



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

Phone : +91-2646 -251519/ 252626 Fax : +91 -2646 - 250051

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Page 1 of 2

Name of Finished Drug su	bstance: Fluoxetine H	ydrochloride Ph.E	Page 1 of 2 cur/BP+IH.
Manufactured By.	Cadila Pharmaceutical	s Limited, Ankleshw	ar
Bàtch 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		The second secon	erature. (Not more than 25°C, excursion
	allowed 15°C to 30°C).		
		te of Analysis	
Test	Require	ments	Results
Characters: A. Appearance	A. White or almost white	e crystalline powder.	White crystalline powder.
B. Solubility	B. Sparingly soluble	in water and in	Sparingly soluble in water and in
4 14 1	methylene chloride,		methylene chloride, Freely soluble in
	methanol.		methanol.
Identification			~ ~
A. By IR	A. The infrared absorpti		The infrared absorption spectrum obtained
·•	from the sample should the spectrum obtaine		from the sample is concordant with the spectrum obtained from Fluoxetine
~	Hydrochloride for ID		Hydrochloride working standard.
-	Fluoxetine Hydrochlorid		Trydrodnoride working standard.
3. Test for chloride	B. Should be responds th		Complies
Appearance of solution	Solution should be clear	and colorless	Solution clear and colorless
рН	Between 4.5 and 6.5	40	5.76
Optical rotation	Between - 0.05° and + 0.	05°	+0.00°
Water content (By KF)	Not more than 0.50 % w/	w y	0.06 % w/w
Sulfated ash	Not more than 0.10 % w/	w ,	0.02 % w/w
Related substances (By HPLC)		1	
mpurity A	Not more than 0.15%	<b>Y</b>	Below Quantification limit
mpurity B	Not more than 040 %		Below Detection limit
Dimethyl amine impurity	Not more than 0.10 %		Not Detected
Inspecified impurity  Total impurities	Not more than 0.10 %		0.01 %
Assay (By HPLC)	Not more than 0.30 %	h., a., 4	0.02 %
issay (by III LC)	Not less than 98.0 % w/ 102.0 % w/w of C <sub>17</sub> H <sub>18</sub> !		100.2 % w/w
- '	on the anhydrous basis	3110.11CI, Calculated	
Residual solvents (By GC)	N/		
Benzene	Not more than 1 ppm		Not Detected
Ethyl acetate	Not more than 5000 ppm		Not Detected
`oluene	Not more than 100 ppm		Not Detected
additional Test:			
article size By Malvern apalyzer)	90 % less than 50 μm		90 % particles are 23.8 µm
	rks: The material complies	with respect to the above	ua appoifications
tatement of Compliance: We, hereb	by confirm that this batch is ma	nufactured in accordance	with current Good Manufacturing Practices.
P	repared By	Checked By	Approved By
	ivek Magare	Ankit Pokar	Purshottam Dubey
esignation S	r.Officer-QA	Executive-QA	Manager-QA
ignature	(V)M	(AR)	- 12
Pate	24.04.24	24.04.2	4 84.04.24
F/QA007/06/12.12.22	2-11-0 1-0 1	24,04,2	1 10000

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

Phone
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Website

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: U24231GJ1991PLC015132

**METAPHARMACEUTICA** 

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The Care Continues ..

09/08/2024





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Page	~	- 0	
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		Pag	e 2 of 2
substance: Fluoxetine	Hydrochloride Ph	.Eur/BP+IH.	
24FH074	A.R. No.	24FP0591	
APRIL 2024	Qty. Mfgd.	150.25 Kg.	
MARCH 2029			
FPS/239	CEP No.		A
Store in a tightly clos allowed 15°C to 30°C	ed container at room ten	nperature. (Not more than 25°C, excur	
	Cadila Pharmaceuti 24FH074  APRIL 2024  MARCH 2029  FPS/239  Store in a tightly clos	Cadila Pharmaceuticals Limited, Anklesh 24FH074 A.R. No.  APRIL 2024 Qty. Mfgd.  MARCH 2029 Sample Qty.  FPS/239 CEP No.	Substance: Fluoxetine Hydrochloride Ph.Eur/BP+IH.  Cadila Pharmaceuticals Limited, Ankleshwar  24FH074  A.R. No.  24FP0591  APRIL 2024  Qty. Mfgd.  150.25 Kg.  MARCH 2029  Sample Qty.  121.48 gm  FPS/239  CEP No.  R1-CEP 2004-207-Rev 06  Store in a tightly closed container at room temperature. (Not more than 25°C, excur

Certificate of Analysis

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	6:010
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
Vivek Magare	Ankit Pokar	Purshottam Dubey
Sr.Officer-QA	Executive-QA	Manager-QA
OW	a All	8
24.06.96	211214	24.04.24
	Vivek Magare Sr.Officer-QA	Vivek Magare Ankit Pokar  Sr.Officer-QA Executive-QA

F/QA007/06/12.12.22



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

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CIN

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