

Certificate of Analysis

Vonoprazan Fumarate

CAS No.	1260141-27-2	Code	BIOJVON001
Batch No	083250401	Manufacture Date	Apr.13, 2025
Retest Date	Apr.12, 2027	Quantity	300Grams

Testing Items		Specifications	Results
Appearance		White or off-white crystalline powder	Complies
Solubility		Soluble in dimethyl sulfoxide, sparingly soluble in N,N-dimethylacetamide, slightly soluble in methanol and water, almost insoluble in isopropyl alcohol and acetonitrile	Complies
Identification	HPLC	The retention time of the major peak of the sample shall be consistent with that of the standard solution.	Complies
	UV	The UV absorption spectrum of the test solution shall be consistent with that of the reference solution	Complies
	IR	The IR spectrum of the sample shall be consistent with that of the reference substance	Complies
Fluorine content		3.9%~4.3%, calculated on the anhydrous basis	4.2%
Chloride		NMT 0.05%	Complies
Sulfate		NMT 0.05%	Complies
Ammonium salt		NMT 0.05%	Complies
Phosphate		NMT 0.0025%	Complies
Particle size distribution		D(0.9) less than 30μm	12μm
Organic impurities		Impurity E: NMT 0.15%	0.0064%
		Impurity T: NMT 0.15%	0.035%
		Impurity J: NMT 0.10%	N/D
		Impurity F: NMT 0.15%	0.056%
		Impurity I: NMT 0.15%	0.053%
		Impurity C: NMT 0.15%	0.0016%
		Impurity D: NMT 0.15%	0.059%
		Individual impurity: NMT 0.10%	0.032%
		Total impurities: NMT 1.0%	0.25%
Residual solvents		Methanol: NMT 0.3%	0.001%
		Ethanol: NMT 0.5%	N/D
		Acetonitrile: NMT 0.041%	0.00077%
		Dichloromethane: NMT 0.06%	N/D
		Ethyl acetate: NMT 0.5%	N/D
		Tetrahydrofuran: NMT 0.072%	N/D

Pyridine-3-sulfonic acid	NMT 0.07%	0.02%
Benzene and Pyridine	Benzene: NMT 0.0002%	N/D
	Pyridine: NMT 0.02%	N/D
N,N-Dimethylacetamide	NMT 0.109%	N/D
N,N-Diisopropylethylamine	NMT 0.1%	N/D
Monomethylamine	NMT 0.07%	N/D
Acetic acid	NMT 0.5%	0.009%
Fumaric acid	NLT 23.9% and NMT 26.4%, calculated on the anhydrous basis	24.8%
Water	NMT 0.4%	0.06%
Residue on ignition	NMT 0.1%	0.03%
Heavy metals	NMT 20ppm	Complies
Microbial limit	TAMC: NMT 1000cfu/g	<250cfu/g
	TYMC: NMT 100cfu/g	10cfu/g
	Escherichia coli must not be detected/g	N/D
Assay	98.0%~10.2% of the $C_{17}H_{16}FN_3O_2S \cdot C_4H_4O_4$ Calculated on the anhydrous basis	100.1%
Conclusion	This product conforms to In-house standard	

***Storage condition: Store between 2°C~8°C, Protect from moisture and light.**