**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/319

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| **PRODUCT** | BDGEF 250 mg TABLETS | | **REF. NO: NDQD201608068** |
| **DATE RECEIVED:** 04-08-2016 | **LABEL CLAIM:** | Each film coated tablet contains: Gefitinib 250 mg. | |
| **BATCH NO.:** TGFA140116 | **PRESENTATION:** | Light pink coloured, caplet shaped, biconvex faced tablets, single scored on one face and plain on the other, packed in a white plastic multidose container of 30 tablets in a printed box. | |
| **MFG. DATE:** Jan. 2016 | **MANUFACTURER:** | BDR Pharmaceuticals Int'l Pvt. Ltd. | |
| **EXP. DATE:**  Dec. 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, 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 tablet weight | One Deviates (-7%) | **COMPLIES** |
| **Disintegration** | Disintegration | Manufacturer's Method | NMT 30 Minutes | All Tablets Disintegrated Within 23 minutes | **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 6.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | Manufacturer's Method | No Tablet More Than 80% | Average | **COMPLIES** |
| **Dissolution** |  |  |  | 91% (Range |  |
| **Dissolution** |  |  |  | 89 - 93%) (RSD=1.7%; n=6) |  |
| **Assay** | HPLC | Manufacturer's Method | 90.0 - 110.0% | 102.6% (RSD=0.4%; 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 |