CERTIFICATE OF ANALYSIS
化 验 报 告 单

产品名称 Product name	Pregabalin		
批　号 Batch No.	19102201	生产日期 Mfg. Date	2019.10.22
发放日期 Release Date	2019.10.22	有效期至 Exp. Date	2021.10.21
Quantity 数量	500 Kg	Quality standard 检验依据	Enterprise standard USP38
Tests **检验项目**	**Specifications** **标准规定**		**Results** **检验结果**
Appearance 外观	Off-white to white powder 类白色至白色粉末		White powder 白色粉末
Identification 鉴别	The infrared absorption spectrum of the sampleshould concordant with that of the spectrum of working standard of product 红外吸收图谱应与对照图谱一致。		Conforms 符合规定
Solubility 溶解度	Sparingly soluble in water 略溶于水		Conforms 符合规定
Specific Optical Rotation (On anhydrous basis) （°） 比旋度	+10.0° to +12.0°		+11.19°
Loss ondrying(w/w) 干失	≤0.5%		0.42%
Sulphate ash 硫酸灰分	≤0.1%		0.062%
Heavy Metals(%)	≤20ppm		Conforms 符合规定
Enantiomeric purity 对映体纯度	The area of peak due to R-Pregabalin is not more than 0.5 % the area of the S-Pregabalin. R-普瑞巴林峰面积不得超过 S-普瑞巴林的 0.5%		Conforms 符合规定
Related substances 色谱纯度（HPLC）	Lactam impurities ≤0.5% 内酰胺杂质		Not detected 未检出
	Individual impurities ≤0.5% 任意单杂		0.227%
	Total impurities ≤1.0% 总杂		0.845%
Assay(%) 含量	It content not less than 98.0% and not more than 102.0% on dried basis.		99.46%
Conclusion 结论	The results conform to the USP38 standard. 本品结果符合 USP38 标准。		