



XIAMEN MAYAH PHARMA CO., LTD.

厦门明扬医药有限公司

TEL: +86-592-2160173; FAX: +86-592-2160175

CERTIFICATE OF ANALYSIS

Product Name:	Levomilnacipran HCl (1S,2R)-2-(aminomethyl)-N,N-diethyl-1-phenylcyclopropanecarboxamide hydrochloride
Batch No.:	20131101
MFG. Date:	Nov. 10, 2013
Expire Date:	Nov. 09, 2015
Quantity:	5kgs

ITEMS	SPECIFICATION	RESULTS
Description	White to off-white crystalline powder	Conforms
Solubility	Freely soluble in water and methanol	Conforms
Identification By IR	Conforms to Reference Standard/Working Standard similarly determined.	Conforms
Identification By HPLC	The RT of the major peak in the chromatogram of the sample preparation corresponds to that of the standard preparation, as obtained in the assay	Conforms
PH (1%w/v solution)	4.0 ~ 6.0	5.5
Loss on Drying	≤0.5%	0.21%
Residue On Ignition	≤0.1%	0.08%
Heavy Metals	≤10ppm	Conforms
Specific Optical Rotation	+ 82° ~ +92°	+ 86.5°
Optical purity	99%Min	99.5%
Related Substance		
Single impurity	≤0.20%	0.09%
Total impurities	≤0.50%	0.17%

Residue solvent		
Ethanol	$\leq 5000\text{ppm}$	Conforms
Methanol	$\leq 3000\text{ppm}$	Conforms
DMF	$\leq 880\text{ppm}$	Conforms
Dichloromethane	$\leq 600\text{ppm}$	Conforms
Isopropanol	$\leq 5000\text{ppm}$	Conforms
Ethyl Acetate	$\leq 5000\text{ppm}$	Conforms
Assay on Dried Basis	98.5% ~ 101.5%	100.6%
Conclusion:	It conforms to our in-house specification.	