

# Kalchem International

## Chemicals & Compounding Supplies

### ANALYSIS CERTIFICATE

生产日期 PROD.DATE: 2014.07.07

失效日期 EXP.DATE:2017.07.07

|                    |                 |                 |          |
|--------------------|-----------------|-----------------|----------|
| 品名<br>Product Name | <b>Baclofen</b> | 批号<br>Batch No. | 20140703 |
|                    |                 | 数量<br>Quantity  | 100kg    |

| 项目<br>Items  | 标准<br>Standard   | 检验结果<br>Results |
|--|--|-----------------|
| 1.外观 Appearance  | 白色或类白色粉末<br>A white or almost white powder   | 符合 Complies     |
| 2.鉴别 Identification<br>a. IR-Spectrum<br>b. HPLC         | Complies with IR   | 符合 Complies     |
|  | The retention time of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay | 符合 Complies     |
| 3.水分 Water%  | ≤3.0   | 0.12            |
| 4.炽灼残渣 Residue on ignition %                             | ≤0.3   | 0.01            |
| 5.重金属 Heavy metals μg/g                                  | ≤10  | <10             |
| 6.相关物质 Related compounds %                               | Impurity A ≤1.0<br>Other single impurity ≤0.1<br>Total impurities ≤2.0   | 符合 Complies     |
| 7.有机挥发物<br>Organic volatile impurities                   | Meets the requirements   | 符合 Complies     |
| 8.含量 Assay %(calculated on the anhydrous basis, by HPLC) | 98.0 - 102.0   | 99.5            |
| 9.包装 Package   | 25kg/桶 25kg/barrel   | 符合 Complies     |
| 结论:<br>Determination                                     | 本品符合 USP37<br>Complies with USP37  |                 |

公章  
REMARKS:

质检科长  
Q.C.DIRECTOR:

化验员  
ANALYST:

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