

Nantong Chanyoo Pharmatech Co., Ltd

CERTIFICATE OF ANALYSIS

We hereby certify that the following product has been manufactured by our factory and that the relative statements below are true and correct.

Product: Pregabalin

Quantity: 101.4Kg Batch NO : CI-150401 Manufacturing Date: Apr. 09, 2015

Retest Date: Apr. 09 2017

Batch NO.: CI-150401 Retest Date: Apr. 0		est Date: Apr. 09, 2017
Tests	Specifications	Results
Appearance	A white to off-white crystalline powder	White crystalline powder
Specific rotation	+10°~+13°	+12°
Identification	A. IR: similar to Reference Substance	Complies
	B. Retention Time: similar to Reference Substance	Complies
Chlorides	≤0.1%	Complies
Loss on drying	≤0.5%	0.06%
Residue on ignition	≤0.1%	0.01%
Enantiomer	≤0.15%	Undetected
	CI-4 ≤0.15%	Undetected
Related substances	Mandelic Acid≤0.10%	Undetected
	CI-6≤0.15%	Undetected
	CI-Lactam≤0.15%	Undetected
	Single unknown impurity ≤0.10%	Undetected
	Total impurities ≤0.8%	Undetected
Heavy metals	≤0.001%	Complies
Residual solvents	Ethyl acetate≤5000ppm	Undetected
	Isopropyl alcohol≤5000ppm	318ppm
	Tetrahydrofuran≤720ppm	Undetected
	Isopropyl ether≤1000ppm	Undetected
	Ethanol≤5000ppm	441ppm
Assay	98.0%~102.0% (Calculated on the dried basis)	99.2%

The results above meet all requirements under Pregabalin in In-House Standard

Analysis NO.: CI-150004

Date: Apr. 13, 2015

Signature:

Quality Control Department