

SHIJIAZHUANG LONZEAL PHARMACEUTICALS CO., LTD.

NO. 16, WEST RING ROAD, SHENZE, SHIJIAZHUANG,
HEBEI PROVINCE, CHINA, 052560

CERTIFICATE OF ANALYSIS

COMMERCIAL NAME: Pregabalin
 CHEMICAL NAME: (3S)-3-(Aminomethyl)-5-methylhexanoic acid
 CAS No. : 148553-50-8
 CHEMICAL FORMULA: C₈H₁₇NO₂

Batch No.	Date of Manufacture	Date of Retest	Date of Analysis	Package	Batch Size
1900036141	2019.04.23	2021.04.22	2019.05.02	25Kg/Drum	81.6kg
TEST ITEMS	SPECIFICATION			TEST RESULTS	
Description	White or to off-white crystalline powder.			white crystalline powder	
Solubility	Sparingly soluble in water, and freely soluble in dilute hydrochloric acid.			Complies	
Identification	The IR spectrum of the test sample corresponds to the standard IR spectrum of Pregabalin.			Complies	
	The retention time of the Pregabalin peak in the chromatogram of the test solution corresponds to that in the chromatogram of the standard solution, as obtained in the test of Assay.			Complies	
Loss on Drying	Not more than 0.50%			0.06%	
Specific Optical Rotation	+10.0°~+ 12.0°			+11.0°	
Residue on Ignition	Not more than 0.10%			0.08%	
Heavy Metals	Not more than 20ppm			Complies	
Chloride and Sulfate	Not more than 0.1%			Complies	
Enantiomeric Purity	Not more than 0.15%			Not Detected	
Organic Impurities, Procedure 1, By HPLC	Isobutylglutaric acid is not more than 0.15%			Not Detected	
	Isobutylglutaramonoamide is not more than 0.15%			Not Detected	
	(4S)-4-(2-methylpropyl)pyrrolidin-2-one is not more than 0.15%			0.0041%	
	Any other individual impurity is not more than 0.10%			0.056%	
	Total impurities is not more than 0.50%			0.090%	
Assay	98.0%~102.0% (Calculated on the dried basis)			100.3%	
Residual Solvents	Isopropanol is not more than 0.3%			<0.0091%	
	Dichloromethane is not more than 0.06%			Not Detected	
Conclusion	Batch No: <u>1900036141</u> complies with USP42 specification				

No mandelic acid is used in the synthesis of Pregabalin.

REPORT BY: 任超 2020.04.15

CHECK BY: 马廷 2020.04.15

ADMIN: 任超 2020.04.15

