**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/305

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| **PRODUCT** | ZIDAN(R) 50 mg/2 mL INJECTABLE SOLUTION | | **REF. NO: NDQD201605964** |
| **DATE RECEIVED:** 24-05-2016 | **LABEL CLAIM:** | Each ampoule of 2 mL contains Ranitidine Hydrochloride equivalent to Ranitidine 50 mg. | |
| **BATCH NO.:** 019009 | **PRESENTATION:** | Clear colourless solution for intramuscular and intravenous administration, contained in a 2 mL clear colourless glass ampoule, packed on a paper rack of 5 ampoules in a printed box. | |
| **MFG. DATE:** Nov. 2015 | **MANUFACTURER:** | ARWAN Phamaceutical Industries Lebanon, s.a.l. | |
| **EXP. DATE:**  Nov. 2017 | **ADDRESS:** | Jadra LEBANON. | |
| **CLIENT REF NO:** | **CLIENT:** | Goodman Agencies Ltd., P. O. Box 38823 - 00623, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Sterility, Identification, Bacterial Endotoxin, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Sterility** | Membrane Filtration | BP Vol V 2016 App. XVI A | No Microbial growth | No Microbial growth | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | USP 38 NF 33 Page 5139 | Not more than 7.0 EU/mg | 1.5 x 10-4 EU/mg | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 5139 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 2.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Page 5139 | 6.7 - 7.3 | 7.0 | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5139 | 90.0 - 110.0% | 98.4% (RSD = 0.2%; 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:** | ERNEST MBAE | .......................................................... | DATE: 11-23-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-29-2016 |