



Certificate of analysis

Product name:Lacosamide

Cas number:175481-36-4

Molecular Formula: C₁₃H₁₈N₂O₃

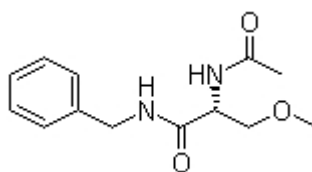
Molecular Weight: 250.29

Date of production:Feb. 28, 2013

Batch NO:20130228

EXP DATE: Feb. 27, 2015

Chemical structure:



| Items | Specifications | Results |
|--------------------------|--|-------------------------|
| Description | white to off-white powder | Conform |
| Identification | HPLC:The HPLC retention time correspond to reference standard assay item IR:The infrared absorption spectrum of test sample exhibits maxima only at same wavelengths as that of the working standard. | Conform |
| Solubility | Freely soluble in Ethanol and Methanol Sparingly soluble in water | Conform |
| Loss on Drying | NMT0.5% | 0.04 |
| Specific Rotation | [α] ₂₀ ^d +15.0° ~ +17.0° (C=1 in MEOH) | +15.2° |
| Related Substance | Single impurities:NMT 0.5% Total impurities:NMT 1.0% | 0.03% 0.07% |
| Chiral purity | S-isomer:NMT 0.5% | 0.03% |
| Residual solvents | Ethyl acetate:NMT1500PPM Dichloromethane:NMT 600PPM t-Butanol:NMT 5000PPM Toluene:NMT 890ppm | 45PPM ND ND ND |

Conclusion: It complies with the Enterprise Standard.

Analyst:Zhao

Checker:Liu

