



Certificate of Analysis

Product name : Mirtazapine
 Batch number : A112100201M
 Mfg. date : 2009/12/16
 Exp. Date : 2011/12/15

TESTS	STANDARDS	RESULTS
Character	A white or almost white crystalline powder	Complies
Identification	A. IR absorption spectrum is accordant with the spectrum obtained with CRS	Complies
	B. The RT of the major peak in the chromatogram of the assay preparation corresponds to that of the standard preparation, as obtained in the assay	Complies
Specific rotation	-2.0° ~ + 2.0°	0.1°
Water	NMT 1.0%	0.64%
Residue on ignition	NMT 0.1%	0.04%
Heavy metals	NMT 0.001%	Complies
Residual solvents	Dimethylformamide NMT 880ppm	ND
	Tetrahydrofuran NMT 720ppm	ND
	Toluene NMT 890ppm	ND
	Chloroform NMT 60ppm	ND
	N-heptane NMT 500ppm	0.4ppm
	Ethanol NMT 5000ppm	52ppm
Impurity	Individual impurity NMT 0.1%	ND
	Total impurities NMT 0.5%	ND
Assay	98.0~102.0%	98.5%

Conclusion : The product meets the requirement of USP30