

Kalchem International

Chemicals & Compounding Supplies

CERTIFICATE OF ANALYSIS

Product Name: Gabapentin USP 产品名称: 加巴喷丁		Date of Mfg.: 2015/05/13 生产日期:		
Batch No.: CGD20150501-02 批号:		Report Date: 2015/06/07 报告日期:		
Batch Size: 225kg 批量:		Retest Date: 2018/05/12 复验期:		
Quality Specification: USP38 质量规格:		Package: 25 kg/drum 包装: 25 kg/箱		
Subject 项目	Specification 标准	Result 结果		
Appearance 外观	White or almost white crystalline powder 白色或类白色结晶性粉末	Almost white crystalline powder 类白色结晶性粉末		
Identification A 鉴别 A	The sample IR absorption spectrum should match the reference standard 样品的红外光吸收图谱应与对照品的图谱匹配	The sample IR absorption spectrum matches the reference standard 样品的红外光吸收图谱与对照品的图谱匹配		
Identification B 鉴别 B	The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation 含量项中主峰的保留时间应与标准溶液中主峰保留时间匹配	The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation 含量项中主峰的保留时间与标准溶液中主峰保留时间匹配		
pH	6.5~8.0	7.1		
Water 水分	≤0.5%	0.06%		
Residue on ignition 炽灼残渣	≤0.1%	0.05%		
Heavy metals 重金属	≤0.002%	<0.002%		
Related compounds 相关物质	early eluting 先洗脱	Related Compound E 杂质 E	≤0.10%	Not detected 未检出
	late eluting 后洗脱	Related Compound A 杂质 A	≤0.1%	Not detected 未检出
		Related Compound B 杂质 B	≤0.06%	Not detected 未检出
		Individual unknown impurity 单个未知杂质	≤0.10%	0.02%
	Total impurities 总杂质	Related Compound D 杂质 D	≤0.10%	Not detected 未检出
		Individual unknown impurity 单个未知杂质	≤0.10%	0.02%
	Total impurities 总杂质		≤0.5%	0.04%
Residual solvent 残留溶剂	Ethanol 乙醇	≤5000ppm	232ppm	
Assay, on anhydrous basis 含量 (以无水物计)		98.0%~102.0%	99.3%	
Conclusion: Up to the standard USP38. 结论: 合格。				

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