Lote: 0110215

Divis Pharmaceuticals Pvt. Ltd.

CERTIFICATE OF ANALYSIS

PRODUCT	FLUOXETINE HCL EP		
BATCH NO.	0090115	MFG. DATE	JAN - 2015
Q.C.R.NO.	FH/011/15	EXP. DATE	DEC - 2019

Sl.No.	TESTS	SPECIFICATIONS	RESULTS
01.	DESCRIPTION	A White or almost white crystalline powder	Almost white crystalline powder
02.	SOLUBILITY	Sparingly soluble in water, methylene chloride, freely soluble in methanol	Complies
03.	IDENTIFICATION	A. IR Absorption spectrum	Complies
		B. Reaction (a) of chlorides	Complies
04.	APPEARANCE OF SOLUTION	Solution S is clear and colourless	Complies
05.	pH	4.5 to 6.5	5.88
06.	OPTICAL ROTATION	-0.05° to +0.05°	Complies
07.	RELATED COMPOUNDS		
i)	Impurity A	NMT 0.25%	0.03%
ii)	Impurity B	NMT 0.25%	0.03%
iii)	Impurity C	NMT 0.15%	Not detected
iv)	Unknown individual impurity	NMT 0.1%	0.02%
v)	Sum of impurities	NMT 0.5%	0.08%
08.	ACETONITRILE	Acetonitrile is not using in the manufacturing process	
09.	HEAVY METALS [ppm]	NMT 20 ppm	<20 ppm
10.	WATER [%]	NMT 0.5%	0.15%
11.	SULPHATED ASH [%]	NMT 0.1%	0.05%
12.	ASSAY (on anhydrous basis)	98.0% to 102.0% w/w	99.91%
13.	ADDITIONAL TESTS		
i)	RESIDUAL SOLVENTS	Methanol : NMT 3000 ppm	12 ppm
		Toluene : NMT 890 ppm	Not detected
		Dimethyl sulfoxide : NMT 5000 ppm	Complies
		Ethyl Acetate : NMT 5000 ppm	519 ppm

REPORT : The above product complies with standard quality of European Pharmacopoeia & Customer specifications with reference to the tests carried out above.

ANALYSED BY
DATE : 31.2.15

APPROVED BY
DATE : 3/2/15

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