**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/224

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| **PRODUCT** | TRIAXONE 2 g INJECTION | | **REF. NO: NDQD2016061175** |
| **DATE RECEIVED:** 09-06-2016 | **LABEL CLAIM:** | Each vial contains: Sterile Ceftriaxone Sodium (USP) equivalent to Ceftriaxone 2 g. | |
| **BATCH NO.:** 0002 | **PRESENTATION:** | Off white coloured, free flowing powder for intravenous infusion, contained in a clear colourless glass vial fitted with a grey rubber closure, aluminum band and a white plastic flip off cap packed in a printed box. | |
| **MFG. DATE:** Dec. 2015 | **MANUFACTURER:** | GULF Pharmaceutical industries | |
| **EXP. DATE:**  Dec. 2018 | **ADDRESS:** | Ras Al Khaimah, U.A.E. | |
| **CLIENT REF NO:** | **CLIENT:** | Goodman Agencies Ltd., P. O. Box 38823 - 00623, 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 content weights deviate by more than 10% from the mean vial weight | One Deviates (+17%) | **COMPLIES** |
| **Sterility** | Membrane Filtration | BP Vol. V 2016 App. XVI A | No Microbial Growth | No Microbial Growth | **COMPLIES** |
| **Bacterial Endotoxin** | Kinetic Chromogenic | USP 34 NF 29 Page 2250 | NMT 0.2 EU/mg | 1.5 x 10-06 EU/mg | **COMPLIES** |
| **Identification** | HPLC | USP 34 NF 29 Page 2250 | 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** | 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% | 110.1% (RSD = 1.8%; n = 6) | **COMPLIES** |

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

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| **ANALYST:** | MR. F. NAULA | .......................................................... | DATE: 02-11-2016 |
| **ANALYST:** | MR. M. SANGALE | .......................................................... | DATE: 15-07-2016 |
| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 27-07-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 11-03-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-08-2016 |