

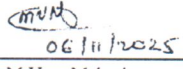
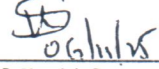
Issue date: 06-11-2025

CERTIFICATE OF ANALYSIS

PO No.	QJA/FA250228	PO Date	08-10-2025
Product	SERTRALINE HYDROCHLORIDE USP		
CAS No.	79559-97-0	HSN Code	29214590,2921.49.00
Batch No.	SET401125CD-I	Batch Quantity	275.300Kgs
A.R.No.	AR/FP/2025623	Date of Analysis	06-11-2025
Date of Mfg.	26-07-2025	Date of Expiry	25-07-2030
Ref.Spec&MOA	SMA/FP/SET4V/01-02		
Name of the Customer	PT. Qwinjaya Aditama	Dispatch Quantity	50.000 Kgs

S.No	Test	Specification	Result
7	Organic impurities by GC		
	3,4-Deschloro Sertraline	Not more than 0.2%	Not detected
	3-Deschloro Sertraline and 4-Deschloro Sertraline	Not more than 0.8%	0.26%
	Sertraline Related compound A	Not more than 0.2%	Not detected
	Sertralone	Not more than 0.2%	Not detected
	Any individual 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	0.08%
*10	Heavy Metal	Not more than 30 ppm	Less than 20 ppm

Remarks: The material complies as per above specification. * Additional test as per customer requirement.

Prepared by	Reviewed by	Approved by
		
Ch. Vidyasagar	M. Uma Mahesh	S. Kondala Rao
Executive - QCD	Dy. Manager - QCD	AGM - QCD

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

CHEMECA DRUGS PRIVATE LIMITED (CIN No.: U24239AP2003PTC041849)

Corporate Office : Plot No: 238, Road No:35,100 Feet Road, Ayyappa Society (Survey of India), Madhapur, Hyderabad-500081.

Reg. Office & Manufacturing facility: Plot No. 7, J.N. Pharma City, Tadi Village, Parawada Mandal, Anakapalli District-53101

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Ref.Spec&MOA		SMA/FP/SET4V/01-02					
Name of the Customer		PT. Qwinjaya Aditama		Dispatch Quantity		50.000 Kgs	
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	By Infrared absorption	The infrared absorption spectrum of the test sample should match with that of the working standard.			IR Sample Spectrum matched with Standard Spectrum	
	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.			Sample Retention time matched with Standard Retention time	
	C	Chloride	Meets the requirement for the Silver nitrate precipitate test.			Complies	
4	Assay by HPLC (On anhydrous basis)		Not less than 97.0% and Not more than 102.0% w/w			98.6%	
5	Residue on ignition		Not more than 0.30% w/w			0.08%	
6	Limit of (R,R) Sertraline Hydrochloride		Not more than 1.5% w/w			0.54%	

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