**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/146

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| **PRODUCT** | VAXCEL(R) INJECTION | | **REF. NO: NDQD201508241** |
| **DATE RECEIVED:** 25-08-2015 | **LABEL CLAIM:** | Each vial contains: Ceftriaxone Sodium equivalent to Ceftriaxone 1g | |
| **BATCH NO.:** B1501009 | **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, aluminum band and a blue plastic flip off cap packed in a unit box. | |
| **MFG. DATE:** Jan. 2015 | **MANUFACTURER:** | KOTRA Pharma (M) Sdn.Bhd. | |
| **EXP. DATE:**  Jan. 2017 | **ADDRESS:** | 1, Jalan TTC 12, Cheng Industrial Estate, 75250 Melaka. MALAYSIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kotra Pharma C/O Harleys Ltd, P.O. Box 42718-00100, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Sterility, Identification, Bacterial Endotoxin, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App. XII C | NMT 2 vial contents deviate by more than 10% from mean vial content weight | None Deviates | **COMPLIES** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App. XVI A | No microbial growth | No microbial growth | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | USP 38 NF 33 Page 2705 | Less than 0.2 EU/mg | 4.1—10-6 EU/mg | **COMPLIES** |
| **Identification** | HPLC | USP 34 NF 29 Page 2249 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation. | Super-imposable peak at RT 3.2 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** |  | USP 38 NF 33 Page 2705 | 6.0 - 8.0 | 6.9 | **COMPLIES** |
| **Assay** | HPLC | USP 34 NF 29 Page 2249 | 90.0 - 115.0% | 109.6% (RSD = 1.93%; n = 6) | **COMPLIES** |

**CONCLUSION:**

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| **ANALYST:** |  | .......................................................... | DATE: 09-10-2015 |
| **ANALYST:** | ERIC NGAMAU | .......................................................... | DATE: 09-10-2015 |
| **ANALYST:** | DAVID MOENGA | .......................................................... | DATE: 10-27-2015 |
| **ANALYST:** | MICHAEL SANGALE | .......................................................... | DATE: 06-21-2016 |
| **ANALYST:** | MATTHEW KWENA | .......................................................... | DATE: 07-19-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-09-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-04-2016 |