Divis Pharmaceuticals Pvt. Ltd.

CERTIFICATE OF ANALYSIS

Lote 0100512

PRODUCT	FLUOXETINE HCL EP		
BATCH NO.	0150412	MFG. DATE	APR - 2012
Q.C.R.NO.	FH/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 : 27/5/12

DIVI TOWERS, 7-1-77/E/1/303, DHARAM KARAN ROAD, AMEERPET, HYDERABAD - 500 016. INDIA.
TEL : 91-40-23734841 / 23743924, FAX : 91-40-23746424, E-mail : info@divispharma.com, URL : www.divispharma.com
FACTORY : SURVEY NO. : 10, GADDAPOTARAM (V), KHAZIPALLY I.D.A. JINNARAM (M), MEDAK DIST., A.P. TEL : 91-8458-202027

Fujian Kerui Pharmaceutical Co.,Ltd.

Yuan'an Industrial Area,HaiKou,LuQing,Fujian Province [illegible] China

Certificate of Analysis

CYCLOSPORINE EP

Lot: 000502

BATCH NUMBER	110402(N)	TEST DATE	May.4,2011
		MANUFACTURE DATE	Apr.27,2011
QUANTITY	1000g	EXPIRATION DATE	Apr.26,2014

TEST	SPECIFICATION	RESULT
Characters	White powder,practically insoluble in water,freely soluble in ethanol and methylene chloride	Conforms
Identification	Conforms to EP	Conforms
Appearance of solution	Conforms to EP	Conforms
Specific optical rotation	—185°to —193°	—189°
loss on drying	Not More Than 2.0%	1.69%
Heavy metals	Not More Than 0.002%	Conforms
Related compounds		
Individual	Not More Than 0.7%	0.24%
Total	Not More Than 1.5%	1.08%
Assay	98.5% to 101.5% calculate on the dried basis	99.8%
Residual Solvents		
Ethanol	Not More Than 0.1%	Not Detected
Petroleum Ether	Not More Than 0.1%	Not Detected
Acetone	Not More Than 0.1%	Not Detected
Butyl Acetate	Not More Than 0.1%	Not Detected

Manufactured By: Fujian Kerui Pharmaceutical Co., Ltd.

FINAL BATCH DISPOSITION: Approved (√) [√] By:

Analyst Date: 2011.5.4

Checker Date: 2011.5.4

Supervisor Date: 2011.5.5

Version 2.01

01-13-2010