



Certificate of analysis

Product name: Alogliptin benzoate

Cas number: 850649-62-6

Molecular Formula: $C_{18}H_{21}N_5O_2 \cdot C_7H_6O_2$

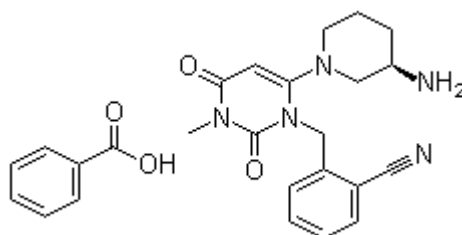
Molecular Weight: 461.52

Date of production: Jun. 28, 2017

Batch NO: 20170628

EXP DATE: Jun. 28, 2019

Chemical structure:



Items	Specifications	Results
Description	White to off-white solid	Conform
Identification	IR: Spectrum of the sample corresponds to that of reference standard.	Conform
	HPLC: The retention time of major peak of test solution should correspond to that of comparison solution.	Conform
Solubility	This product is dissolved in dimethyl sulfoxide, in water, slight soluble in methanol, in ethanol, slightly soluble in acetonitrile, in the 0.01 mol/L HCL slightly soluble	Conform
Specific Rotation	+13° ~ +18°	+16.4°
Heavy Metal	≤20ppm	Conform
Loss on drying	≤1.0%	0.09%
Residual on Ignition	≤1.0%	0.04%
Isomer	≤0.1%	N.D
Melting Point	180~183 °C	181.1~181.6 °C
Related substances	Single impurity ≤0.5%	0.25%
	Total impurities ≤2.0%	0.80%
Residual solvents	EtoH ≤0.5%	0.15%
	Isopropamol ≤0.5%	N.D
	Carren ≤0.06%	N.D
	Toluene ≤0.089%	N.D
	Tert-Butyl methyl ether ≤0.5%	N.D
	Ethyldiisopropylamine ≤0.1%	0.007%
Assay	≥98%	99.2%

Conclusion: It complies with the Enterprise Standard.

Analyst: Zhao

Checker: Liu

Q.C Director. Fang