



Certificate of analysis

Productname: Posaconazole

Cas number: 171228-49-2

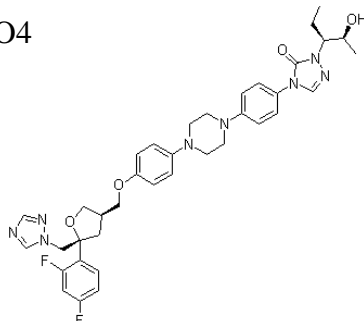
Molecular Formula: C₃₇H₄₂F₂N₈O₄

Molecular Weight: 700.78

Date of production: Dec.09,2016

Batch No:20161209

Exp Date: Dec.08,2018



Chemical structure:

Items	Specifications	Results
Appearance	White or off-white crystalline powder	Conform
Polymorphic form	Must comply with crystalline form-I of Posaconazole.	Conform
Identification	HPLC, IR	Conform
Clarity and color of solution	It should be clear, if turbidity not darker than compared with 1 turbidity standard solution.	Conform
	It should be colorless, if color not darker than compared with yellow or orange yellow 2 standard solution.	Conform
Specific optical rotation	-27.0 and -33.0	Conform
Loss on drying	NMT 1.0%	0.5%
Water	NMT 2.0%	0.2%
Related substances I	Impurity A NMT 0.12%	N.D
	Impurity B NMT 0.12%	N.D
	Impurity C NMT 0.12%	N.D
	Impurity D NMT 0.12%	0.01%
	Any unspecified impurity NMT 0.10%	0.01%
	Total impurities NMT 1.0%	0.04%
Particle size	d(0.9): Not more than 10 μm.	Conform
Sulfated ash	NMT 0.1%	0.02%
Heavy metals	NMT 20ppm	Conform
Assay	98.0%~102.0%(on anhydrous basis)	99.9%
	98.0%~102.0%(on anhydrous and solvents free basis)	99.9%

Conclusion: It complies with the Enterprise Standard.

Analyst: Zhao

Checker: Liu

Q.C Director: Fang F