CADILA PHARMACEUTICALS LIMITED
CHEMICALS SBU

Works :
294, G.I.D.C., Estate,
Ankleshwar - 393 002.
Gujarat, India.

Phone : +91-2646 -251519/ 252626
Fax : +91 -2646 - 250051
Website : www.cadilapharma.com

Name of Finished Drug substance: Fluoxetine Hydrochloride USP +IH			
Manufactured By	Cadila pharmaceuticals limited, Ankleshwar		
Batch No.	23FH089	A.R. No.	23FP0453
Manufacturing Date	MARCH 2023	Qty. Mfgd.	153.16 Kg.
Expiry Date	FEBRUARY 2028	Sample Qty.	120.01 gm
Specification No	FPS/238		
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
A. Description B. Solubility	A. White to off white crystalline powder. B. Sparingly soluble in water and in dichloromethane; freely soluble in alcohol and in methanol; practically in soluble in ether.	White crystalline powder. Sparingly soluble in water and in dichloromethane; freely soluble in alcohol and in methanol; practically in soluble in ether.
Identification A. By IR B. Test for chloride C. By HPLC	A. The infrared absorption spectrum of the substance being examined should be concordant with the infrared absorption spectrum obtained from Fluoxetine hydrochloride USP working standard. B. Should be responds the chlorides C. Retention time of major peak in the chromatogram obtained from the sample preparation should match with retention time of major peak in the chromatogram obtained from Fluoxetine hydrochloride working standard preparation during assay analysis by HPLC.	The infrared absorption spectrum of the substance is examined concordant with the infrared absorption spectrum obtained from Fluoxetine hydrochloride USP working standard. Conform the test. Retention time of major peak in the chromatogram obtained from the sample preparation is match with retention time of major peak in the chromatogram obtained from Fluoxetine hydrochloride working standard preparation during assay analysis by HPLC.
Water content (By KF)	Not more than 0.50 % w/w	0.07 % w/w
Organic impurities (By HPLC) Related Compound A Related Compound B α-[2-[(methylamino)ethyl]benzene methanol 4-Triflurомethylphenol Dimethyl amine Impurity at RRT about 1.35 Any Individual unspecified impurity Total impurities	 Not more than 0.15 % Not more than 0.25 % Not more than 0.25 % Not more than 0.10 % Not more than 0.10 % Not more than 0.10 % Not more than 0.50 %	 Below Quantification limit Below Detection limit Not Detected Not Detected Not Detected Below Disregard limit 0.07 %
Residual solvents (By GC) Benzene Ethyl acetate Toluene	 Not more than 1 ppm Not more than 5000 ppm Not more than 100 ppm	 Not Detected Not Detected Not Detected
Assay (By HPLC) (On anhydrous basis)	Not less than 98.0 % w/w and not more than 102.0 % w/w of Fluoxetine hydrochloride ($C_{17}H_{18}F_3NO.HCl$,)	98.7 % w/w
Additional Tests:		
Particle size (By Malvern analyzer)	90 % less than 50 µ	90 % Particles are 28.2 µ

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	Mukesh Kosada	Ankit Pokar	Purshottam Dubey
Designation	Executive-QA	Executive-QA	Manager-QA
Signature			
Date	28.04.23	28.04.23	28.04.23

Registered Office :
"Cadila Corporate Campus,"
Sarkhej-Dholka Road, Bhat,
Ahmedabad - 382 210, Gujarat, India.

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) %
[α-[2-(methylamino)ethyl] benzene methanol(Aminomethyl-1-phenylpropanol) Or 3-Methylamino-1-phenylpropan-1-ol [Impurity-A]	0.001	0.002
Related compound-B [Impurity-B]	0.001	0.003
Related compound-A [Impurity-C]	0.016	0.046
4-trifluoromethyl phenyl	0.007	0.020
Dimethyl amine	0.007	0.018
Fluoxetine	0.004	0.012

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	Mukesh Kosada	Ankit Pokar	Purshottam Dubey
Designation	Executive-QA	Executive-QA	Manager-QA
Signature			
Date	28.04.23	28.04.23	28.04.23

F/QA007/06/12.12.22

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