



Certificate of analysis

Product name: Saxagliptin hydrochloride

Cas number: 709031-78-7

Molecular Formula: C₁₈H₂₅N₃O₂.HCl

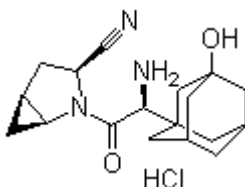
Molecular Weight: 351.87

Date of production: Mar. 06, 2016

Batch NO: 20160306

Exp Date: Mar. 05, 2018

Chemical structure:



Items	Specifications	Results
Appearance	White or whiteish solid powder	Conform
Identification	NMR HPLC	Conform
Water content	Not more than 5.0%	3.3%
Residue on ignition	Not more than 0.1%	0.04%
Related impurity	Total impurity not more than 2.0%	0.5%
	Single impurity not more than 0.5%	Conform
Heavy metal	Not more than 20ppm	Complies
Assay (Optical HPLC)	More than 98%	99.5%

Conclusion: It complies with the Enterprise Standard.

Analyst: Zhao

Checker: Liu

Q.C Director. Fang F