



湖北源梦生物科技有限公司

Hubei Yuanmeng Biological & Technology Co., Ltd.

Add: 430000 Hongshan District, WUHAN CITY, Hubei PROV., CHINA

TEL:+86-18971268569 FAX:027-68897569 E-mail: sales@yuanmengbio.com

CERTIFICATE OF ANALYSIS

Product name	Pregabalin		
Batch No.	19100501	Mfg. Date	2019.10.05
Release Date	2020.10.10	Exp. Date	2022.10.04
Quantity	200 Kg	Quality standard	Enterprise standard USP40
Tests	Specifications		Results
Appearance	Off-white to white powder		White powder
Identification	The infrared absorption spectrum of the sample should concordant with that of the spectrum of working standard of product		Conforms
Solubility	Sparingly soluble in water		Conforms
Specific Optical Rotation (On anhydrous basis) (°)	+10.0° to +12.0°		+11.39°
Loss on drying(w/w)	≤0.5%		0.29%
Sulphate ash	≤0.1%		0.052%
Heavy Metals(%)	≤20ppm		Conforms
Enantiomeric purity	The area of peak due to R-Pregabalin is not more than 0.5 % the area of the S-Pregabalin.		0.162%
Related substances (HPLC)	Lactam impurities ≤0.5%		0.085%
	Individual impurities ≤0.5%		0.187%
	Total impurities ≤1.0%		0.365%
Assay(%)	It content not less than 98.0% and not more than 102.0% on dried basis.		99.36%
Conclusion	The results conform to the USP40 standard.		