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Certificate of Analysis

Product Name	Pregabalin	CAS No	148553-50-8
Batch No.	20181201	Report date	2018.12.30
Produce date	2018.12.22	Expiry date	2020.12.21
Analysis according: Enterprise Standard			

ITEM	STANDARD	RESULT
Assay	98.0% ~ 102.0%(Anhydrous substance)	99.20%
Appearance	White or almost white powder	Qualified
Identification	IR:similar with the reference spectrum	Qualified
	Retention Time: similar to Reference Substance	Qualified
Specific rotation	+10°~+13°	+11°
Sulfated ash	≦0.1%	0.06%
Water	≦0.5%	0.03%
Enantiomer	Impurity B ≦0.15%	Not Detected
Benzene	≦2ppm	Qualified
Related Substances	Impurity A ≦0.15%	Not Detected
	Test A ≦0.10%	0.06%
	Test B ≦0.10%	Not Detected
	Total test A and test B	0.06%
Residual solvents	Ethyl acetate ≦500ppm	Not Detected
	Isopropyl alcohol ≦5000ppm	72ppm
	Tetrahydrofuran ≦250ppm	Not Detected
	Isopropyl ether ≦500ppm	Not Detected
	Ethanol ≦1000ppm	Not Detected
Conclusion :	This product conforms with requirement	
Storage:	Store in sealed containers at cool & dry place. Protect from light, moisture and pest infestation	
Shelf life:	2 years if properly stored	
Operator: Kai Guo		Approval: Qiang Liu

