



AUROBINDO PHARMA LIMITED
UNIT III: Sy.No.313&314, Bachupally Village,
Quthubullapur Mandal, R.R.Dist. Hyderabad.

CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

Product Name: SERTRALINE TABLETS 100 mg

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

S. No.	TEST	RESULT	SPECIFICATION
1	Description	White coloured, biconvex, capsule shaped film coated tablets debossed with A on one side and 82 on the other side.	White coloured, biconvex, capsule shaped film coated tablets debossed with A on one side and 82 on the other side.
2	Identification		
2.1	By HPLC	The retention time of the Sertraline peak in the chromatogram of the sample solution corresponds to that of the Sertraline peak in the chromatogram of standard solution as obtained in Assay.	The retention time of the Sertraline peak in the chromatogram of the sample solution should correspond to that of the Sertraline peak in the chromatogram of standard solution as obtained in Assay.
2.2	By Chemical Test (with potassium permanganate solution)	A reddish brown colour is formed.	A reddish brown colour / precipitate should be formed.
3	Average Weight (Mass)	305.88 mg	309.00 mg $\pm$ 2.0% (302.82 - 315.18 mg)
4	Thickness	Minimum: 4.46 mm Maximum: 4.56 mm	4.40 $\pm$ 0.30 mm (4.10 mm - 4.70 mm)
5	Water (By KF, determined on 0.2 g)	3.22 % m/m	Not more than 5.0% m/m
6	Dissolution (By HPLC)	Minimum: 94.2 % Maximum: 102.5 % Average: 100.0 %	Not less than 80% (Q) of the labeled amount of Sertraline (C ₁₇ H ₁₇ Cl ₂ N) is dissolved in 30 minutes.
7	Uniformity of Dosage Units (By mass variation) Acceptance Value (AV)	2.4	Not more than 15
8	Related Substances (By HPLC)		
8.1	Individual Known Related Substances		
8.1.1	(R)-(-)-Mandellic acid	Below LOQ	Not more than 0.10% m/m
8.1.2	2,3-Dichlorosertraline	Below LOQ	Not more than 0.10% m/m
8.1.3	3,4-Deschlorosertraline	Below LOQ	Not more than 0.10% m/m
8.1.4	Tetralone	Below LOQ	Not more than 0.10% m/m
8.1.5	4-Deschlorosertraline	0.03 % m/m	Not more than 0.10% m/m

Remarks: APPROVED (Sample Conforms to above Specification)

Prepared By	G.Yugandhar	Approved By	Subramanyam.P
Prepared On	Jan 29 2016 5:56PM	Approved On	Jan 29 2016 5:59PM
Printed By: G.Yugandhar	Printed on: Jan 29 2016 6:30PM	Copy No.: 3	Page No.: 1 of 2
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8.1.6	3-Deschlorosertraline	Below LOQ	Not more than 0.10% m/m
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 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)		
9.1	Each film coated tablet contains Sertraline hydrochloride equivalent to Sertraline (C ₁₇ H ₁₇ Cl ₂ N), in mg	98.83 mg	97.00 - 105.00
9.2	% Labeled Amount	98.8 %	97.0 - 105.0
10	Disintegration Time	1 Min 50 Sec	Not more than 15 minutes.

Remarks: APPROVED (Sample Conforms to above Specification)

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