CADILA PHARMACEUTICALS LIMITED
CHEMICALS SBU

Works :
294, G.I.D.C., Estate,
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Gujarat, India.

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Fax : +91-2646-250051
Website : www.cadilapharma.com

METAPHARMACEUTICAL

N DE LOTE: 0030725

02/07/2025

Name of Finished Drug substance: Fluoxetine Hydrochloride Ph.Eur/BP+IH.			
Manufactured By.	Cadila Pharmaceuticals Limited, Ankleshwar.		
Batch No.	25FH185	A.R. No.	25FP0666
Manufacturing Date	MAY 2025	Qty. Mfgd.	150.20 Kg.
Expiry Date	APRIL 2030	Sample Qty.	121.13 gm
Specification No	FPS/239		
Storage condition	Store in a tightly closed container at room temperature. (Not more than 25°C, excursion allowed 15°C to 30°C).		

Certificate of Analysis

Test	Requirements	Results
Characters: A. Appearance	A. White or almost white crystalline powder.	White crystalline powder.
B. Solubility	B. Sparingly soluble in water and in methylene chloride, Freely soluble in methanol.	Sparingly soluble in water and in methylene chloride, Freely soluble in methanol.
Identification A. By IR	A. The infrared absorption spectrum obtained from the sample should be concordant with the spectrum obtained from Fluoxetine Hydrochloride for ID and assay CRS/ Fluoxetine Hydrochloride working standard.	The infrared absorption spectrum obtained from the sample is concordant with the spectrum obtained from Fluoxetine Hydrochloride working standard.
B. Test for chloride	B. Should be responds the chlorides	Complies
Appearance of solution	Solution should be clear and colorless	Complies
pH	Between 4.5 and 6.5	6.01
Optical rotation	Between – 0.05° and + 0.05°	+0.00°
Water content (By KF)	Not more than 0.50 % w/w	0.07 % w/w
Sulfated ash	Not more than 0.10 % w/w	0.03 % w/w
Related substances (By HPLC)		
Impurity A	Not more than 0.15 %	Below Quantification limit
Impurity B	Not more than 0.10 %	Below Quantification limit
Dimethyl amine impurity	Not more than 0.10 %	0.05 %
Unspecified impurity	Not more than 0.10 %	0.01 %
Total impurities	Not more than 0.30 %	0.07 %
Assay (By HPLC)	Not less than 98.0 % w/w and not more than 102.0 % w/w of $C_{17}H_{18}F_3NO.HCl$, calculated on the anhydrous basis	99.2 % w/w
Residual solvents (By GC)		
Benzene	Not more than 1 ppm	Not Detected
Ethyl acetate	Not more than 5000 ppm	Not Detected
Toluene	Not more than 100 ppm	Not Detected
Additional Test:		
Particle size (By Malvern analyzer)	90 % less than 50 µm	90 % particles are 17.0 µm

Remarks: The material complies with respect to the above specifications.

Statement of Compliance: We, hereby confirm that this batch is manufactured in accordance with current Good Manufacturing Practices.

	Prepared By	**Checked By**	**Approved By**
Name	Vivek Magare	Mukesh Kosada	Bhushan Chandratre
Designation	Sr.Officer-QA	Executive-QA	Dy.Manager-QA
Signature			
Date	12.06.25	12.06.25	12.06.25

F/QA007/06/12.12.22

Registered Office :
"Cadila Corporate Campus,"
Sarkhej-Dholka Road, Bhat,
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Phone : +91-2718-225001-15
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CIN : U24231GJ1991PLC015132

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Limit of Detection (LOD) and Limit of Quantification (LOQ) table:

Name of compound	Limit of Detection (LOD) %	Limit of Quantification (LOQ) %
Impurity A	0.002	0.004
Impurity B	0.002	0.005
Fluoxetine	0.004	0.010
Dimethyl amine impurity	0.004	0.009

Limit of Detection (LOD) and Limit of Quantification (LOQ) table:

Name of compound	Limit of Detection (LOD) ppm	Limit of Quantification (LOQ) ppm
Ethyl Acetate	0.495	1.500
Benzene	0.050	0.150
Toluene	0.165	0.500

	Prepared By	Checked By	Approved By
Name	Vivek Magare	Mukesh Kosada	Bhushan Chandratre
Designation	Sr.Officer-QA	Executive-QA	Dy.Manager-QA
Signature			
Date	12.06.25	12.06.25	12.06.25

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