**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/139

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| **PRODUCT** | GLIPITA(R) - M 50/1000 TABLETS | | **REF. NO: NDQD201510448** |
| **DATE RECEIVED:** 22-10-2015 | **LABEL CLAIM:** | Each film coated tablets contains: Sitagliptin Phosphate INN equivalent to 50 mg of Sitagliptin and Metformin Hydrochloride BP 1000 mg. | |
| **BATCH NO.:** SYE064 | **PRESENTATION:** | Peach coloured, caplet shaped, biconvex faced tablets, imprinted 'BPL' on one face and plain on the other, packed in a blister strip of 10 tablets in a printed box. | |
| **MFG. DATE:** May 2015 | **MANUFACTURER:** | BEXIMCO PharmaceuticalS Ltd. | |
| **EXP. DATE:**  May 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** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's In - House Method | RT of the Major Peaks in the assay sample preparation corresponds to those in the assay standard preparation | Super-imposable peaks at RT 2.5 & 8.1 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In - House Method | No tablet less than 80% (n = 6) | Metformin Hydrochloride Average = 92% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 92 - 93%, (RSD=0.6%, n=6) |  |
| **Dissolution** |  |  |  | Sitagliptin Average = 90% Range |  |
| **Dissolution** |  |  |  | 89 - 94%, (RSD=2.3%, n=6) |  |
| **Assay** | HPLC | Manufacturer's In - House Method | 90.0 - 110.0 % | Metformin Hydrochloride 96.6% (RSD=0.6%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Sitagliptin 99.0% (RSD=0.7%, n=9) |  |

**CONCLUSION:** The sample complies with the specifications for the tests performed. However, it was noted that some information had been blacked out on the secondary packaging material.

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| **ANALYST:** | JOYFRIDA CHEPCHUMBA | .......................................................... | DATE: 03-02-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 08-02-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 08-10-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-30-2016 |