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## INTAS PHARMACEUTICALS LIMITED, SELAQUI

|            |                         |             |
|------------|-------------------------|-------------|
| Department | Quality Control         |             |
| Title      | Certificate of Analysis | Page 1 of 1 |

| Name of Working Standard: TORSEMIDE  |  |  |   |
|--|--|--|---|
| Raw material Batch No.   | : TOR/002/16-17  | Reference  | : USP & In house specification  |
| Working Standard No.   | : S TORS 161   | Date of preparation  | : 13-07-2016  |
| Reference Standard Lot No.   | : R025J0   | Use before   | : 12-07-2017  |
| Storage Condition: Store in well closed light resistant containers below 25°C. |  |  |   |
| Sr. No.  | Tests  | Result   | Limits  |
| 1.   | Description  | Off white crystalline powder.  | A white to off white crystalline powder.  |
| 2.   | Identification   | A) The IR spectrum of test substance is concordant with that of Torsemide reference standard.<br>B) The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation. | A) The IR spectrum of test substance should be concordant with that of Torsemide reference standard.<br>B) The retention time of the major peak in the chromatogram of the assay preparation should correspond to that in the chromatogram of the standard preparation. |
| 3.   | Water  | 0.42 %.  | Not more than 1.0%.   |
| 4.   | Related Compounds<br>a. Torsemide Related compound. A<br>b. Torsemide Related compound. B<br>c. Torsemide Related compound. C<br>d. Any other impurity<br>e. Total other impurities<br>f. Total impurities | 0.092 %.<br><br>Not detected.<br><br>0.018%.<br>0.004 %.<br>0.006 %.<br>0.116 %.   | Not more than 0.5%.<br><br>Not more than 0.3%.<br><br>Not more than 0.2%.<br>Not more than 0.1%.<br>Not more than 0.2%.<br>Not more than 1.0%.  |
| 5.   | Assay  | a. 99.8 % on anhydrous basis.<br>b. 99.4 % on as is basis.   | a. 98.0% to 102.0% calculated on anhydrous basis.<br>b. To record.  |

REMARKS: The above material is compared with Torsemide USP reference standard for above tests and is suitable to use as a WORKING STANDARD.

Prepared By

13-07-2016

Reviewed By

13-07-2016

Approved By

13-07-2016

QC019/F07-02

