**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/227

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| **PRODUCT** | VANCOLON 1 g INJECTION | | **REF. NO: NDQD2016061199** |
| **DATE RECEIVED:** 23.06.2016 | **LABEL CLAIM:** | Each vial contains Vancomycin Hydrochloride USP 1 g. | |
| **BATCH NO.:** 0008 | **PRESENTATION:** | White powder for reconstitution into solution for intravenous infusion, contained in a clear colourless glass vial fitted with a grey rubber closure, aluminium band and a blue plastic flip off cap packed in a in printed box. | |
| **MFG. DATE:** Sep. 2015 | **MANUFACTURER:** | GULF Pharmaceutical industries. | |
| **EXP. DATE:**  Sep. 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, Microbial Assay, Identification, Bacterial Endotoxin, 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 | 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 5751 | NMT 0.33 EU/mg | 1.8 — 10-5 EU/mg | **COMPLIES** |
| **Identification** | HPLC | BP 2016 Vol. III Page 1232 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 4.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | BP 2016 Vol. III Page 1232 | 2.5 - 4.5 | 3.4 | **COMPLIES** |
| **Microbial Assay** | Microbial Assay | BP 2016 Vol. III Page 1232 | 95.0 - 115.0% | 100.0% (RSD = 1.1%; n = 6) | **COMPLIES** |

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

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| **ANALYST:** | MR. E. NGAMAU | .......................................................... | DATE: 06-27-2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 09-23-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 11-03-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-08-2016 |