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CERTIFICATE OF ANALYSIS

CAS: 1260141-27-2

Product name		Vonoprazan Fumarate	
According to	Enterprise standard	Batch No.	104-20230703BD
Package	Aluminum foil bag	Manufacturing date	2023.07.08
Package size	50g/bag	Report date	2023.08.11
Quantity	50g	Retest date	2025.07.07
Items	Specification		Results
Appearance	White to almost white powder		White powder
Solubility	Freely soluble in DMSO, slightly soluble in methanol and water		Conform
Identification	HPLC-RT should comply with the WS		Conform
	IR spectrum should comply with the WS		Conform
Water	Not more than 0.5%		0.1%
Residue on ignition	Not more than 0.1%		0.1%
Heavy metals	Not more than 20ppm		Less than 20ppm
pH	3.0~4.0		3.8
Assay of fumaric acid	23-26%		25%
Related substance	Test A	Impurity VOPZ-ZBB: not more than 0.15%	N.D
		Impurity VOPZ-SJJ: not more than 0.15%	N.D
		Impurity VOPZ-SOOH: not more than 0.15%	N.D
		Other max individual impurity: not more than 0.10%	0.03%
		Total impurity: not more than 0.5%	0.1%
	Test B	Impurity VOPZ-ZBC: not more than 28ppm	N.D
Residual solvent	Ethanol: not more than 5000ppm		6ppm
	Toluene: not more than 890ppm		3ppm
	Ethyl acetate: not more than 5000ppm		4ppm
	Acetone: not more than 5000ppm		626ppm
	Dichloromethane: not more than 600ppm		N.D
	Benzene: not more than 2ppm		N.D
	THF: not more than 720ppm		1ppm
Methanol: not more than 3000ppm		N.D	
Assay(calculated on the anhydrous basis)	98.0-102.0%		99.9%
Conclusion: <u>Complies with Enterprise standard</u>			

