

Certificate Of Analysis

Name: Posaconazole
CAS NO.: 171228-49-2
Cat NO.: A811306
Batch No.: P11112016
Mfg.Date: 2016.11.11
Exp.Date: 2018.11.10



Items	Specifications	Results
Appearance	White to off-white powder	White powder
Specific rotation	-28° - -34°	-32°
Identification	IR: Spectrum of the sample corresponds to that of reference standard	Conforms
	XRPD: The sample spectrum corresponds to that of standard spectrum of Posaconazole crystalline III	Conforms
	HPLC: The retention time of major peak of test solution should correspond to that of comparison solution	Conforms
Water	NMT 2.0%	0.7%
Related substances I	PO-R1(POC) NMT 0.10%	0.03%
	PO-R2(PON) NMT 0.10%	ND
	PO-R3(POA) NMT 0.10%	ND
	PO-R4(POB) NMT 0.10%	ND
	PO-D3 & PO-D5 NMT 0.10%	0.01%
	PO-D7 & PO-D10 NMT 0.10%	ND
	Any other individual impurity NMT 0.10%	0.06%
	Total impurities NMT 0.5%	0.1%
Related substances II	PO-E NMT 0.10%	ND
	PO-D1 NMT 0.10%	ND
	PO-R5 NMT 0.10%	ND

Residual solvents	Methanol NMT 3000ppm	1212ppm
	Ethanol NMT 5000ppm	2ppm
	Dichloromethane NMT 600ppm	ND
	Tetrahydrofuran NMT 720ppm	ND
	Triethylamine NMT 100ppm	0.3ppm
	Toluene NMT 890ppm	1ppm
	N,N-Dimethylformamide NMT 880ppm	131ppm
	Dimethyl sulfoxide NMT 5000ppm	97ppm
Residue on ignition	NMT 0.1%	0.02%
Heavy metals	NMT 10ppm	Conforms
Purity	98.0%-102.0%	98.7%
Conclusion	The product tested complies with the specifications.	

Storage condition: Store in a tightly closed container in a cool and dry place.

Checker:

 * if you have any comments and suggestions, please contact us by sales@amadischem.com