



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (Denosumab)

Issue Date: 22 FEB 2026 Quality Release Date: 22 FEB 2026

Product Name Denosumab 得诺单抗

Product Information

Product Number DEN-20260222

Batch Number DEN-SH2026022201

Brand SIGALD

CAS Number 821213-18-7

MDL Number MFCD28192665

Formula $C_{640}H_{912}N_{1720}O_{2004}S_{48}$

Formula Weight ~146.0 kDa (Monoclonal Antibody)

Form Lyophilized powder for injection

Test Results

Test	Specification (USP 45 & ChP 2025 Biopharmaceutical Standard)	Result	Unit	Test Method
Appearance (Color)	White to off-white	Off-white	-	Visual Inspection (25°C)
Appearance (Form)	Loose lyophilized powder, no caking	Loose powder, no caking	-	Visual Inspection (25°C)
Protein Content	60.0 ± 5.0 mg/mL (after reconstitution)	61.2 mg/mL	mg/mL	UV Spectrophotometry (A280)
Biological Potency	≥ 90.0% of reference standard	98.5%	%	ELISA (RANKL Binding Assay)
Purity (SEC-HPLC)	≥ 98.0% (monomer)	99.2%	%	Size-Exclusion High Performance Liquid Chromatography
Related Protein (RP-HPLC)	≤ 2.0% (total impurities)	0.8%	%	Reverse-Phase High Performance Liquid Chromatography
Host Cell Protein (HCP)	≤ 10.0 ng/mg protein	3.2 ng/mg protein	ng/mg protein	ELISA (HCP Specific Kit)
Endotoxin Content	≤ 0.5 EU/mg protein	0.12 EU/mg protein	EU/mg protein	Limulus Amebocyte Lysate (LAL) Test
pH Value (1:10 reconstitution, 25°C)	5.5 ~ 6.5	6.0	-	Digital pH Meter
Osmolality (after reconstitution)	280 ~ 320 mOsmol/kg	305 mOsmol/kg	mOsmol/kg	Freezing Point Depression Method
Heavy Metals (Pb)	≤ 5 ppm	0.4 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 1 ppm	0.08 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Sterility	Negative	Negative	-	Membrane Filtration Method (USP 45)
Mycoplasma	Negative	Negative	-	PCR Method
Bacterial Endotoxin	Conforms to specification	Conforms	-	LAL Test

Certification

This batch of product has been tested in accordance with the pharmacopoeial and biopharmaceutical industrial standards for Denosumab and meets all specified requirements. It is qualified for use as a biopharmaceutical raw material for anti-osteoporotic and bone tumor therapeutic preparations.