**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/223

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| **PRODUCT** | TRIAXONE 1g for INJECTION | | **REF. NO: NDQD2016061198** |
| **DATE RECEIVED:** 23-06-2016 | **LABEL CLAIM:** | Each vial contains Sterile Ceftriaxone sodium (USP) equivalent to Ceftriaxone 1g. Each ampoule contains Lidocaine Hydrochloride 1%. | |
| **BATCH NO.:** Powder 0074 Diluent 0094 | **PRESENTATION:** | White coloured, free-flowing powder for injection packed in a clear glass vial with an orange coloured flip-off cap packed along a 3.5 mL clear glass ampoule of Lidocaine Hydrochloride in a printed box. | |
| **MFG. DATE:** Powder Jun. 2015 Diluent May 2015 | **MANUFACTURER:** | GULF Pharmaceutical industries | |
| **EXP. DATE:**  Powder Jun. 2018 Diluent Nov. 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 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 34 NF 29 Page 2250 | Ceftriaxone NMT 0.2 EU/mg | 1.1 x 10-05 EU/mg | **COMPLIES** |
| **Bacterial Endotoxin** |  | USP 38 NF 33 Page 4097 | Lidocaine Hydrochloride NMT 1.1 EU/mg | 6.7 x 10-09 EU/mg |  |
| **Identification** | HPLC | Ceftriaxone | RT of the major peaks in the assay sample preparations correspond to those in the assay standard preparations | Super-imposable peak at RT 3.2 and 3.4 -/+ 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 34 NF 29 Page 2250 | Ceftriaxone 90.0 - 115.0% | 110.0% (RSD = 2.0%; n = 7) | **COMPLIES** |
| **Assay** |  | USP 38 NF 33 Page 4097 | Lidocaine Hydrochloride 95.0 -105.0% | 101.2% (RSD = 0.3%; n = 9) |  |

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

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| **ANALYST:** | MR. E. NGAMAU | .......................................................... | DATE: 02-11-2016 |
| **ANALYST:** | MR. M. SANGALE | .......................................................... | DATE: 18-07-2016 |
| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 29-07-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 11-03-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-08-2016 |