



# 武汉福鑫化工有限公司

## Wuhan Fortuna Chemical Co.,Ltd

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### CERTIFICATE OF ANALYSIS

Product: Ketoconazole

Mfg. date: Jan. 29<sup>th</sup>, 2019

Exp. date: Jan. 28<sup>th</sup>, 2021

Batch No.: 19012908

Quantity: 900 KGS

Items	Specifications	Results
Appearance	Off-white to white powder	White powder
Identification	Chemical identification	Conforms
	Infrared spectrometry	Conforms
Solubility	Freely soluble in methylene chloride; Soluble in methanol; Sparingly soluble in ethanol; Practically insoluble in water.	Conforms
Melting point	148°C~152°C	148°C~149°C
Specific rotation	-1°~+1°	-0.12°
Loss on drying	≤0.5%	0.16%
Residue on ignition	≤0.1%	0.02%
Heavy metals	≤0.002%	Conforms
Chromatographic purity (TLC)	The principal spot obtained from the test solution has about the same size and RF value as that obtained from the standard solution, and the sum of the intensities of any secondary spots obtained from the test solution does not exceed the intensity of the principal spot obtained from the diluted standard solution.	Conforms
Assay	98.0%~102.0%	101.74%
Residual solvents	Methanol ≤3000ppm	Conforms
	Acetone ≤5000ppm	Conforms
	Methyl Chloride ≤600ppm	Conforms
	Ethyl Acetate ≤5000ppm	Conforms
	Toluene ≤900ppm	Conforms
Conclusion	The product complies with the standard of USP38.	

QC: Luo Xiaofeng

Tester: AT02

Re-tester: AT03