



Certificate of analysis

Productname: Sitagliptin phosphate monohydrate

Cas number: 654671-77-9

Molecular Formula: $C_{16}H_{15}F_6N_5O \cdot H_3PO_4 \cdot H_2O$

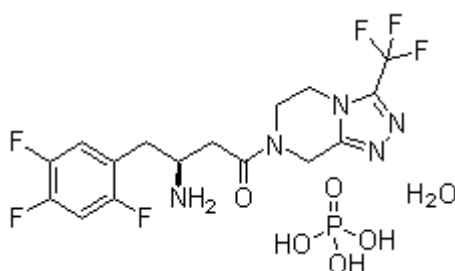
Molecular Weight: 523.33

Date of production: May. 25, 2019

Batch No: 20190525

Exp Date: May. 24, 2021

Chemical structure:



Items	Specifications	Results
Appearance	White or almost white crystalline powder	Complies
High-performance liquid chromatograph HPLC	The retention time of test sample major peak complies to reference standard	Almost the same
Water content	Not more than 3.5%	3.0%
Melting point	In-house	203~204°C
Chiral impurity	Not more than 0.5%	0.2%
Residue on ignition	Not more than 0.1%	0.03%
Related impurity	Total impurity not more than 1.0%	0.7%
	Single impurity not more than 0.5%	0.4%
Solvent remain	alcohol impurity not more than 0.5%	Complies
	methanol impurity not more than 0.5%	Complies
Heavy metal	Not more than 20ppm	Complies
Assay (Optical HPLC)	99% ~ 101%	99.20%

Conclusion: It complies with the Enterprise Standard.

Analyst: Zhao

Checker: Liu

Q.C Director. Fang F