**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/104

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| **PRODUCT** | KEZOLE TABLETS USP 200 mg | | **REF. NO: NDQD201605954** |
| **DATE RECEIVED:** 17-05-2016 | **LABEL CLAIM:** | Each uncoated tablet contains Ketoconazole USP 200 mg. | |
| **BATCH NO.:** S12454 | **PRESENTATION:** | Light pink coloured, circular shaped, flat faced, bevel edged tablets, single scored and embossed 'INTAS' on one face and plain on the other, packed in a blister strip of 10 tablets and 3 such strips in a unit box. | |
| **MFG. DATE:** Sep. 2015 | **MANUFACTURER:** | INTAS Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Aug. 2018 | **ADDRESS:** | Matoda - 382 201, Dist. Ahmedabad, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | INTAS Pharmaceuticals Limited 2nd Flr, Chinunmay Centre, Ashiram Road, Ahmedabad | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Friability, 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 tablets deviate by more than 5% from the mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | TLC | USP 38 NF 33 Page 4006 | RF(subscript) value of the principal spot of the sample solution corresponds to that of the standard solution | RF(subscript) value of 0.3 -/+ 5% present in the both the sample and standard solutions | **COMPLIES** |
| **Friability** | Friability | BP 2016 Vol. V App XVII G | Percentage weight loss NMT 1.0% | 0.5% | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 4006 | No capsule less than 85% [n=6] | Average = 105% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 102-106% (RSD=1.3%, n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 4006 | 90.0 - 110.0% | 97.2% (RSD=0.6%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | DR. L. KARANJA | .......................................................... | DATE: 22-08-2016 |
| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 22-08-2016 |
| **ANALYST:** | DR. E. MBAE | .......................................................... | DATE: 22-08-2016 |
| **DIRECTOR:** | DR. H. K. CHEPKWONY | .......................................................... | DATE: 22-08-2016 |