

Certificate of Analysis

Product Name	Atipamezole hydrochloride		
CAS No.	104075-48-1	Batch No.	ATH2602001
Mfg. Date	2026.02.02	Report Date	2026.02.09
Retest Date	2028.02.01	Standard	In-house Standard

Item	Specification	Result
Description	White powder	Conforms
Identification	HPLC: The retention time of the major peak of the sample solution corresponds to that of the standard solution.	Conforms
	IR:Conforms to structure	Conforms
Clarity of solution	1% solution in water shall be colorless	Conforms
Melting point	216°C~221°C	217.8~219.3°C
Related substance	Any single impurity ≤0.5%	0.16%
	Total impurities ≤1.0%	0.25%
Water (KF)	≤0.5%	0.09%
Residue on ignition	≤0.5%	0.14%
pH	4~6	4.52
Heavy metal	≤20ppm	Conforms
Residual solvent	Diethylene glycol ≤1000ppm	N.D.
	Dichloromethane ≤600ppm	N.D.
	Ethyl acetate ≤5000ppm	247 ppm
Assay	98.0%~102.0%	99.5%
Microbiology	TAMC ≤1000cfu/g	<10cfu/g
	TYMC ≤100cfu/g	<10cfu/g
Conclusion: The product tested conforms with in-house standard		

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