



# 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 (Enoxaparin Sodium)

Issue Date: 20 FEB 2026 Quality Release Date: 20 FEB 2026

### Product Name

Enoxaparin Sodium 依诺肝素钠

### Product Information

Product Number ENO-20260220

Batch Number ENO-SH2026022001

Brand SIGALD

CAS Number 9002-84-4

MDL Number MFCD00081452

Formula  $(C_{12}H_{19}NO_{20}S_7)_n \cdot Na$

Formula Weight 4500 ~ 5500 Da (Average Molecular Weight)

Form White to off-white amorphous powder

### Test Results

Test	Specification (USP 45 & ChP 2025 Pharmaceutical Standard)	Result	Unit	Test Method
Appearance (Color/Form)	White to off-white amorphous powder	Conforms	-	Visual Inspection (25°C)
Average Molecular Weight	4500 ~ 5500 Da	5020 Da	Da	Gel Permeation Chromatography (GPC)
Molecular Weight Distribution (Mw/Mn)	≤ 1.8	1.52	-	GPC
Anti-Xa Factor Activity	≥ 100 IU/mg	112 IU/mg	IU/mg	Chromogenic Substrate Assay
Anti-IIa Factor Activity	20 ~ 40 IU/mg	31 IU/mg	IU/mg	Chromogenic Substrate Assay
Anti-Xa / Anti-IIa Activity Ratio	2.5 ~ 4.0	3.61	-	Calculation
pH Value (1% aq. solution, 25°C)	5.5 ~ 7.5	6.3	-	Digital pH Meter
Water Content	≤ 5.0%	3.8%	%	Karl Fischer Titration
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	10.0 ~ 13.0%	11.5%	%	Flame Photometry
Total Organic Carbon (TOC)	≤ 0.5%	0.28%	%	TOC Analyzer
Sterility	Negative	Negative	-	Membrane Filtration Method (USP 45)
Bacterial Endotoxin	≤ 0.1 EU/IU	0.05 EU/IU	EU/IU	Limulus Amebocyte Lysate (LAL) Test
Protein Impurities	Negative	Negative	-	SDS-PAGE Electrophoresis

### Certification

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