



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis

Product Information

Item	Details
Product Name	Clomifene Citrate (克罗米芬柠檬酸盐)
Product Number	CC-20260222
Batch Number	CC-SH2026022201
Brand	SIGALD
CAS Number	50-41-9
MDL Number	MFCD00010585
Formula	$C_{26} H_{28} ClNO \cdot C_6 H_8 O_7$
Formula Weight	609.09 g/mol
Quality Release Date	22 FEB 2026

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 (Clomifene Citrate)	$\geq 98.5\%$	99.2%	%	High Performance Liquid Chromatography (HPLC)
Loss on Drying	$\leq 0.5\%$	0.12%	%	105°C, 2 hours
Residue on Ignition	$\leq 0.1\%$	0.005%	%	600±25°C Ignition Method
Heavy Metals (Pb)	≤ 2 ppm	0.03 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 1 ppm	0.008 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	$\leq 1.0\%$	0.15%	%	High Performance Liquid Chromatography (HPLC)
pH Value (1% aqueous suspension, 25°C)	3.0-5.0	4.1	-	Digital pH Meter
Melting Point	110-116°C (dec.)	112-114°C (dec.)	°C	Melting Point Apparatus
Total Bacterial Count	≤ 5 CFU/g	0 CFU/g	CFU/g	Plate Count Method
E. coli	Negative	Negative	-	Microbiological Detection
Yeast & Mold	≤ 5 CFU/g	0 CFU/g	CFU/g	Plate Count Method
Solubility in Methanol	Freely soluble	Complies	-	Pharmacopoeia Method
Supplier Information	Confirmed	Confirmed	-	-

Certification

This batch of product has been tested in accordance with the pharmacopoeial and industrial standards for Clomifene Citrate and meets all specified requirements. It is qualified for use.
Issue Date:22 FEB 2026