



# NEWAY SINOPHC TECH. LIMITED

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## Certificate of Analysis

### Product Name: Naltrexone Product Information

Product Number NAL-20260220  
Batch Number NAL-SH2026022001  
Brand SIGALD  
CAS Number 16590-41-3  
MDL Number MFCD00058477  
Formula  $C_{20}H_{23}NO_4$   
Formula Weight 337.40 g/mol  
Quality Release Date 20 FEB 2026

### Test Results

Test	Specification (Pharmacopoeial Standard)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection
Appearance (Form)	Crystalline powder	Crystalline powder	-	Visual Inspection
Assay (Naltrexone)	98.5-101.5%	99.7%	%	High Performance Liquid Chromatography (HPLC)
Melting Point	169-173°C	171.2°C	°C	Melting Point Apparatus
Loss on Drying	≤ 0.5%	0.12%	%	105°C, 2 hours
Residue on Ignition	≤ 0.1%	0.002%	%	600±25°C Ignition Method
Heavy Metals (Pb)	≤ 2 ppm	0.2 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 1 ppm	0.04 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	≤ 0.5%	0.15%	%	High Performance Liquid Chromatography (HPLC)
Optical Rotation ([α] <sub>20</sub> <sup>D</sup> )	+205° to +215°	+210.5°	°	Polarimeter
Solubility in Ethanol	Freely soluble	Complies	-	Pharmacopoeia Method
pH Value (1% aqueous suspension, 25°C)	6.0-8.0	6.8	-	Digital pH Meter
Total Bacterial Count	≤ 10 CFU/g	0 CFU/g	CFU/g	Plate Count Method
E. coli	Negative	Negative	-	Microbiological Detection
Yeast & Mold	≤ 10 CFU/g	0 CFU/g	CFU/g	Plate Count Method
Supplier Information	Confirmed	Confirmed	-	-
Registered Trademark	Confirmed	Confirmed	-	-

### Certification

This batch of product has been tested in accordance with pharmacopoeial and industrial standards for Naltrexone and meets all specified requirements. It is qualified for use.  
Issue Date:20 FEB 2026