**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/246

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| **PRODUCT** | LUGANOR 40 mg INJECTION I.V. | | **REF. NO: NDQD201605961** |
| **DATE RECEIVED:** 24-05-2016 | **LABEL CLAIM:** | Each vial contains Pantoprazole Sodium Sesquihydrate equivalent to 40 mg Pantoprazole. | |
| **BATCH NO.:** 014004 | **PRESENTATION:** | Off-White, free flowing powder for intravenous administration contained in a clear colourless glass vial fitted with a purple plastic flip off cap packed in a unit box. | |
| **MFG. DATE:** Jun. 2015 | **MANUFACTURER:** | ARWAN Phamaceutical Industries Lebanon s.a.l. | |
| **EXP. DATE:**  Jun. 2017 | **ADDRESS:** | Jadra, LEBANON | |
| **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 vials deviate by more than 10% from the mean vial weight | One Deviates (12.1%) | **COMPLIES** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App XVI A | No microbial growth | No microbial growth | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | BP 2016 Vol. V App. XVI C | NMT 3.9 EU/mg | 3.6 X 10-4 EU/mg | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of the component peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 7.7 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | Adopted In-House Method | 9.0 - 10.5 | 9.7 | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | 99.0% (RSD = 1.1%; n = 9) | **COMPLIES** |

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

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| **ANALYST:** | MR. F. NAULA | .......................................................... | DATE: 06-21-2016 |
| **ANALYST:** | DR. E. MUTUA | .......................................................... | DATE: 06-22-2016 |
| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 07-04-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 11-09-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-15-2016 |