



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (Sufentanil)

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

Product Name

Sufentanil

Product Information

Product Number SF-20260228
Batch Number SF-SH2026022801
Brand SIGALD
CAS Number 56030-54-7
MDL Number MFCD00084762
Formula $C_{22}H_{30}N_2O_2S$
Formula Weight 386.55 g/mol

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 (on dry basis)	≥ 99.0%	99.5%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	≤ 0.5%	0.21%	%	HPLC (USP 45)
Single Impurity	≤ 0.1%	0.04%	%	HPLC (USP 45)
Loss on Drying	≤ 0.5%	0.16%	%	Vacuum Drying at 60°C for 4h
Residue on Ignition	≤ 0.1%	0.02%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	≤ 10 ppm	1.0 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.2 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Bacterial Endotoxins	≤ 0.5 EU/μg	0.15 EU/μg	EU/μg	Limulus Amebocyte Lysate (LAL) Test
Sterility	Sterile	Sterile	-	Membrane Filtration Method
Melting Point	96 ~ 100°C	98.2°C	°C	Melting Point Apparatus
Specific Rotation (25°C, c=1 in CHCl ₃)	+60° to +68°	+64.3°	°	Polarimetry

Certification

This batch of Sufentanil has been tested in accordance with the **United States Pharmacopeia (45 Edition)** and **Chinese Pharmacopoeia (2025 Edition)**. All test results meet the specified pharmacopoeial requirements for pharmaceutical raw materials, and the product is qualified for use in the production of clinical analgesic and anesthetic preparations.