

ZHEJIANG CHIRAL MEDICINE CHEMICALS CO., LTD

浙江手心医药化学品有限公司

CERTIFICATE OF ANALYSIS

REC-QC-GF-010-00

Product name:	GABAPENTIN 加巴喷丁	CAS NO.:	60142-96-3
Batch No.	产品批号 GAA-1311065	Test Basis	检验依据 CMC-SOP-QC-001-03-05-02
Specification	质量标准 DOC	Test Date	检验日期 2013/11
Batch Size	生产批量 250kg	Manufacturing Date	生产日期 2013/11
Sales Quantity	本次销量 100kg	Retest Date	复验日期 2016/10

TESTS	SPECIFICATIONS	RESULTS
Appearance 性状	White or almost-white crystalline powder	White crystalline powder
Identification 鉴别	IR spectrum of sample is consistent with that of EP Gabapentin CRS	Conform
→IR (红外检查)		
XRD (Form II)	Form III≤5%	Conform
Appearance of solution 溶液外观	The solution is clear and colorless	Conform
PH	6.5~7.5	7.3
Water 水分	≤0.3%	0.04%
Sulfated ash 灼烧残渣	≤0.1%	0.03%
Heavy metals 重金属	≤20ppm	<20ppm
Ethanol 乙醇	≤0.50%	0.04%
Chlorides 氯化物	≤100ppm	37ppm
Assay 含量	97.5%~102.0%	100.4%

Related substances 相关物质

→Method A 方法A

→→Impurity A 杂质A	≤0.15%	0.002%
→→Unspecified impurities 未知单一杂质	≤0.10%	Not detected

→Method B方法B

→→Unspecified impurities 未知单一杂质	≤0.05%	Not detected
→Total impurities 总杂质	≤0.5%	0.002%

CONCLUSION: The batch conforms with EP specifications

REPORT: 13.12.24 QC Director 2013.12.24 QA 2013.12.24
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