Lte: 0040413

Divis Pharmaceuticals Pvt. Ltd.

CERTIFICATE OF ANALYSIS

PRODUCT	FLUOXETINE HCL EP		
BATCH NO.	0340313	MFG. DATE	MAR - 2013
Q.C.R.NO.	FH/044/13	EXP. DATE	FEB - 2018

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	6.18
06.	OPTICAL ROTATION	-0.05° to +0.05°	Complies
07.	RELATED COMPOUNDS		
i)	Impurity A	NMT 0.25%	Not detected
ii)	Impurity B	NMT 0.25%	0.02%
iii)	Impurity C	NMT 0.15%	Not detected
iv)	Unknown individual impurity	NMT 0.1%	0.02%
v)	Sum of impurities	NMT 0.5%	0.05%
08.	ACETONITRILE	Acetonitrile is not using in the manufacturing process	
09.	HEAVY METALS [ppm]	NMT 20 ppm	<20 ppm
10.	WATER [%]	NMT 0.5%	0.16%
11.	SULPHATED ASH [%]	NMT 0.1%	0.04%
12.	ASSAY (on anhydrous basis)	98.0% to 102.0% w/w	99.81%
13.	ADDITIONAL TESTS		
i)	RESIDUAL SOLVENTS	Methanol : NMT 3000 ppm	46 ppm
		Toluene : NMT 890 ppm	82 ppm
		Dimethyl sulfoxide : NMT 5000 ppm	Complies
		Ethyl Acetate : NMT 5000 ppm	402 ppm

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

ANALYSED BY V. 4/4/13.
DATE :

APPROVED BY 4/4/13
DATE :

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