



# NEWAY SINOPHC TECH. LIMITED

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## Certificate of Analysis (Propofol)

Issue Date: 25 FEB 2026 Quality Release Date: 25 FEB 2026

### Product Name

Propofol

### Product Information

Product Number PP-20260225  
Batch Number PP-SH2026022501  
Brand SIGALD  
CAS Number 2078-54-8  
MDL Number MFCD00002811  
Formula  $C_{12}H_{18}O$   
Formula Weight 178.27 g/mol

### Test Results

Test	Specification (Pharmacopoeial Standard)	Result	Unit	Test Method
Appearance (Color)	Colorless to pale yellow	Colorless	-	Visual Inspection
Appearance (Form)	Clear oily liquid	Clear oily liquid	-	Visual Inspection
Assay (on anhydrous basis)	$\geq 99.0\%$	99.7%	%	Gas Chromatography (GC)
Related Substances (Total)	$\leq 0.5\%$	0.19%	%	GC (USP 45)
Single Impurity	$\leq 0.1\%$	0.03%	%	GC (USP 45)
Water Content	$\leq 0.1\%$	0.04%	%	Karl Fischer Titration
Residue on Ignition	$\leq 0.05\%$	0.01%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	$\leq 10$ ppm	0.9 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	$\leq 2$ ppm	0.2 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Bacterial Endotoxins	$\leq 0.5$ EU/ $\mu$ g	0.12 EU/ $\mu$ g	EU/ $\mu$ g	Limulus Amebocyte Lysate (LAL) Test
Sterility	Sterile	Sterile	-	Membrane Filtration Method
Refractive Index (25°C)	1.512 ~ 1.514	1.513	-	Abbe Refractometer
Specific Gravity (25°C)	0.950 ~ 0.956	0.953	-	Pycnometer Method

### Certification

This batch of Propofol 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 anesthetic preparations.