



Certificate of Analysis

Product name : Lamotrigine
 Batch number : 20081201

TESTS	STANDARDS	RESULTS
Appearance	White or almost white powder	Complies
Solubility	Very slightly soluble in water, slightly soluble in anhydrous ethanol. It is slightly soluble indilute hydrochloric acid	Complies
Identification	The infrared absorption spectrum corresponds to that of lamotrigine reference standard	Complies
Related substances		
Impurity A	NMT 0.1%	Complies
Impurity F	NMT 0.2%	Complies
Any other impurity	NMT 0.1%	Complies
Total impurities	NMT 0.2%	Complies
Impurity E	NMT 0.1%	Complies
Residual solvents	Ethanol: NMT 5000ppm	78ppm
Loss on drying	NMT 0.25%	0.04%
Sulphated ash	NMT 0.1%	0.07%
Heavy metals	NMT 10ppm	Complies
Assay	99.0%~101.0%	99.6%
Storage	Protected from light	

Conclusion : The product meets the requirement of In House Standard