (RSD=0.2%, n=9) | **COMPLIES** |
| **Acidity/Alkalinity** | pH: | B.P. 2012 Vol V App VL | - | 4.6 |  |

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

|  |  |  |  |
| --- | --- | --- | --- |
| 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 |