

ZHEJIANG CHIRAL MEDICINE CHEMICALS CO., LTD
浙江手心医药化学有限公司
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-1404010		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 2014/04	
Batch Size 生产批量 405.5kg		Manufacturing Date 生产日期 2014/04	
Sales Quantity 本次销量 400kg		Retest Date 复验日期 2017/03	

TESTS	SPECIFICATIONS	RESULTS
Appearance 性状	White or almost-white crystalline powder	White crystalline powder
Identification 鉴别		
→IR (红外检查)	IR spectrum of sample is consistent with that of EP Gabapentin CRS	Conform
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	7.1
Water 水分	≤ 0.3%	0.05%
Sulfated ash 灼烧残渣	≤ 0.1%	0.05%
Heavy metals 重金属	≤ 20ppm	< 20ppm
Ethanol 乙醇	≤ 0.50%	0.06%
Chlorides 氯化物	≤ 100ppm	70ppm
Assay 含量	97.5%~102.0%	100.1%
Related substances 相关物质		
→Method A 方法A		
→→Impurity A 杂质A	≤ 0.15%	0.01%
→→Unspecified impurities 未知单一杂质	≤ 0.10%	0.01%
→Method B 方法B		
→→Unspecified impurities 未知单一杂质	≤ 0.05%	Not detected
→Total impurities 总杂质	≤ 0.5%	0.01%

CONCLUSION: The batch conforms with EP specifications

REPORT: 赵永平 2014.5.28

QC Director

2014.5.28

QA

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