

Certificate of Analysis

Product name : Alogliptin Benzoate CAS:850649-62-6		
Batch No. : 2022040201	Report Date: 2022.04.04	
Manufacturing Date: 2022.04.02	Expiry Date : 2025.04.01	
Enterprise standard		
Item	Standard	Result
Appearance	White or off-white crystalline powder	Conforms
Melting point	181-185 C,	183-185- C
Specific rotation	+13 ~+18	+17.48
Identification	UV & IR & HPLC	Conforms
Water	≤0.5%	0.03%
Residue on ignition	≤0.2%	0.13%
Heavy metals	≤20ppm	Conforms
Enantiomer	≤0.5%	N.D
Residual solvents	EtOH ≤5000ppm DMF ≤880ppm DCM ≤600ppm TOL ≤890ppm IPA ≤5000ppm	800ppm N.D N.D N.D 70ppm
Related substances	Single impurity	0.06%
	Total impurity	0.10%
Assay	98.0%~102	100.7%