**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/273

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| **PRODUCT** | BDOCIN 500 TABLETS USP | | **REF. NO: NDQD201608062** |
| **DATE RECEIVED:** 04.08.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Capecitabine USP 500 mg. | |
| **BATCH NO.:** TCP2A140515 | **PRESENTATION:** | Pink coloured, biconvex faced, ovoid shaped tablets, single scored on one face and packed in blister strips in a box containing a single strip of 10 tablets. | |
| **MFG. DATE:** Nov. 2015 | **MANUFACTURER:** | BDR Pharmaceuticals Int'l. Pvt. Ltd. | |
| **EXP. DATE:**  Oct. 2017 | **ADDRESS:** | R.S. No. 578, Near Effluent Channel Road, Vill. Luna, Tal. Padra, Dist. Vadodara - 391440 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** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2012 Vol. V App. XII C | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 2567 | Retention time of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 15.5 +/- 10% min present in both the assay sample and standard preparations. | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 2567 | No tablet less than 85% | Average | **COMPLIES** |
| **Dissolution** |  |  |  | 90% Range |  |
| **Dissolution** |  |  |  | 90 - 91% (RSD = 0.6%; n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 2567 | 93.0% - 105.0% | 96.6% (RSD = 0.2%; n=9) | **COMPLIES** |

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

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| **ANALYST:** | SARAH KARIUKI | .......................................................... | DATE: 09-06-2016 |
| **ANALYST:** |  | .......................................................... | DATE: 10-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-13-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-18-2016 |