



# NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.  
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

## Certificate of Analysis (COA)

Issue Date: 28 FEB 2026 Quality Release Date: 28 FEB 2026

### Product Information

Product Number MIL-20260228

Batch Number MIL-SH2026022801

Brand SIGALD

CAS Number 83700-79-0

MDL Number MFCD00072019

Formula  $C_6 H_{11} NO_4$

Formula Weight 161.16 g/mol

### Test Results

Test	Specification (Pharmacopoeial Standard)	Result	Unit	Test Method
Appearance (Form)	White crystalline powder or crystals	White crystalline powder	-	Visual Inspection
Identification	Conforms to standard	Conforms	-	IR Spectroscopy + HPLC
Assay (on dry basis)	$\geq 98.5\%$	99.6%	%	HPLC
Loss on Drying	$\leq 0.5\%$	0.12%	%	105°C, 2h Gravimetry
Residue on Ignition	$\leq 0.1\%$	0.01%	%	550°C Ignition Method
Heavy Metals (Pb)	$\leq 5$ ppm	0.7 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	$\leq 1$ ppm	0.2 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	Each impurity $\leq 0.5\%$ ; Total $\leq 1.0\%$	Each $\leq 0.12\%$ ; Total $\leq 0.35\%$	%	HPLC
Melting Point	170-174°C	172.1°C	°C	Capillary Melting Point Method
pH Value (1% aq. solution, 25°C)	6.0-7.5	6.8	-	Digital pH Meter
Solubility	Freely soluble in water, slightly soluble in ethanol	Conforms	-	Pharmacopoeial Solubility Test
Sulfate Content	$\leq 0.03\%$	0.004%	%	Volumetric Titration
Chloride Content	$\leq 0.01\%$	0.002%	%	Volumetric Titration

### Certification

This batch of Mildronate has been tested in accordance with EP 10.0, USP 45 and Chinese Pharmacopoeia (2020) standards. All test results meet the specified quality requirements, and the product is qualified for use as a pharmaceutical raw material.