**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/249

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| **PRODUCT** | ALCIZON 1 g INJECTION I.M./I.V. | | **REF. NO: NDQA201509323** |
| **DATE RECEIVED:** 26-09-2016 | **LABEL CLAIM:** | Each vial contains: Sterile Ceftriaxone Sodium USP equivalent to Ceftriaxone 1g. | |
| **BATCH NO.:** Powder: 14136204Diluent: 050 | **PRESENTATION:** | Off white coloured, free flowing powder for intramuscular and intravenous administration, contained in a clear colourless glass vial fitted with a grey rubber closure and aluminum band, packed along with sterile water for injection in a 10 mL clear colourless plastic ampoule in a unit box. | |
| **MFG. DATE:** Powder: Mar. 2014 Diluent: Jan. 2014 | **MANUFACTURER:** | Powder: ALEMBIC Pharmaceuticals Limited. Diluent: VIFOR Pharma Pvt Ltd. | |
| **EXP. DATE:**  Powder: Feb. 2016 Diluent: Dec. 2018 | **ADDRESS:** | Powder: Alembic Road, Vadodara 390 003, Diluent: Ksez Kandla, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board, P. O. Box 27663 - 00506 Nairobi, KENYA. | |
| CFT/08/11/03/2015/00106 | **TEST(S) REQUESTED:** | Sterility, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Sterility** | Membrane Filtration | BP Vol. V 2016 App. 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** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Page 2705 | 6.0 - 8.0 | 6.6 | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2705 | 90.0 - 115.0% | 107.6% (RSD = 1.6%; n = 6) | **COMPLIES** |

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

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| **ANALYST:** | MR. F. NAULA | .......................................................... | DATE: 17-11-2016 |
| **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 |