

杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Posaconazole

Batch No.: DR20130501	Quantity: 1.49kg
Manufacture Date: 2013.05.01	Expiry Date: 2015.04

TESTS:

Items	Specification	Results
Appearance	Off-white or white crystalline powder, odorless, easy to absorb moisture	Conforms
Particle	Min. 10%<50µm, min .50% <100µm, min.90% <200µm	Conforms
Melting point	165°C--170°C	169°C--170°C
Specific optical rotation	-28° ~-32°	-28°
Identification	HPLC :The retention time of major peak in the chromatogram of the assay preparation correspond to that in the chromatogram of the standard preparation.	Conforms
	IR: IR spectrum is concordance with that of CRS	Conforms
Related substance	1002 Not more than 0.1%	N,D
	3006 Not more than 0.1%	N,D
	1001 Not more than 0.1%	0.02%
	2001 Not more than 0.1%	N,D
	Max.unidentified impurity 0.1%	0.02%
	Total impurities 0.5%	0.05%
3S,5S-2R,3R Isomer	Not more than 0.1%	N,D
Related solvent	Methanol Not more than 0.3%	0.02%
	Dichloromethane Not more than 0.06%	N,D
	Acetone Not more than 0.5%	N,D
	Dimethyl sulfoxide Not more than 0.5%	N,D
Water	Not more than 2.0%	1.6%
Chloride	Not more than 0.02%	Conforms

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Residue on ignition	Not more than 0.1%	0.02%
Heavy metals	Not more than 10ppm	Conforms
Assay	$\geq 98.0\%$ (dried basis, C ₃₇ H ₄₂ F ₂ N ₈ O ₄)	99.5%
Conclusion: The results conform to in-house standard.		

Analyst: Joe Yu Checker: Agnes Zhong QA.Manager: Sun Wenhua



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