



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (Fentanyl Citrate)

Issue Date: 15 FEB 2026 Quality Release Date: 15 FEB 2026

Product Name

Fentanyl Citrate

Product Information

Product Number FC-20260215

Batch Number FC-SH2026021501

Brand SIGALD

CAS Number 297-19-8

MDL Number MFCD00012065

Formula $C_{22}H_{28}N_2O_4 \cdot C_6H_8O_7$

Formula Weight 528.55 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%	99.6%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	≤ 0.5%	0.23%	%	HPLC (USP 45)
Single Impurity	≤ 0.1%	0.05%	%	HPLC (USP 45)
Loss on Drying	≤ 0.5%	0.19%	%	Vacuum Drying at 60°C for 4h
Residue on Ignition	≤ 0.1%	0.02%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	≤ 10 ppm	1.3 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.4 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Bacterial Endotoxins	≤ 0.5 EU/μg	0.18 EU/μg	EU/μg	Limulus Amebocyte Lysate (LAL) Test
Sterility	Sterile	Sterile	-	Membrane Filtration Method
Melting Point	148 ~ 151°C	149.5°C	°C	Melting Point Apparatus
Specific Rotation (25°C, c=1 in H ₂ O)	+21° to +26°	+23.8°	°	Polarimetry

Certification

This batch of Fentanyl Citrate 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.