



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (COA)

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

Product Information

Product Number PFL-20260228

Batch Number PFL-SH2026022801

Brand SIGALD

CAS Number 2269-15-4

MDL Number MFCD00058710

Formula $C_{28} H_{27} ClF_2NO$

Formula Weight 467.97 g/mol

Test Results

Test	Specification (Pharmacopoeial Standard)	Result	Unit	Test Method
Appearance (Form)	White to off-white crystalline powder	White crystalline powder	-	Visual Inspection
Identification	Conforms to standard	Conforms	-	IR Spectroscopy + HPLC
Assay (on dry basis)	$\geq 98.5\%$	99.2%	%	HPLC
Loss on Drying	$\leq 0.5\%$	0.19%	%	105°C, 2h Gravimetry
Residue on Ignition	$\leq 0.1\%$	0.02%	%	550°C Ignition Method
Heavy Metals (Pb)	≤ 10 ppm	1.1 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.3 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	Each impurity $\leq 0.5\%$; Total $\leq 1.0\%$	Each $\leq 0.2\%$; Total $\leq 0.4\%$	%	HPLC
Melting Point	250-256°C	253°C	°C	Capillary Melting Point Method
Solubility	Sparingly soluble in ethanol, slightly soluble in water	Conforms	-	Pharmacopoeial Solubility Test
Chloride Content	$\leq 0.01\%$	0.003%	%	Volumetric Titration
Sulfate Content	$\leq 0.03\%$	0.007%	%	Volumetric Titration
Acidity/Alkalinity	Neutral (pH 6.0-8.0, 0.1% in ethanol)	6.8	-	Digital pH Meter

Certification

This batch of Penfluridol has been tested in accordance with EP 10.0, USP 45 and Chinese Pharmacopoeia (2020) standards. All test results meet the specified quality requirements, and the product is qualified for use as a pharmaceutical raw material.