

## 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-1305008 | Test Basis         | 检验依据 CMC-SOP-QC-001-03-5-02 |
| Specification  | 质量标准 EP          | Test Date          | 检验日期 2013/07                |
| Batch Size     | 生产批量 404.5kg     | Manufacturing Date | 生产日期 2013/05                |
| Sales Quantity | 本次销量             | Retest Date        | 复验日期 2016/04                |

| 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 II ≤5.0%                                                      | 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%                                                              | 0.04%                    |
| Heavy metals 重金属                | ≤20ppm                                                             | <20ppm                   |
| Ethanol 乙醇                      | ≤0.50%                                                             | 0.02%                    |
| Chlorides 氯化物                   | ≤100ppm                                                            | 67ppm                    |
| Assay 含量                        | 97.5%~102.0%                                                       | 99.6%                    |
| Related substances 相关物质         |                                                                    |                          |
| →Method A 方法A                   |                                                                    |                          |
| →→Impurity A 杂质A                | ≤0.15%                                                             | 0.001%                   |
| →→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%                                                              | 0.001%                   |

CONCLUSION: The batch conforms with EP specifications

REPORT: 汪佳俊 2013.7.12

QC Director

2013.7.12 QA

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