**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/248

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | TRIXONE 1 g INJECTION IM/IV | | **REF. NO: NDQA201509322** |
| **DATE RECEIVED:** 29-09-2016 | **LABEL CLAIM:** | Each vial contains: Sterile Ceftriaxone Sodium USP equivalent to anhydrous Ceftriaxone 1 gm. | |
| **BATCH NO.:** Powder: C765Diluent: 211 | **PRESENTATION:** | Cream coloured, free flowing powder for intramuscular and intravenous administration, contained in a clear colourless glass vial fitted with a grey rubber closure, aluminum band and a white plastic flip off cap, along with sterile water for injection in a 10 mL clear colourless plastic ampoule in a unit box. | |
| **MFG. DATE:** Powder: Jul. 2014Diluent: Apr. 2014 | **MANUFACTURER:** | Powder: FLAMINGO Pharmaceuticals Ltd. Diluent: VIFOR Pharma PVt Ltd. | |
| **EXP. DATE:**  Powder: Jun.2017 Diluent: Mar. 2019 | **ADDRESS:** | Powder: Rabale, Navi Mumbai 400 701, Diluent:Ksez Kandla, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board, P. O. Box 27663 - 00506 Nairobi, KENYA. | |
| CFT/10/09.3.2015/00006 | **TEST(S) REQUESTED:** | Uniformity of Weight, Sterility, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | NMT 2 vials deviate by more than 10% from the mean vial weight | None Deviates | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Page 2705 | 6.0 - 8.0 | 6.7 | **COMPLIES** |
| **Sterility** | Membrane Filtration | BP Vol. V 2016 Appendix XVI A | Powder & Diluent No microbial growth | Powder & Diluent No microbial growth | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 2705 | RT of the major peak in the sample preparation corresponds to that in the standard preparation | Super-imposable peak at RT 3.2 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2705 | 90.0 - 115.0% | 112.7% (RSD = 0.4%; n = 6) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | MR. F. NAULA | .......................................................... | DATE: 08-03-2016 |
| **ANALYST:** | MR. M. SANGALE | .......................................................... | DATE: 18-07-2016 |
| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 27-07-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 11-09-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-15-2016 |