The Government Pharmaceutical Organization
Rangsit Pharmaceutical Production Plant

DOCUMENT NUMBER:	RPP-SP-QC-RM-103
DOCUMENT TITLE:	SPECIFICATION OF TORSEMIDE (ITEM NO. 44111525)
DOCUMENT NOTES:	

Document Information

Revision:	01	Vault:	RPP STP_SP-rel
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Date Information

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Control Information

Author:	PORNTHIP_W	Previous Number:	
Owner:	PORNTHIP_W	Change Number:	

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION RANGSIT PHARMACEUTICAL PRODUCTION PLANT		
TITLE	**SPECIFICATION OF TORSEMIDE (ITEM NO. 44111525)**	**Rev. 01**
DEPARTMENT	**QUALITY CONTROL DIVISION**	**PAGE 1 of 3**

REVISION HISTORY

Rev.No.	Change & Reason For Change	Effective Date
01	Initial Release	As per effective date in electronic system

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A. Specification

No.	Test parameters	Specifications
01	Description	White to off-white, crystalline powder.
02	Solubility	Slightly soluble in 0.1 N sodium hydroxide, in 0.1 N hydroxide acid, in alcohol, and in methanol; very slightly soluble in acetone and in chloroform; practically insoluble in water and in ether.
03	Identification A. FT-IR B. HPLC C. X-ray diffraction*	 The infrared absorption spectrum of the sample exhibits maxima only at the same wavelengths as that of a similar preparation of the USP reference standard (Form-I). The retention time of the major peak in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the assay. X-ray diffractogram of the sample should match with that of Torsemide (modification-I)
04	Assay	98.0-102.0%w/w of Torsemide ($C_{16}H_{20}N_4O_3S$) calculated on the anhydrous basis.
05	Related compounds a. Torsemide related compound A b. Torsemide related compound B c. Torsemide related compound C d. Any other impurity e. Total other impurities f. Total impurities (including torsemide related compounds A,B and C)	 Not more than 0.5%. Not more than 0.3%. Not more than 0.2%. Not more than 0.1%. Not more than 0.2%. Not more than 1.0%.
06	Water content (KF)	Not more than 1.0%
07	Residue on ignition	Not more than 0.1%
08	Heavy metals	Not more than 0.001%
09	Residual solvent* A. Procedure 1 - Methanol - Ethanol - Acetone - Methylene chloride - Toluene	 Not more than 3000 ppm. Not more than 5000 ppm. Not more than 5000 ppm. Not more than 600 ppm. Not more than 890 ppm.

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No.	Test parameters	Specifications
	B. Procedure 2 - Acetic acid	Not more than 5000 ppm.
	C. Procedure 3 - Triethylamine	Not more than 50 ppm.
10	Impurity 2*	Not more than 0.15%

* Additional specification

C. Packaging and Storage

Preserve in well-closed containers.

D. Reference

- Raw Material Specification, Spec No. RMS-RA-79N54040-03, Title : Torasemide (or Torsemide) Rev: 00.
- USP37, Torsemide, page 5007-5008.

E. Product Information

Approved source (s)	Refer to current version of Approved Vendor List (AVL) of Torsemide (Item No. 44111525).
Sampling plan	Identification : Every container. Other tests : $\sqrt{N} + 1$.
Testing procedure	Test to be performed as per current version of Standard Testing Procedure of Torsemide (Item No. 44111525).
Retest period	1 year.

MASTER

Signature Manifest

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Pls. review RPP-SP-QC-RM-103

Step 1. Preparer

Name/Signature	Title	Date	Meaning/Reason
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Step 2. Reviewer

Name/Signature	Title	Date	Meaning/Reason
SUTAN OTAMO (SUTAN_O)	DIRECTOR OF QC DIVISION	26 Sep 2019, 06:01:15 PM	Approved
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Step 4. Notify

Name/Signature	Title	Date	Meaning/Reason
DONNAPA PUEKWATTANA (DONNAPA_P)	QA-IT&Doc	28 Sep 2019, 11:40:06 AM	Email Sent
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