**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/318

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| **PRODUCT** | EVERBLISS 10 mg TABLETS | | **REF. NO: NDQD201608067** |
| **DATE RECEIVED:** 04-08-2016 | **LABEL CLAIM:** | Each uncoated tablet contains: Everolimus 10 mg. | |
| **BATCH NO.:** TEVA141315 | **PRESENTATION:** | White coloured, circular shaped, biconvex faced tablets, packed in an aluminum blister strip of 10 tablets in a printed box. | |
| **MFG. DATE:** Dec. 2015 | **MANUFACTURER:** | BDR Pharmaceuticals Int'l Pvt. Ltd. | |
| **EXP. DATE:**  Nov. 2017 | **ADDRESS:** | R. S. No. 578, Near Effluent Channel Road, Vill. Luna, Tal. Padra, Dist. Vadodara - 391 440, Gujarat, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Ripple Pharmaceuticals Ltd., P. O. BOX 10935 - 00100, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Friability, Dissolution, Disintegration, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App. XII C | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Friability** | Weight | BP 2016 Vol. V App. XVII G | Percentage weight loss NMT 1% | 0.01% | **COMPLIES** |
| **Disintegration** | Disintegration | Manufacturer's In-House Method | All tablets disintegrate within 15 Minutes | All Tablets Disintegrated Within 12 minutes | **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 12.1 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | No Tablet More Than 80% | Average | **COMPLIES** |
| **Dissolution** |  |  |  | 107% (Range |  |
| **Dissolution** |  |  |  | 105 - 110%) (RSD=1.7%; n=6) |  |
| **Assay** | HPLC | Manufacturer's In-House Method | 90.0 - 110.0% | 104.7% (RSD=1.2%; n=9) | **COMPLIES** |

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

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| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 09-06-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 11-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-11-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 12-02-2016 |