**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/222

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| **PRODUCT** | JULMENTIN INTRAVENOUS INJECTION 1.2 g | | **REF. NO: NDQD201605950** |
| **DATE RECEIVED:** 12-05-2016 | **LABEL CLAIM:** | Each vial contains: 1 g amoxicillin as amoxicillin sodium and 200 mg clavulanic acid as potassium clavulanate. | |
| **BATCH NO.:** EA7198 | **PRESENTATION:** | Off white powder for reconstitution into a solution for intravenous injection or infusion, contained in a clear colourless glass vial fitted with a red plastic flip off cap in a printed box. | |
| **MFG. DATE:** Feb. 2014 | **MANUFACTURER:** | GULF Pharmaceutical Industries. | |
| **EXP. DATE:**  Feb. 2017 | **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 content weight and none deviates by more than 20% | Two Deviate (-27%, +27%) | **DOES NOT COMPLY** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App. XVI A | No microbial growth | No microbial growth | **COMPLIES** |
| **Bacterial Endotoxin** | Kinetic ChromoLAL | Adopted In-House method | NMT 0.25 EU/mg | 3.8 x 10-06 EU/mg | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House method | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 3.5 and 5.2 -/+ 10% min, present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | Adopted In-House method | 8.0 - 10.0 | 9.1 | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House method | 90.0 - 107.5% | Amoxicillin 99.5% (RSD = 1.8%; n = 9) | **COMPLIES** |
| **Assay** |  |  |  | Clavulanic Acid 105.8% (RSD = 1.1%; n = 6) |  |

**CONCLUSION:** The sample fails to comply with the specifications for the uniformity of weight test.

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| **ANALYST:** | MR. E. NGAMAU | .......................................................... | DATE: 01-09-2016 |
| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 01-09-2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 01-09-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-22-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-03-2016 |