

Issue date: 13-09-2024

CERTIFICATE OF ANALYSIS

PO No.	Not Applicable	PO Date	Not Applicable
Product	SERTRALINE HYDROCHLORIDE USP		
CAS No.	79559-97-0	HSN Code	29214590
Batch No.	SET401023CD-I	Batch Quantity	365.500Kgs
A.R.No.	AR/FP/230288	Date of Analysis	22-09-2023
Date of Mfg.	03-09-2023	Date of Retest/Expiry	02-09-2028
Ref.Spec&MOA	SMA/FP/SET4V/01-02		
Name of the Customer	Not Applicable	Dispatch Quantity	Not Applicable
S.No	Test	Specification	Result
1	Description	White or off white crystalline powder. ✓	White Crystalline Powder
2	Solubility	Sparingly soluble or slightly soluble in absolute alcohol, slightly soluble in water and in isopropanol and slightly or very slightly soluble in Acetone. ✓	Complies
3	Identification		
	A	Infrared absorption spectrophotometry	The infrared absorption spectrum of the test sample should match with that of the working 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	Meets the requirement for the Silver nitrate precipitate test. ✓
4	Assay by HPLC (On anhydrous basis)	Not less than 97.00% and Not more than 102.00% w/w ✓	100.1%
5	Residue on ignition	Not more than 0.30% w/w ✓	0.05%
6	Limit of (R,R) Sertraline Hydrochloride	Not more than 1.5% w/w ✓	0.09%

Ref. SOP.: QCD/GEN/040, Format No.: QCDGEN/F-147-00

CHEMECA DRUGS PRIVATE LIMITED (CIN No.: U24239AP2003PTC041849)

 Corporate Office : Plot No. 70 & 71, 2nd Floor, Road No. 7, ALEAP Industrial Estate, Pragathi Nagar, Kukatpally, Hyderabad – 500090
 Telangana, India. Tel: +91 99519 55522. E-mail : info@chemeca.com URL : www.chemeca.com

Reg. Office & : Plot No. 7, J.N. Pharma City, Tadi Village – 531 019, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, India.

Manufacturing Facility Tel: +91-8924-236060, 236065.



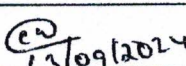
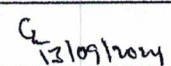
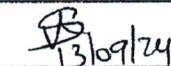
Handwritten signature and stamp of a representative, dated 28/09/24, with a circular stamp containing the text 'MERSIFARMA TM' and 'KP SURI'.

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Name of the Customer	Not Applicable	Dispatch Quantity	Not Applicable
S.No	Test	Specification	Result
7	Organic impurities by GC		
	Sertraline compound A	Not more than 0.2% ✓	Not detected
	3,4-Deschloro Sertraline	Not more than 0.2% ✓	Not detected
	Sertralone	Not more than 0.2% ✓	Not detected
	3-Deschloro Sertraline and 4-Deschloro Sertraline	Not more than 0.8% ✓	0.26%
	Any individualn unspecified impurity	Not more than 0.10% ✓	Not Detected
	Total impurities	Not more than 1.5% ✓	0.26%
8	Limit of Mandelic acid	Not more than 0.2% w/w ✓	Not detected
9	Water Determination	Not more than 0.50%w/w ✓	0.07%

Note : Additional test as per customer requirements. BDRL - Below disregarded Limit.

Prepared by	Reviewed by	Approved by
 Ch. Vidyasagar	 G.S.V.V.Kanth	 S. Kondala Rao
Sr.Chemist - QCD	Asst.Manager - QCD	AGM - QCD

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