**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/27

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| **PRODUCT** | GLYPRIDE 4 mg TABLETS | | **REF. NO: NDQD201601728** |
| **DATE RECEIVED:** 28.01.2016 | **LABEL CLAIM:** | Each tablet contains: Glimepiride 4 mg. | |
| **BATCH NO.:** 0015 | **PRESENTATION:** | Light blue coloured, telophase shaped, flat faced tablets, single scored on both faces and alternately embossed ' G' and '4' on either side of the score on one face, packed in a blister strip of 10 tablets and 3 such strips packed in a unit box. | |
| **MGF. DATE:** Mar. 2015 | **MANUFACTURER:** | JULPHAR Gulf Pharmaceutical Industries. | |
| **EXP. DATE:**  Mar. 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, Friability, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Content** | HPLC | USP 38 NF 33 Page 3673 | Acceptance Value of the 10 dosage units NMT 15 (AV) [n=10] | AV = 5 [n=10] | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 3673 | RT of the major peak in the assay sample preparation corresponds to that in the standard preparation | Super-imposable peak at RT 7.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Friability** | Friability | BP 2016 Vol. V App. XVII G | Percentage loss NMT 1 % | 1% | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 3673 | No tablet less than 85% [n=6] | Average = 90% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 89% - 92% (RSD=0.8%, n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 3673 | 90.0 - 110.0% | 94.3 % (RSD=1.8%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | DR. S. MWANGI | .......................................................... | DATE: 27-06-2016 |
| **ANALYST:** | DR. G. WANG'ANG'A | .......................................................... | DATE: 16-06-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 07-04-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-27-2016 |