**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/269

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | ABIRON TABLETS 250 mg | | **REF. NO: NDQD201608063** |
| **DATE RECEIVED:** 04.08.2016 | **LABEL CLAIM:** | Each uncoated tablet contains Abiraterone Acetate 250 mg. | |
| **BATCH NO.:** TARA143615 | **PRESENTATION:** | Off-white coloured, ovoid shaped, biconvex faced tablets, single scored on one face, 120 tablets packed in a white plastic multi-dose container with a child-proof cap 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 Effuent 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**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **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 | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 39 NF 34 Page 2286 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 57.4 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 39 NF 34 Page 2286 | No tablet less than 90% | Average | **COMPLIES** |
| **Dissolution** |  |  |  | 102% Range |  |
| **Dissolution** |  |  |  | 101 - 103% (RSD=0.6%; n=6) |  |
| **Assay** | HPLC | USP 39 NF 34 Page 2286 | 90.0% - 110.0% | 99.7% (RSD=0.3%; n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | SARAH KARIUKI | .......................................................... | DATE: 09-06-2016 |
| **REVIEWED** | NICHOLAS MWAURA | .......................................................... | DATE: 10-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-19-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-18-2016 |