

Hebei Huanhao Biotechnology Ltd.,co

Address: No.1103,FuBang Building,Intersection of Zhonghua
Avenue and Yuhua Road, Shijiazhuang city,Hebei
Province, China.

质量报告单

CERTIFICATE OF ANALYSIS

产品名称 Product name	普瑞巴林 Pregabalin		
CAS 号 CAS No.	148553-50-8	包装规格 Outer Packing	25KG 25KG
生产日期 Production date	2018.12	有效期 Shelf life	2020.12
执行标准 Standard adopted	EP		
分析项目 Items of analysis	质量标准 Specification	实测结果 Results	
外观 Appearance	白色或类白色粉末 White or almost white powder	符合 conforms	
鉴别 Identification	IR 和 HPLC IRandHPLC	符合 conforms	
干燥失重 Loss on drying	$\leq 0.5\%$ $\leq 0.5\%$	0.2% 0.2%	
比旋度 Specific Rotation	$+10^{\circ} \sim +12^{\circ}$ $+10^{\circ} \sim +12^{\circ}$	$+10.77^{\circ}$ $+10.77^{\circ}$	
炽灼残渣 Residue on ignition	$\leq 0.1\%$ $\leq 0.1\%$	0.08% 0.08%	
重金属 Heavy metals	$\leq 20\text{ppm}$ $\leq 20\text{ppm}$	符合 conforms	
杂质 C impurity C	$\leq 0.1\%$ $\leq 0.1\%$	符合 conforms	
其他单杂 Any impurity	$\leq 0.1\%$ $\leq 0.1\%$	0.044% 0.044%	
总杂质 Total impurity	$\leq 1.0\%$ $\leq 1.0\%$	0.14% 0.14%	
含量 Assay(HPLC)	98%-101% 98%-101%	99.6% 99.6%	
R-异构体(HPLC)	$\leq 0.15\%$	0.033%	

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R-isomer	≤0.15%	0.033%
溴化物（滴定法） Bromide content(Titrimetry)	≤500ppm ≤500ppm	26ppm 26ppm
乙醇 Ethanol	≤5000ppm ≤5000ppm	符合 conforms
异丙醇 Isopropyl alcohol	≤5000ppm ≤5000ppm	142ppm 142ppm
乙酸乙酯 Ethyl Acetate	≤5000ppm ≤5000ppm	符合 conforms
氯仿 Chloroform	≤60ppm ≤60ppm	符合 conforms
结论 Conclusion	合格 Qualified	

