**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2016-17/XYZ

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| **PRODUCT** | GLYPRIDE 1 mg TABLETS | | REF. NO: NDQD201511542 |
| **DATE RECEIVED:** 10.11.2015 | **LABEL CLAIM:** | Each tablet contains: Glimepiride 1 mg. | |
| **BATCH NO.:** 0008 | **PRESENTATION:** | Pink coloured, figure '8' shaped, flat faced tablets, single scored on both faces and alternately embossed 'G' and '1' 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:** Jul. 2015 | **MANUFACTURER:** | JULPHAR Gulf Pharmaceutical Industries. | |
| **EXP. DATE:**  Jul. 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 Weight, Uniformity of Content, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | NMT 2 tablets deviate by more than 7.5% from mean weight | None Deviates | **COMPLIES** |
| **Uniformity of Content** | HPLC | USP 38 NF 33 Page 3673 | Acceptance value (AV) of 10 dosage units is < 15% | AV | **COMPLIES** |
| **Uniformity of Content** | HPLC | USP 38 NF 33 Page 3673 | Acceptance value (AV) of 10 dosage units is < 15% | 8% (n=10) | **COMPLIES** |
| **Uniformity of Content** | HPLC | USP 38 NF 33 Page 3673 | Acceptance value (AV) of 10 dosage units is < 15% |  | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 3673 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 6.4 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 3673 | No tablet less than 85% [n=6] | 94.8% (RSD=0.6%; n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 3673 | 90.0 - 110.0 % | 104.5% (RSD=1.0%; n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. S. MWANGI |  | DATE:10-02-2016 |
| ANALYST: | DR. S. MUTERU |  | DATE:10-02-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:02-10-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:02-22-2016 |