

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-1410003	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 2014/10
Batch Size	生产批量 400kg	Manufacturing Date	生产日期 2014/10
Sales Quantity	本次销量 200	Retest Date	复验日期 2017/09

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	6.5~7.5	7.1
PH	≤0.3%	0.02%
Water 水分	≤0.1%	0.02%
Sulfated ash 灼烧残渣	≤20ppm	<20ppm
Heavy metals 重金属	≤0.50%	0.03%
Ethanol 乙醇	≤100ppm	5ppm
Chlorides 氯化物	97.5%~102.0%	100.0%
Assay 含量	Related substances 相关物质	
→Method A 方法A		
→→Impurity A 杂质A	≤0.15%	0.004%
→→Unspecified impurities 未知单一杂质	≤0.10%	0.02%
→Method B 方法B		
→→Unspecified impurities 未知单一杂质	≤0.05%	Not detected
→Total impurities 总杂质	≤0.5%	0.02%

CONCLUSION: The batch conforms with EP specifications

REPORT: 2014.10.15 QC Director 2014.10.15 QA 2014.10.15
Tel: +86-571-82623231 Fax: +86-571-82654686 Website: www.chiralchem.com E-mail: David@chiralchem.com
Manufacture site: Nanyang Economy Development Zone, Xiaoshan, Hangzhou, Zhejiang, China