

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-1312004	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 2013/12
Batch Size	生产批量 400kg	Manufacturing Date	生产日期 2013/12
Sales Quantity	本次销量 400kg	Retest Date	复验日期 2016/11

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	7.0
Water 水分	≤ 0.3%	0.05%
Sulfated ash 灼烧残渣	≤ 0.1%	0.04%
Heavy metals 重金属	≤ 20ppm	< 20ppm
Ethanol 乙醇	≤ 0.50%	0.03%
Chlorides 氯化物	≤ 100ppm	50ppm
Assay 含量	97.5%~102.0%	100.2%
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%	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%	0.02%

CONCLUSION: The batch conforms with EP specifications

REPORT:

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