**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/226

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| **PRODUCT** | PANTONIX TABLETS 20 mg | | **REF. NO: NDQD2016061202** |
| **DATE RECEIVED:** 23-06-2016 | **LABEL CLAIM:** | Each enteric coated tablet contains: Pantoprazole Sodium sesquihydrate equivalent to pantoprazole 20 mg. | |
| **BATCH NO.:** 0001 | **PRESENTATION:** | Yellow coloured, ovoid shaped, biconvex faced tablets, plain on both faces, packed in an aluminium blister strip of 10 tablets and 3 such strips packed in a printed box. | |
| **MFG. DATE:** Dec. 2015 | **MANUFACTURER:** | (JULPHAR) Gulf Pharmaceutical industries | |
| **EXP. DATE:**  Dec. 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 Content, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Content** | HPLC | USP39 NF34 Page 736 | Acceptable value (AV) of 10 dosage units is NMT 15% | AV=8% [n=10] | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 7.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | Adopted In-House Method | Acid Stage No tablet more than 10% [n=6] | Average | **COMPLIES** |
| **Dissolution** |  |  | Buffer stage No tablet less than 80% [n=6] | 2% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 1.6 - 1.9% (RSD=6.4%; n=6) |  |
| **Dissolution** |  |  |  | Average |  |
| **Dissolution** |  |  |  | 88% Range |  |
| **Dissolution** |  |  |  | 87 - 89% (RSD=0.9%, n=6) |  |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | 93.3% (RSD=0.8%; n=9) | **COMPLIES** |

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

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| **ANALYST:** | DR. J. CHEPCHUMBA | .......................................................... | DATE: 28-06-2016 |
| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 10-08-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 11-03-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-08-2016 |