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Divis Pharmaceuticals Pvt. Ltd.

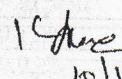
CERTIFICATE OF ANALYSIS

PRODUCT		FLUOXETINE HCL EP		
BATCH NO.	1801213	MFG. DATE	DEC - 2013	
Q.C.R.NO.	FH/249/13	EXP. DATE	NOV - 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		5.32
06.	OPTICAL ROTATION	-0.05° to +0.05°		Complies
07.	RELATED COMPOUNDS			
	i) Impurity A	NMT 0.25%		0.02%
	ii) Impurity B	NMT 0.25%		0.06%
	iii) Impurity C	NMT 0.15%		Not detected
	iv) Unknown individual impurity	NMT 0.1%		0.02%
	v) Sum of impurities	NMT 0.5%		0.11%
08.	ACETONITRILE	Acetonitrile is not using in the manufacturing process		
09.	HEAVY METALS [ppm]	NMT 20 ppm		<20 ppm
10.	WATER [%]	NMT 0.5%		0.15%
11.	SULPHATED ASH [%]	NMT 0.1%		0.05%
12.	ASSAY (on anhydrous basis)	98.0% to 102.0% w/w		99.73%
13.	ADDITIONAL TESTS			
	i) RESIDUAL SOLVENTS	Methanol : NMT 3000 ppm		11 ppm
		Toluene : NMT 890 ppm		79 ppm
		Dimethyl sulfoxide : NMT 5000 ppm		Complies
		Ethyl Acetate : NMT 5000 ppm		445 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: 10/11/14

APPROVED BY: 

DATE: 10/11/14

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