**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/308

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | ZANIDE-L SUSPENSION 120 mL | | **REF. NO: NDQD2016061190** |
| **DATE RECEIVED:** 21.06. 2016 | **LABEL CLAIM:** | Each mL contains Oxyclozanide BP (Vet) 30 mg and Levamisole Hydrochloride BP 15 mg | |
| **BATCH NO.:** S1513 | **PRESENTATION:** | Yellow coloured oral drench for veterinary use packed in a 120 mL plastic bottle. | |
| **MFG. DATE:** Oct. 2015 | **MANUFACTURER:** | VETINDIA Pharmaceuticals Limited. | |
| **EXP. DATE:**  Mar. 2017 | **ADDRESS:** | A-6/1, Electronic Complex, Kushaiguda, Hyderabad - 500062, INDIA | |
| **CLIENT REF NO:** | **CLIENT:** | AIVEEN Kenya Ltd., P. O. Box 41601 - 00100, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Microbial Load | BP 2016 Vol. V Appendix XVI B & D | TAMC NMT 200 CFU/mL TYMC NMT 20 CFU/mL | TAMC < 10 CFU/mL TYMC < 10 CFU/mL | **COMPLIES** |
| **Identification** | HPLC | Adopted From USP 39 NF 34 | Retention time of Levamisole hydrochloride component peak in the assay sample corresponds to that in the assay standard preparation | Levamisole Super-imposable peak at RT 2.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | BP 2016 Vol. V App. V L | - | 3.1 |  |
| **Assay** | Titration | Adopted BP 2016 (Vet) page 170 | 92.5 - 107.5% | Levamisole Hydrochloride 95.9% (RSD=0.4%; n=3) | **COMPLIES** |

**CONCLUSION:** The product complies with the adopted specifications for Levamisole hydrochloride content.

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | KENNEDY RUTTO | .......................................................... | DATE: 06-24-2016 |
| **ANALYST:** | ERIC NGAMAU | .......................................................... | DATE: 06-27-2016 |
| **ANALYST:** | NICHOLAS MWAURA | .......................................................... | DATE: 10-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 11-07-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-29-2016 |