The Government Pharmaceutical Organization
Rangsit Pharmaceutical Production Plant

DOCUMENT NUMBER:	RPP-SP-QC-RM-063
DOCUMENT TITLE:	SPECIFICATION OF SERTRALINE HYDROCHLORIDE (FORM II) (ITEM NO. 44111405)
DOCUMENT NOTES:	

Document Information

Revision:	05	Vault:	RPP STP SP-rel
Doc Type:	SP-QC-RM	Status:	Release

Date Information

Effective Date:	26 Jan 2021	Next Review Date:	26 Jan 2023
Release Date:	26 Jan 2021	Expiration Date:	

Control Information

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Owner:	PORANEE S	Change Number:	Packet-1584

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION RANGSIT PHARMACEUTICAL PRODUCTION PLANT		
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REVISION HISTORY

Rev.No.	Change & Reason For Change	Effective Date
01	Initial Release (In-house's specification, Matrix laboratories Limited/India)	15 Mar 2016
02	Update follow USP39 (Refer to Rama VI document) - Change specification for solubility, heavy metals, impurities and assay - Change Loss on drying to Water determination (KF) - Change name of test and limit of Sulphated ash to Residue on ignition - Cancel test of melting range, specific optical rotation, chloride content (by potentiometry) and residual solvents (by GC)	10 Jun 2016
03	Periodic review	6 Oct 2018
04	Update for this revision (Change-0201) - Add specification for "Organic impurities (Procedure 2)" and "Limit of Mandelic acid", according to USP39 - Add additional specification for each of the manufacturer.	29 Oct 2019
05	Update for this revision - Update specification according to USP42 (equivalent to USP39), Change-19-040: Update specification and test method for Sertraline Hydrochloride form II (API) - Revise specification of Residual solvents as per USP<467> - Revise specification particle size of d(0.9) to 30-100 micron as per Change-19-190	As per effective date in electronic system

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A. Specification

No.	Test parameters	Specifications
01	Description ($)	White to off-white crystalline powder.
02	Solubility	Slightly soluble in absolute alcohol and in water.
03	Identification A. By Infrared absorption ($)	The absorption maxima in the spectrum obtained with the sample should correspond in position and relative size to those in the spectrum obtained with Sertraline hydrochloride (Form II) standard.
	B. By HPLC	The retention time of the major peak of the Sample solution corresponds to that of sertraline hydrochloride from the System suitability solution, as obtained in the test for Limit of (*R,R*) Sertraline Hydrochloride.
	C. Chloride test	Meets the requirements for the silver nitrate precipitate test.
	D. By X-ray Diffraction (*)	Conform to standard spectrum (form II).
04	Assay ($)	Not less than 97.0% and not more than 102.0% of Sertraline Hydrochloride ($C_{17}H_{17}Cl_2N.HCl$), calculated on the anhydrous basis.
05	Residue on ignition	Not more than 0.3%.
06	Heavy metals (*)	Not more than 30 ppm.
07	Limit of (*R,R*) Sertraline Hydrochloride ($)	Not more than 1.5%.
08	Organic impurities (Procedure 1) ($)	
	a. 2,3-Isosertraline	Not more than 0.15%.
	b. 4-Deschlorosertraline	Not more than 0.20%.
	c. 3-Deschlorosertraline	Not more than 0.20%.
	d. Mandelic acid	Not more than 0.10%.
	e. Sertraline related compound A (trans-*R,S* isomer)	Not more than 0.10%.
	f. Sertraline related compound A (trans-*S,R* isomer)	Not more than 0.10%.
	g. Any individual unspecified impurity	Not more than 0.10%.
	h. Total impurities	Not more than 0.5%.
09	Organic impurities (Procedure 2) (#,$)	
	a. 3,4-Deschlorosertraline	Not more than 0.2%.
	b. 3-Deschlorosertraline and 4-Deschlorosertraline	Not more than 0.8%.
	c. Sertraline related compound A	Not more than 0.2%.
	d. Sertralone	Not more than 0.2%.
	e. Any individual unspecified impurity	Not more than 0.10%.
	f. Total impurities	Not more than 1.5%.
10	Limit of Mandelic acid (##,$)	Not more than 0.2%.

No.	Test parameters	Specifications
11	Water determination ($)	Not more than 0.50%.
12	Residual solvents (*)	As per the manufacturer's DMF.
	a. Methanol	Not more than 3000 ppm.
	b. Ethyl acetate	Not more than 5000 ppm.
	c. n-Butyl alcohol	Not more than 5000 ppm.
13	Particle size (By Laser diffraction) (*)	
	- 90% of the particles, d(0.9)	30-100 µm.
	- 50% of the particles, d(0.5)	8-50 µm.
	- 10% of the particles, d(0.1)	Not more than 20 µm.
14	Tapped density (*)	0.4-0.8 g/ml.
15	Bulk density (*)	0.15-0.55 g/ml.

* *: In-house specification.*

\# *: Perform Organic Impurities Procedure 2 instead of Organic Impurities Procedure 1, if sertralone is a known process impurity.*

\## *: Perform Limit of Mandelic acid only if Organic Impurities Procedure 2, is used.*

$ *: Tests to be performed at retesting.*

C. Storage condition

Preserve in tight, light-resistant containers at a temperature not more than 40°C.

D. Reference

- USP 42, Sertraline hydrochloride monograph, page 3992-3995.
- USP General chapter <467>, Residual solvents.
- Raw material specification of Sertraline HCl USP (form II), SP-AK30-S85, Raw Material Standard Section 1.
- Standard test procedure of Sertraline hydrochloride (Form II), STP No. SA-004-04, Hetero Drugs Limited (Unit-I)

E. Product Information

Approved source (s)	Refer to current version of Approved Vendor List (AVL) of Sertraline hydrochloride (Form II) (Item No. 44111405).
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 Sertraline hydrochloride (Form II) (Item No. 44111405).
Retest period	1 year.

Signature Manifest

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All dates and times are in GMT +7.

Pls review spec sertraline RM

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