**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/264

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| **PRODUCT** | BDTEM 20 CAPSULES | | **REF. NO: NDQD201608065** |
| **DATE RECEIVED:** 04-08-2016 | **LABEL CLAIM:** | Each hard gelatin capsules contains: Temozolomide USP 20 mg. | |
| **BATCH NO.:** CTMB140115 | **PRESENTATION:** | Hard gelatin capsules with navy blue coloured cap and white coloured body filled with an off white powder, 5 capsules packed in a multi-dose plastic container fitted with a childproof cap in a printed box. | |
| **MFG. DATE:** Aug. 2015 | **MANUFACTURER:** | BDR Pharmaceuticals Int'l Pvt. Ltd. | |
| **EXP. DATE:**  Jul. 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, 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 capsule content weights deviate by more than 7.5% from mean capsule content weight | One Deviates (+9.3%) | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's Method | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 6.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's Method | No Capsule Less Than 85% | Average | **COMPLIES** |
| **Dissolution** |  |  |  | 95% Range |  |
| **Dissolution** |  |  |  | 89 - 100% (RSD = 4.5%; n = 6) |  |
| **Assay** | HPLC | Manufacturer's Method | 95.0 - 105.0% | 99.5% (RSD = 0.8%; n = 9) | **COMPLIES** |

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

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| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 09-06-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 26-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-26-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-18-2016 |