Divis Pharmaceuticals Pvt. Ltd.

CERTIFICATE OF ANALYSIS

Late ent: 01/05/12

PRODUCT	FLUOXETINE HCL EP		
BATCH NO.	0150412	MFG. DATE	APR - 2012
Q.C.R.NO.	FII/083/12	EXP. DATE	MAR - 2017

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	5.64
06.	OPTICAL ROTATION	-0.05° to +0.05°	Complies
07.	RELATED COMPOUNDS		
i)	Impurity A	NMT 0.25%	0.05%
ii)	Impurity B	NMT 0.25%	0.02%
iii)	Impurity C	NMT 0.15%	Not detected
iv)	Unknown individual impurity	NMT 0.1%	0.03%
v)	Sum of impurities	NMT 0.5%	0.11%
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%	0.06%
12.	ASSAY (dried substance)	98.0% to 102.0% w/w	99.38%
13.	ADDITIONAL TESTS		
i)	RESIDUAL SOLVENTS	Methanol : NMT 3000 ppm	Not detected
		Toluene : NMT 890 ppm	24 ppm
		Dimethyl sulfoxide : NMT 5000 ppm	Complies
		Ethyl Acetate : NMT 5000 ppm	1168 ppm

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

ANALYSED BY
DATE :

APPROVED BY
DATE : 21/5/12

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