



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 (Rosuvastatin Calcium)

Issue Date: 25 FEB 2026

Quality Release Date: 25 FEB 2026

Product Name

Rosuvastatin Calcium 罗舒伐他汀钙

Product Information

Product Number ROS-20260225

Batch Number ROS-SH2026022501

Brand SIGALD

CAS Number 147098-20-2

MDL Number MFCD02093356

Formula $C_{44}H_{54}CaF_2N_6O_{12}S_2$

Formula Weight 1001.15 g/mol

Test Results

Test	Specification (USP 45 & ChP 2025 Pharmaceutical Standard)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection (25°C)
Appearance (Form)	Amorphous or crystalline powder	Amorphous powder	-	Visual Inspection (25°C)
Assay (on dry basis)	98.0 ~ 102.0%	99.5%	%	High Performance Liquid Chromatography (HPLC)
Related Substances (Total)	≤ 1.0%	0.06%	%	HPLC (USP 45 Method)
Single Impurity	≤ 0.2%	0.01%	%	HPLC (USP 45 Method)
Loss on Drying	≤ 1.0%	0.08%	%	Vacuum Drying at 60°C for 4h
Residue on Ignition	0.9 ~ 1.1% (calcium content)	0.98%	%	Gravimetric Method (ChP 2025)
Heavy Metals (Pb)	≤ 5 ppm	0.5 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 1 ppm	0.1 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Calcium Content	4.0 ~ 4.4%	4.2%	%	Complexometric Titration
pH Value (0.5% aq. suspension, 25°C)	5.0 ~ 7.0	6.1	-	Digital pH Meter
Dissolution (30min, water)	≥ 80%	92.3%	%	Paddle Method (USP 45)
Total Bacterial Count	≤ 100 CFU/g	7 CFU/g	CFU/g	Plate Count Method
E. coli	Negative	Negative	-	Microbiological Detection
Salmonella	Negative	Negative	-	Microbiological Detection

Certification

This batch of product has been tested in accordance with the pharmacopoeial and industrial standards for Rosuvastatin Calcium and meets all specified requirements. It is qualified for use as a pharmaceutical raw material for lipid-lowering preparations.