



# 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 (Montelukast Sodium)

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

### Product Name

Montelukast Sodium 孟鲁司特钠

### Product Information

Product Number MON-20260228

Batch Number MON-SH2026022801

Brand SIGALD

CAS Number 151767-02-1

MDL Number MFCD00867624

Formula  $C_{35}H_{39}NNaO_6S$

Formula Weight 608.75 g/mol

### Test Results

Test	Specification (USP 45 & ChP 2025 Pharmaceutical Standard)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection (25°C)
Appearance (Form)	Crystalline powder	Crystalline powder	-	Visual Inspection (25°C)
Assay (on dry basis)	98.0 ~ 102.0%	99.6%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	≤ 1.0%	0.07%	%	HPLC (USP 45 Method)
Single Impurity	≤ 0.2%	0.01%	%	HPLC (USP 45 Method)
Loss on Drying	≤ 0.5%	0.04%	%	Vacuum Drying at 60°C for 4h
Residue on Ignition	≤ 0.1%	0.01%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	≤ 5 ppm	0.6 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 1 ppm	0.1 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Sodium Content	3.6 ~ 4.0%	3.8%	%	Flame Photometry
pH Value (1% aq. solution, 25°C)	6.5 ~ 8.5	7.2	-	Digital pH Meter
Melting Point	Decomposes at ~146°C	145.8°C (decomp.)	°C	Melting Point Apparatus
Total Bacterial Count	≤ 100 CFU/g	8 CFU/g	CFU/g	Plate Count Method
E. coli	Negative	Negative	-	Microbiological Detection
Salmonella	Negative	Negative	-	Microbiological Detection
Water Solubility (25°C)	≥ 60 g/100 mL	65.2 g/100 mL	g/100 mL	Shake Flask Method

### Certification

This batch of product has been tested in accordance with the pharmacopoeial and industrial standards for Montelukast Sodium and meets all specified requirements. It is qualified for use as a pharmaceutical raw material for anti-asthmatic and anti-allergic preparations.