**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/275

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | DUECLIN VETERINARY INJECTION | | **REF. NO: NDQA201602775** |
| **DATE RECEIVED:** 23-02-2016 | **LABEL CLAIM:** | Each mL contains: Oxytetracycline Hydrochloride BP 50 mg. | |
| **BATCH NO.:** 1506 | **PRESENTATION:** | Yellow coloured, clear solution for veterinary use, packed in an 100 mL amber coloured glass bottle fitted with a cream coloured flip off cap, in a printed box. | |
| **MFG. DATE:** Feb. 2015 | **MANUFACTURER:** | DUEFUL Healthcare Pvt. Ltd. | |
| **EXP. DATE:**  Jan. 2017 | **ADDRESS:** | Village Benad, Tehsil Amber, Dist. Jaipur, INDIA | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board, P. O. Box 27663 - 00506 Nairobi, KENYA. | |
| INSD/2015/011/007 | **TEST(S) REQUESTED:** | Sterility, Identification, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Identification** | HPLC | USP 38 NF 33 Page 4723 | RT of the Major Peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 6.6 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 4723 | 90.0 - 120.0% | 96.6% (RSD=0.3%, n=9) | **COMPLIES** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App. XVI A | No microbial growth | No microbial growth | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | MR. E. NGAMAU | .......................................................... | DATE: 02-24-2016 |
| **ANALYST:** | DR. L. WANGARI | .......................................................... | DATE: 07-29-2016 |
| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 09-01-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-18-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-18-2016 |