



Certificate of analysis

Productname: Midostaurin(PKC 412)

Cas number: 120685-11-2

Molecular Formula: C₃₅H₃₀N₄O₄

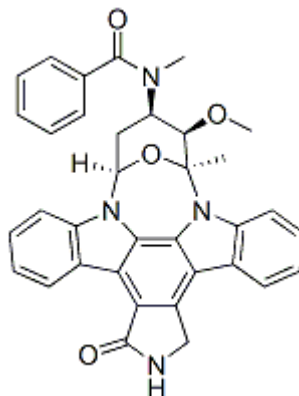
Molecular Weight: 570.64

Date of production:May. 09, 2019

Batch NO:20190509

Exp Date: May. 10, 2021

Chemical structure:



Items	Specifications	Results
Appearance	White to light yellow or light green crystalline powder	Complies
Identification(HPLC)	The retention time of major peak of test solution should correspond to that of comparison solution.	Complies
Identification(IR)	The IR spectrum of the sample corresponds to the spectrum of reference standard.	Complies
Optical Rotation	+168 °to +180 °	+173°
Colour and clarity of solution(ChP)	The solution is clear and not more intensely colored than reference solution YG5	Complies
Related Substances	Individual impurities ≤0.10	0.071%
	Total impurities ≤2.0%	0.34%
Residue solvents	Methanol ≤0.3%	0.0017%
	Ethanol ≤0.5%	0.014%
	Dichloromthane ≤0.06%	N.D
	Ethyl acetate ≤0.5%	0.001%
	Tetrahydrofuran ≤0.072%	0.0009%
	Buly acetate ≤0.5%	N.D
Water	≤0.5%	3.08%
Heavy metal	≤20ppm	Complies
Residue on ignition	≤0.1%	0.08%
Assay	98%~102%(on anhydrous and solvent free substance)	99.6%

Conclusion: It complies with the Enterprise Standard.

Analyst:Zhao

Checker:Liu

Q.C Director. Fang F