



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (Alfentanil)

Issue Date: 08 FEB 2026 Quality Release Date: 08 FEB 2026

Product Name

Alfentanil

Product Information

Product Number AF-20260208
Batch Number AF-SH2026020801
Brand PHARMASTAND
CAS Number 71195-58-9
MDL Number MFCD00084706
Formula $C_{21}H_{32}N_6 O$
Formula Weight 384.52 g/mol

Test Results

Test	Specification (Pharmacopoeial Standard)	Result	Unit	Test Method
Appearance	White to off-white crystalline powder	White crystalline powder	-	Visual Inspection
Identity (Infrared Spectroscopy)	Complies with reference standard	Complies	-	IR Spectrophotometry (ChP 2025)
Assay (on dry basis)	$\geq 98.5\%$	99.2%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	$\leq 1.0\%$	0.35%	%	HPLC (EP 10.0)
Single Impurity	$\leq 0.5\%$	0.12%	%	HPLC (EP 10.0)
Loss on Drying	$\leq 0.5\%$	0.21%	%	Vacuum Drying at 60°C for 3h
Residue on Ignition	$\leq 0.1\%$	0.03%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	≤ 10 ppm	2.1 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Bacterial Endotoxins	≤ 0.5 EU/ μ g	0.2 EU/ μ g	EU/ μ g	Limulus Amebocyte Lysate (LAL) Test
Sterility	Sterile	Sterile	-	Membrane Filtration Method
Specific Rotation (25°C, c=1 in CH ₃ OH)	-30° to -38°	-34.2°	°	Polarimetry

Certification

This batch of Alfentanil has been tested in accordance with the **Chinese Pharmacopoeia (2025 Edition)** and **European Pharmacopoeia (10.0 Edition)**. All test results meet the specified pharmacopoeial requirements, and the product is qualified for pharmaceutical use as a raw material.