



Certificate of Analysis

Product name	Posaconazole	Manufacture date	Sep.28.2023
Batch number	SW230928	Analysis date	Sep.29.2023
Batch quantity	50kg	Expiry date	Sep.28.2025

Items	Standards	Results
Characteristics	White to off-white powder	White powder
Identification	By IR	Complies
	By HPLC	Complies
Specific Rotation	-28 °~-34 °	-32 °
Water Content	≤ 2.00%	0.20%
Heavy Metals	≤ 10ppm	Complies
Sulfated Ash	≤ 0.10%	0.03%
Residual Solvents	Ethanol: ≤5000ppm	3ppm
	Dichloromethane: ≤600ppm	ND
	Tetrahydrofuran: ≤720ppm	ND
	Triethylamine: ≤100ppm	5ppm
	Toluene: ≤890ppm	ND
	N,N-dimethyl formamide: ≤880ppm	27ppm
	DimethylSulfoxide: ≤5000ppm	324ppm
Related Substances	Any single impurity: ≤0.10%	0.03%
	Total Impurities: ≤0.50%	0.09%
Assay(HPLC basis on drying)	98.0%~102.0%	99.98%

Packing description:	Sealed export grade drum & double of sealed plastic bag
Storage:	Store in cool & dry place not freeze., keep away from strong light and heat
Shelf life:	2 years when properly stored

Quality Assurance Officer: 李强

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Analyst: 方琼

