**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/271

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| **PRODUCT** | GLUCOPHAGE XR 1000 mg TABLET | | **REF. NO: NDQD2016061240** |
| **DATE RECEIVED:** 30.06.2016 | **LABEL CLAIM:** | Each prolonged release tablet contains metformin hydrochloride 1000 mg. | |
| **BATCH NO.:** 5G006A | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, embossed '1000' on one face and 'MERCK' on the other, packed in a blister strip of 15 tablets and 4 such strips in a unit box. | |
| **MFG. DATE:** Jun. 2015 | **MANUFACTURER:** | MERCK (Pty) Ltd. | |
| **EXP. DATE:**  May 2017 | **ADDRESS:** | 1 Friesland Drive, Longmeadow Business Estate South, Modderlontein - 1645, SOUTH AFRICA. | |
| **CLIENT REF NO:** | **CLIENT:** | Ripple Pharmaceuticals Ltd., P. O. BOX 10935 - 00100, 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 | Manufacturer's In- house Method | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's 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; 5.3 ± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | Manufacturer's In- house Method | No tablet outside the range After 1 hr 20 - 40 % (n=6) | Average | **COMPLIES** |
| **Dissolution** |  |  | After 3 hr 45 - 65% (n=6) | 25.8% Range |  |
| **Dissolution** |  |  | After 10 hr No tablet less than 80% (n=6) | 25.5 - 26.8 % (RSD=1.9%; n=6) |  |
| **Dissolution** |  |  |  | Average |  |
| **Dissolution** |  |  |  | 48.9% Range |  |
| **Dissolution** |  |  |  | 47.4 - 50.6% (RSD=2.8%; n=6) |  |
| **Dissolution** |  |  |  | Average |  |
| **Dissolution** |  |  |  | 85.4% Range |  |
| **Dissolution** |  |  |  | 84.0 - 85.7% (RSD=0.9%, n=6) |  |
| **Assay** | HPLC | Manufacturer's In- house Method | 95.0 - 105.0% | 95.7% (RSD=0.8%; n=6) | **COMPLIES** |

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

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| **ANALYST:** | DR. E. MUTUA | .......................................................... | DATE: 28-09-2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 28-09-2016 |
| **ANALYST:** | EMMANUEL TANUI | .......................................................... | DATE: 10-25-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-18-2016 |