



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis (Pentoxifyverine Citrate)

Issue Date: 20 FEB 2026 Quality Release Date: 20 FEB 2026

Product Name

Pentoxifyverine Citrate 戊氧维林柠檬酸盐

Product Information

Product Number PVC-20260220

Batch Number PVC-SH2026022001

Brand SIGALD

CAS Number 23142-01-0

MDL Number MFCD00058134

Formula $C_{24}H_{31}NO_3 \cdot C_6H_8O_7$

Formula Weight 527.59 g/mol

Test Results

Test	Specification (Industry & Pharmacopoeial Standard)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection (25°C)
Appearance (Form)	Crystalline powder	Crystalline powder	-	Visual Inspection (25°C)
Assay (on dry basis)	98.5 ~ 101.5%	99.7%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	≤ 1.0%	0.09%	%	HPLC (USP 45 Method)
Single Impurity	≤ 0.2%	0.02%	%	HPLC (USP 45 Method)
Loss on Drying	≤ 0.5%	0.06%	%	Vacuum Drying at 60°C for 4h
Residue on Ignition	≤ 0.1%	0.01%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	≤ 5 ppm	1.1 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 1 ppm	0.2 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Acidity/Alkalinity (1% aq. solution)	3.0 ~ 4.0	3.6	-	Digital pH Meter
Melting Point	87 ~ 92°C	89.3°C	°C	Melting Point Apparatus
Optical Rotation (25°C, c=5 in H ₂ O)	-62° ~ -68°	-65.0°	°	Polarimetry
Total Bacterial Count	≤ 100 CFU/g	15 CFU/g	CFU/g	Plate Count Method
E. coli	Negative	Negative	-	Microbiological Detection
Supplier Information	Confirmed	Confirmed	-	-
Registered Trademark	Confirmed	Confirmed	-	-

Certification

This batch of product has been tested in accordance with the pharmacopoeial and industrial standards for Pentoxifyverine Citrate and meets all specified requirements. It is qualified for use as a pharmaceutical raw material for antitussive preparations.