纳维盈医化科技
NEWAY SINOPHC TECH

NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com； Phone:+86-021-50350029 https://www.newayphc.com

Certificate of Analysis (Ozagrel Sodium)

Issue Date: 26 FEB 2026**Quality Release Date**: 26 FEB 2026

Product Name

Ozagrel Sodium 奥扎格雷尔钠

Product Information

Product Number	OS-20260226
Batch Number	OS-SH2026022601
Brand	SIGALD
CAS Number	82571-53-7
MDL Number	MFCD00072015
Formula	$C_{13}H_{11}N_2O_2Na$
Formula Weight	249.23 g/mol

Test Results

Test	Specification (USP 45 & ChP 2025)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection
Appearance (Form)	Crystalline powder	Crystalline powder	-	Visual Inspection
Assay (on dry basis)	≥ 99.0%	99.8%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	≤ 0.5%	0.09%	%	HPLC (USP 45)
Single Impurity	≤ 0.1%	0.02%	%	HPLC (USP 45)
Loss on Drying	≤ 0.5%	0.07%	%	Vacuum Drying at 60℃ for 4h
Residue on Ignition	≤ 0.1%	0.01%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	≤ 10 ppm	0.2 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.04 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Bacterial Endotoxins	≤ 0.5 EU/μg	0.03 EU/μg	EU/μg	Limulus Amebocyte Lysate (LAL) Test
Sterility	Sterile	Sterile	-	Membrane Filtration Method
Melting Point	223 ~ 227℃	225.4℃	℃	Melting Point Apparatus
pH Value (1% aqueous solution, 25℃)	7.0 ~ 8.5	7.8	-	Digital pH Meter
Clarity and Color of Solution	Clear, colorless	Clear, colorless	-	Visual Inspection (ChP 2025)

Certification

This batch of Ozagrel Sodium 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 anti-thrombotic pharmaceutical preparations for cerebral infarction and myocardial infarction.