



# 武汉福鑫化工有限公司

## Wuhan Fortuna Chemical Co.,Ltd

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### CERTIFICATE OF ANALYSIS

Products Name	CAS NO.	Batch No.
Isavuconazonium sulfate	946075-13-4	20240215
Mfg. Date	Exp. Date	Package
Feb.,15,2024	Feb., 14,2026	1kg/ Box

ITEMS	SPECIFICATIONS	RESULTS
Appearance	White to light yellow powder	Conform
Solubility	easily soluble in water or methanol	Conform
Specific rotation	$-11^{\circ} \sim -20^{\circ}$	$-13^{\circ}$
Identification	The infrared absorption spectrum of this product should be consistent with that of the reference substance.	Conform
	In the chromatogram recorded under the assay, the retention time of the main peak of the test solution should be consistent with the retention time of the main peak of the reference solution.	Conform
Relative substance1	$S29-ZZ-24 \leq 0.50\%$	0.13%
	$S29-ZZ-23 \leq 0.10\%$	N.D.
	$S29-ZZ-22 \leq 0.30\%$	0.07%
	$S29-ZZ-29 + S29-ZZ-28 \leq 0.20\%$	N.D.
	$S29-ZZ-27 \leq 0.50\%$	0.13%
	$S29-ZZ-26 \leq 1.0\%$	0.48%
	$S29-ZZ-32 \leq 1.0\%$	0.57%
	$4511 \leq 1.0\%$	0.55%
	$4516 \leq 0.10\%$	N.D.
	Any other single Impurity $\leq 0.10\%$	0.08%
	Total Impurities	2.2%

Residual Solvent	Methanol $\leq$ 3000ppm	626ppm
	Ethanol $\leq$ 5000ppm	936ppm
	Isopropyl alcohol $\leq$ 5000ppm	13ppm
	Acetonitrile $\leq$ 410ppm	N.D.
	Dichloromethane $\leq$ 600ppm	32ppm
	Tert-Butanol $\leq$ 3500ppm	869ppm
	Methyl tert-butyl $\leq$ 5000ppm	68ppm
	Ethyl acetate $\leq$ 5000ppm	697ppm
	Pyridine $\leq$ 200ppm	N.D.
	n-Heptane $\leq$ 5000ppm	N.D.
Relative substance2	1633 $\leq$ 0.10%	0.01%
	S29-ZZ-3 $\leq$ 0.30%	0.06%
Sulfate	12.0% ~ 18.0%	15.35
Water	$\leq$ 2.0%	0.3%
Acid Value	PH should be 1.3~2.0	1.6
Residue on Ignition	$\leq$ 0.1%	0.04%
Heavy Metals	$\leq$ 10ppm	Conform
2-Butenal	$\leq$ 50ppm	13ppm
Assay	94.0% ~ 102.0%	96.6%
Bacterial endotoxin	The amount of endotoxin in each 1mg of isavuconazole sulfate should be less than 0.3EU	Conform
Microbial Limit	Total aerobic bacteria $\leq$ 100cfu/g	$\leq$ 50cfu/g
	Molds and yeasts $\leq$ 50cfu/g	$\leq$ 50cfu/g
	Escherichia coli $\leq$ 0/g	N.D.
Conclusion	QUALIFIED.	

Q.C.: Luo Xiaofeng

Tester: AT02

Re-tester: AT03