

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-1406076	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 2014/07
Batch Size	生产批量 407.5kg	Manufacturing Date	生产日期 2014/07
Sales Quantity	本次销量 400 kg	Retest Date	复验日期 2017/06

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)	Form III≤5%	Conform
XRD (Form II)	The solution is clear and colorless	Conform
Appearance of solution 溶液外观	PH	7.2
PH	6.5~7.5	7.2
Water 水分	≤0.3%	0.05%
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%	100.3%
Related substances 相关物质		
→Method A 方法A		
→→Impurity A 杂质A	≤0.15%	0.003%
→→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%	0.003%

CONCLUSION: The batch conforms with EP specifications

REPORT:

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