**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/126

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | PROCTICAD ORAL SOLUTION | | **REF. NO: NDQD201507033** |
| **DATE RECEIVED:** 28.07.2015 | **LABEL CLAIM:** | Each 15 mL contains: Lactilol Monohydrate EP 10 gm, Benzoic Acid BP 0.0225 gm (As preservative), Flavoured aqueous base q.s. | |
| **BATCH NO.:** 13/070/024 | **PRESENTATION:** | Light pink coloured, clear solution for oral administration, contained in a 200 mL amber coloured plastic bottle fitted with a metallic closure, packed along with a 15 mL graduated plastic measuring cap in a unit box. | |
| **MFG. DATE:** May 2015 | **MANUFACTURER:** | CADILA Pharmaceuticals Limited. | |
| **EXP. DATE:** Apr. 2017 | **ADDRESS:** | 1389, Dholka - 387 810, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Cadila pharmaceuticals (E.A.) Ltd, P.O. Box 79642-00200 Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Plate Count | BP 2016 Vol. V App. XVI B | NMT 500 Colony Forming Units (CFU)/mL | < 100 CFU/mL | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's In-House Method | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 4.2 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | Manufacturer's In-House Method | 2.0 - 4.5 | 2.8 | **COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | 80.0 - 120.0% | 94.9% (RSD=0.9%, n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | MR. F. NAULA | .......................................................... | DATE: 09-09-2016 |
| **ANALYST:** | DR . E. MUTUA | .......................................................... | DATE: 09-09-2016 |
| **ANALYST:** | DR . S. MUTERU | .......................................................... | DATE: 09-09-2016 |
| **ANALYST:** | DR . E. MBAE | .......................................................... | DATE: 09-09-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-27-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-29-2016 |