**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | DICLOMED INJECTION | | **REF. NO: NDQA201508082** |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each mL contains Diclofenac Sodium BP 25 mg. | |
| **BATCH NO.:** 140708 | **PRESENTATION:** | Clear, light straw coloured solution for intramuscular administration contained in a 3 mL clear, colourless glass ampoule, packed on a plastic rack of 10 ampoules in a unit box. | |
| **MFG. DATE:** Jul.2014 | **MANUFACTURER:** | CSPC OUYI Pharmaceuticals Co.Ltd. | |
| **EXP. DATE:** Jun.2017 | **ADDRESS:** | No.276, Zhongshan West Road, Shijiazhuang, Hebei, 050051, CHINA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board, P. O. Box 27663 - 00506 Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Sterility, Identification, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App. XVI A. | No Microbial Growth | No Microbial Growth | **COMPLIES** |
| **Identification** | HPLC | Adopted 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 10.0 +/- 10% min. present in both the assay sample and standard preparations. | **COMPLIES** |
| **Assay** | HPLC | Adopted In- House Method | 95.0%-105.0% | 99.5% (RSD = 0.3%, n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | MR. F. NAULA | .......................................................... | DATE: 28-08-2015 |
| **ANALYST:** | MR. D. MOENGA | .......................................................... | DATE: 10-11-2015 |
| **REVIEWER:** | DR.G. WANG'ANG'A | .......................................................... | DATE: 13-11-2015 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 12-21-2015 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 01-12-2016 |