

杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Fluvoxamine maleate

Batch No.: DR20140209	Piece: 200kg
Manufacture Date: 2014.01.24	Expiry Date: 2017.1.23

TESTS:

Items	Specification	Results
Appearance	A white to almost white crystalline powder	A white crystalline powder
Solubility	Sparingly soluble in water, freely soluble in Ethanol(96%) and in methanol	Sparingly soluble in water, freely soluble in Ethanol(96%) and in methanol
Identification	A:Infrared Absorption B:The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.	A:Complies B: Complies
Melting temperature	121° —123°	122.0°
Loss on drying	≤0. 5%	0.3%
Residue on ignition	≤0. 1%	0.03%
Heavy metals	≤0. 001%	< 0. 001%
Related compounds	5-Methoxy-1-[4-(trifluoromethyl)phenyl]-1-pentanone-(E)-O-[2-[(2-succinyl)amino]ethyl]oxime (Limit 0.3%)	0.05%
	5-Methoxy-4'-(trifluoromethyl)valeropentanone-(E)-O-(2-aminoethyl) aminoethyl oxime maleate (Limit 0.2%)	0.01%
	Z-isomer (Limit 0.5%)	0.01%
	4'-(trifluoromethyl)valeropentanone-(E)-O-(2-aminoethyl) aminoethyl oxime maleate (Limit 0.2%)	0.00%
	(E)-O-(2-aminoethyl)-4'-(trifluoromethyl)- α -phenyl- acetophenone oxime maleate (Limit 0.2%)	0.00%

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	4'-(trifluoromethyl)valeropentanone-(E)-O-(2-aminoethyl) oxime maleate (Limit 0.2%)	0.00%
Related compounds	5-Methoxy-4'-(trifluoromethyl)valeropentanone oxime (Limit 0.2%)	0.01%
	5-Methoxy-4'-(trifluoromethyl)valeropentanone ketone (Limit 0.2%)	0.01%
	Unknown impurities (Limit 0.1%)	0.02%
	Total (Limit 1.5%)	0.15%
Assay	Not less than 98.0% and not more than 102.0% (Calculated with reference to the dried substance)	99.8%
Conclusion: The results conform with USP34.		



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