**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/276

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| **PRODUCT** | GLIPITA-M 50/500 TABLETS | | **REF. NO: NDQD201510447** |
| **DATE RECEIVED:** 22 Oct. 2015 | **LABEL CLAIM:** | Each film coated tablet contains: Sitagliptin Phosphate INN equivalent to 50mg Sitagliptin and Metformin Hydrochloride BP 500 mg. | |
| **BATCH NO.:** SYF231 | **PRESENTATION:** | Peach coloured, caplet shaped biconvex tablets, embossed 'BPL' on one face plain on the other, packed in a blister strip of 10 tablets and 3 such strips in a unit box. | |
| **MFG. DATE:** Jun. 2015 | **MANUFACTURER:** | BEXIMCO Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Jun. 2017 | **ADDRESS:** | Tongi, BANGLADESH | |
| **CLIENT REF NO:** | **CLIENT:** | Madawa Pharmaceuticals Ltd. P.O Box 29787-00202, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | Not more than 2 tablets deviate by more than 5% from mean tablet weight | None deviates | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's In-House Method | Retention time of component peaks in sample assay preparation correspond to those in standard assay preparation | Super-imposable peaks at RT 3.2 and 12.2 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | No tablet less than 80% | Metformin Hydrochloride 100.5% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 100.0 - 100.8%, (RSD=0.3%; n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Sitagliptin 102.1% Range |  |
| **Dissolution** |  |  |  | 100.6 - 103.5% (RSD=1.2%; n=6) |  |
| **Assay** | HPLC | Manufacturer's In-House Method | 90.0 - 110.0% | Metformin Hydrochloride 101.4% (RSD=0.3%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Sitagliptin 103.4% (RSD=0.6%; n=9) | **COMPLIES** |

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

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| **ANALYST:** | SARAH KARIUKI | .......................................................... | DATE: 10-10-2016 |
| **REVIEWER:** | NICHOLAS MWAURA | .......................................................... | DATE: 11-18-2016 |
| **ANALYST:** | EMMANUEL TANUI | .......................................................... | DATE: 11-21-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-22-2016 |