F&A PHARMA
F. & A. PHARMA-Handels-GmbH
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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.	20FH170	A.R. No.	20FP1243
Manufacturing Date	SEPTEMBER 2020	Qty. Mfgd.	155.23 Kg.
Expiry Date	AUGUST 2025	Sample Qty.	126.6 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. Description 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 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 colourless	Solution clear and colourless
pH	Between 4.5 and 6.5	6.12
Optical rotation	Between – 0.05° and + 0.05°	+0.01°
Water content (By KF)	Not more than 0.50 % w/w	0.05 % w/w
Sulfated ash	Not more than 0.10 % w/w	0.06 % w/w
Related substances (By HPLC) Impurity A Impurity B Impurity C Dimethyl amine impurity at RRT about 1.35 Unspecified impurity Total impurities	 Not more than 0.25 % Not more than 0.25 % Not more than 0.15 % Not more than 0.10 % Not more than 0.10 % Not more than 0.50 %	 Not Detected Below Quantification limit Below Detection limit Not Detected Below Disregard limit 0.06 %
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	99.6 % 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
*Acetonitrile (By GC)	Not more than 0.1 %	Not Perfomed
Additional Test:		
Particle size	90 % less than 50 µ.	90 % particles are 18.2 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.
*** 'Acetonitrile is not used in the manufacturing process' hence need not to be tested.**

	Prepared By	**Checked By**	**Approved By**
Name	Mukesh Solanki	Nitin Panchal	Nilkanth Chopade
Designation	Sr.Officer-QA	Asst.Manager-QA	Manager-QA
Signature			
Date	07.10.20	07.10.20	07.10.20

F/QA007/14/13.04.18

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

Name of compound	LOD (%)	LOQ (%)
Impurity A	0.001	0.002
Impurity B	0.001	0.003
Impurity C	0.016	0.046
Dimethyl amine	0.007	0.018
Fluoxetine	0.004	0.012

Name of compound	LOD (ppm)	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 Solanki	Nitin Panchal	Nilkanth Chopade
Designation	Sr.Officer-QA	Asst.Manager-QA	Manager-QA
Signature			
Date	07.10.20	07.10.20	07.10.20

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