**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** -

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| **PRODUCT** | TORTAS 10 TABLETS | | **REF. NO: NDQB201604885** |
| **DATE RECEIVED:** 2016-04-26 | **LABEL CLAIM:** | Each uncoated tablet contains: Torsemide USP 10 mg. | |
| **BATCH NO.:** DT0588 | **PRESENTATION:** | White coloured, circular shaped, flat faced, bevel edged tablets, single scored on one face and embossed '10' on the other, packed in blister strip of 10 tablets and 3 such strips packed in a unit box. | |
| **MFG. DATE:** Feb 2016 | **MANUFACTURER:** | INTAS Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Jan 2019 | **ADDRESS:** | Selaqui, Dehradun - 248 197, INDIA | |
| **CLIENT REF NO:** | **CLIENT:** | INTAS Pharmaceuticals Limited 2nd Flr, Chinunmay Centre, Ashiram Road, Ahmedabad | |
|  | **TEST(S) REQUESTED:** | Uniformity of Content, Identification, Friability, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Content** | HPLC | USP 38 NF 33 Page 5628 | Acceptance Value (AV) of 10 dosage units is NMT 15% | AV = 2% (n=10) | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 5628 | RT of the Major Peak in the sample preparation corresponds to that in the standard preparation | Super-imposable peak at RT 5.2 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5628 | No tablet less than 85% | Average = 90% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 89 - 90%, (RSD=0.7%, n=6) |  |
| **Friability** | Friability | BP 2016 Vol. V App. XVII G | Percentage weight loss NMT 1.0% | 0.02% | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5628 | 90 - 110% | 96.8%, (RSD = 0.5%, n = 9) | **COMPLIES** |

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

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| **ANALYST:** | DR. L. KARANJA | .......................................................... | DATE: 24/08/2016 |
| **ANALYST** | DR. G. WANGA'NGA' | .......................................................... | DATE: 24/08/2016 |
| **DIRECTOR** | DR. H. K. CHEPKWONY' | .......................................................... | DATE: 24/08/2016 |