

HANGZHOU DINGYAN CHEM CO.,LTD

TEL: 86-571-87157530,86465881,88025800, FAX:86-571-87156470

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CERTIFICATE OF ANALYSIS

NO: DYC081907172

Product name	PREGABALIN
CAS Number	148553-50-8
Molecule Structure	H ₂ N OH OH
Molecule Formula	C8H17N02
Batch number	CI-703-181104
Manuf. &Exp. date	Nov. 10, 2018&Nov. 10, 2020
Testing date	2019-03-25

Items	Standard	Result
Appearance	White or almost white powder	white powder
Identification	A:IR: similar to reference substance B:Examine the chromatograms obtained in the test for enantiomeric purity: the principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with the test solution time to the principal peak in the chromatogram obtained with the	complies
Water	reference solution ≤0.5%	0.09%
	·	
Sulfated ash	≤0.1%	0. 05%
Related	Impurity A≤0.15%	Not detected
substances	Unspecified impurities eluting before pregabalin(test A) ≤0.10%	Not detected
	Unspecified impurities eluting after pregabalin(test B) ≤0.10%	Not detected
	Total for test A and B≤0.5%	Not detected
Enantiomer	Impurity B≤0.15%	Not detected
Benzene	≤2ppm	complies
Residual	Ethyl acetate≤500ppm	Not detected
solvents	Isopropyl alcohol≤5000ppm	82ppm

Add: Xiasha 571,19TH Street E-COMMERCE 4A601-602, Jianggan Area, Hangzhou, China



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Tetrahydrofuran ≤250ppm		Not detected
	Isopropyl ether ≤500ppm	Not detected
	Ethano1≤1000ppm	Not detected
Assay	98. 0%~102% (anhydrous	99. 5%
	substance)	

QUALITY CONTROL: Parks...

CHECK: 姚仙娟

INSPECTOR: 刘清风