F&A PHARMA

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 Ph.Eur/BP+IH.			
Manufactured By.	Cadila Pharmaceuticals Limited, Ankleshwar		
Batch No.	24FH074	A.R. No.	24FP0591
Manufacturing Date	APRIL 2024	Qty. Mfgd.	150.25 Kg.
Expiry Date	MARCH 2029	Sample Qty.	121.48 gm
Specification No	FPS/239	CEP No.	R1-CEP 2004-207-Rev 06
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 B. Solubility	A. White or almost white crystalline powder. B. Sparingly soluble in water and in methylene chloride, Freely soluble in methanol.	White crystalline powder. Sparingly soluble in water and in methylene chloride, Freely soluble in methanol.
Identification A. By IR B. Test for chloride	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. B. Should be responds the chlorides	The infrared absorption spectrum obtained from the sample is concordant with the spectrum obtained from Fluoxetine Hydrochloride working standard. Complies
Appearance of solution	Solution should be clear and colorless	Solution clear and colorless
pH	Between 4.5 and 6.5	5.76
Optical rotation	Between – 0.05° and + 0.05°	+0.00°
Water content (By KF)	Not more than 0.50 % w/w	0.06 % w/w
Sulfated ash	Not more than 0.10 % w/w	0.02 % w/w
Related substances (By HPLC) Impurity A Impurity B Dimethyl amine impurity Unspecified impurity Total impurities	 Not more than 0.15 % Not more than 0.10 % Not more than 0.10 % Not more than 0.10 % Not more than 0.30 %	 Below Quantification limit Below Detection limit Not Detected 0.01 % 0.02 %
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	100.2 % w/w
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
Additional Test:		
Particle size (By Malvern analyzer)	90 % less than 50 µm	90 % particles are 23.8 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	Ankit Pokar	Purshottam Dubey
Designation	Sr.Officer-QA	Executive-QA	Manager-QA
Signature	[signature]	[signature]	[signature]
Date	24.04.24	24.04.24	24.04.24

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09/08/2024

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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	Ankit Pokar	Purshottam Dubey
Designation	Sr.Officer-QA	Executive-QA	Manager-QA
Signature			
Date	24.04.24	24.04.24	24.04.24

F/QA007/06/12.12.22

COPY QA APPROVED Date 30.04.24 Signature F&A PHARMA Handels GmbH