

Certificate of analysis

Product name: Voriconazole

Cas number: 137234-62-9

Molecular Formula: C₁₆H₁₄F₃N₅O

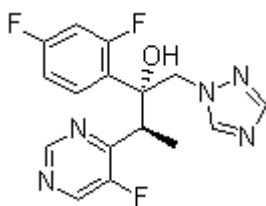
Molecular Weight: 349.31

Date of production: May. 22, 2016

Batch NO: 20160522

Exp Date: May. 21, 2018

Chemical structure:



Items	Specifications	Results
Appearance	White or almost white crystalline powder	Complies
Solubility	Freely soluble in acetone and in methylene chloride; soluble in methanol and in chloroform; practically insoluble in water	Complies
Melting Point	129 ~ 134°C	129.5~131.8°C
Specific Rotation (1% solution in methanol)	-57.0° ~ -61.0°	-58.5°
Identification	A:UV B:HPLC	Complies
Related substances (By HPLC)	Individual impurity:NMT 0.5%	0.21%
	Total impurities:NMT1.0%	0.27%
Optical isomer Residual solvents (By GC)	Not more than 0.5%	ND
	Ethyl Acetate:NMT 0.5%	ND
	Chloroform:NMT 0.006%	ND
	Methanol:NMT 0.3%	ND
	Isopropanol:NMT 0.1%	ND
Loss on drying (In vacuum at 80°C till Constant weight) Residue on ignition Heavy Metals	Not more than 0.5%	0.25%
	Not more than 0.1%	0.05%
	Not more than 20ppm	Complies
Chlorides	Not more than 0.02%	Complies
Sulfates	Not more than 0.02%	Complies
Fluorine	14.7%~17.9%	15.7%
Assay(on dried basis)	Not less than 98.5%	100.1%

Conclusion:It complies with the Enterprise Standard.

Analyst:Zhao

Checker:Liu

Q.C Director. Fang F