

AUROBINDO PHARMA LIMITED

UNIT III:Sy.No.313&314,Bachupally Village, Quthubullapur Mandal, R.R.Dist. Hyderabad. CERTIFICATE OF ANALYSIS

(FINISHED PRODUCT)

Product Name: S	ERTRALINE TABLE	TS 100 mg			
Product Code Batch No.	STSL3B00	Generic Name	SERTRALINE TABLETS	A.R. No.	03FP16000524
Batch Size	XT1015105 975000 TABLETS	Mfg. Date Specification No.	Dec-2015 FPS/STSL3B00-0	Exp. Date Revision No.	Nov-2018

S. No.	TEST	RESULT	SPECIFICATION
1	Description	White coloured, biconvex,	White coloured, biconvex, capsule
		capsule shaped film	shaped film coated tablets debossed with
		coated tablets debossed	A on one side and 82 on the other side.
		with A on one side and 82	of the difference of the other side.
		on the other side.	
2 2.1	Identification		
4.1	By HPLC	The retention time of the	The retention time of the Sertraline peak
		Sertraline peak in the	in the chromatogram of the sample
		chromatogram of the	solution should assessment to the sample
		sample solution	solution should correspond to that of the
		corresponds to that of the	Sertraline peak in the chromatogram of
		Sertraline peak in the	standard solution as obtained in Assay.
	!	chromatogram of standard	
	·	solution as obtained in	
	<u>L</u>	Assay.	
.2	By Chemical Test (with	A reddish brown colour is	A dell'ele
•	potassium permanganate	formed.	A reddish brown colour / precipitate
	solution)	io.med.	should be formed.
	Average Weight (Mass)	305.88 mg	
"	Thickness	Minimum: 4.46 mm	309.00 mg ± 2.0% (302.82 - 315.18 mg)
		Movimum 4.50	4.40 ± 0.30 mm (4.10 mm - 4.70 mm)
	Water (By KF, determined	Maximum: 4.56 mm 3.22 % m/m	
	on 0.2 g)	3.22 % M/M	Not more than 5.0% m/m
	Dissolution (By HPLC)		
	(By HPEC)	Minimum: 94.2 %	Not less than 80% (Q) of the labeled
·		Maximum: 102.5 %	amount of Sertraline (C17H17Cl2N) is
···	Uniformity of Dosage Units	Average: 100.0 %	dissolved in 30 minutes.
	(By mass variation)	2.4	Not more than 15
	Acceptance Value (1)		
	Acceptance Value (AV)		
	Related Substances (By		
	HPLC)		
1	Individual Known Related		
	Substances	·	
	(R)-(-)-Mandelic acid	Below LOQ	Not more than 0.10% m/m
1.2	2,3-Dichlorosertraline	Below LOQ	Not more than 0.10% m/m
.3	3,4-Deschlorosertraline	Below LOQ	Not more than 0.10% m/m
.4	Tetralone	Below LOQ	Not more than 0.40%
.5	4-Deschiorosertraline	0.03 % m/m	Not more than 0.10% m/m
	PROVED (Sample Conforms to a		Not more than 0.10% m/m

Remarks: APPROVED (Sample Conforms to above Specification)

Prepared By	Variation all and	Approved By		
Dranes d O	Yugandhar n 29 2016 5:56PM	Approved On		Subramanyam,P Jan 29 2016 5:59PM
	Printed on: Jan 29 20	D16 6:30PM	Copy No.:	3
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Quthubullapur Mandal, R.R.Dist. Hyderabad.
CERTIFICATE OF ANALYSIS

(FINISHED PRODUCT)

Product Name: SI	ERTRALINE TABLETS	100 mg			
Product Code	STSL3B00	Generic Name	SERTRALINE TABLETS	A.R. No.	03FP16000524
Batch No. Batch Size	XT1015105	Mfg. Date	Dec-2015	Exp. Date	Nov-2018
Daton Size	975000 TABLETS	Specification No.	FPS/STSL3B00-0	Revision No.	01

8.1.6	3-Deschlorosertraline	Below LOQ	Not more than 0.400/
8.1.7	Cis-(1R,4R)-Isomer	Below LOQ	Not more than 0.10% m/m
8.1.8	Trans-(1R,4S)-Isomer	Below LOQ	Not more than 0.10% m/m
8.1.9	Trans-(1S,4R)-Isomer	Below LOQ	Not more than 0.10% m/m
8.2	Any individual unknown		Not more than 0.10% m/m
	related substance	Not Detected	Not more than 0.10% m/m
8.3	Total Related Substances	0.03 % m/m	Not more than 1.0% m/m
9	Assay (By HPLC)		Not more than 1.0% mm
9.1	Each film coated tablet contains Sertraline	98.83 mg	97.00 - 105.00
	hydrochloride equivalent to		ļ
	Sertraline (C17H17Cl2N), in		
9.2	% Labeled Amount	98.8 %	07.0 405.0
10	Disintegration Time	1 Min 50 Sec	97.0 - 105.0 Not more than 15 minutes.

Prepared By		Approved By		
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Prepared On	Jan 29 2016 5:56PM			
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