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## CERTIFICATE OF ANALYSIS

### Factory price Rosuvastatin Calcium CAS 147098-20-2

Rosuvastatin Calcium is the calcium salt form of rosuvastatin, a statin with antilipidemic activity. Rosuvastatin selectively and competitively binds to and inhibits hepatic hydroxymethyl-glutaryl coenzyme A (HMG-CoA) reductase, the enzyme which catalyzes the conversion of HMG-CoA to mevalonate, a precursor of cholesterol. This leads to a decrease in hepatic cholesterol levels and increase in uptake of LDL cholesterol.

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Rosuvastatin calcium is a HYDROXYMETHYLGLUTARYL-COA-REDUCTASE INHIBITOR, or statin, that reduces the plasma concentrations of LDL-CHOLESTEROL; APOLIPOPROTEIN B, and TRIGLYCERIDES while increasing HDL-CHOLESTEROL levels in patients with HYPERCHOLESTEROLEMIA and those at risk for CARDIOVASCULAR DISEASES.

### Specification

Tests	Specifications	Results
Appearance	A White to off-white powder	Complies
Specific Rotation	+17° ~+21°	+20°
Identification	A. Meets the requirement	Complies
	B. UV: $\lambda_{\max}$ =243nm	Complies
	C. IR: similar to Reference Substance	Complies
	D. X-ray: similar to Reference Substance	Complies
Chloride	$\leq 0.1\%$	Complies
Sulphate	$\leq 0.1\%$	Complies
Enantiomer	$\leq 0.15\%$	Undetected
Calcium	3.9%~4.3%	4.1%
Related substances	Diastereomer $\leq 0.15\%$	0.06%

	5-oxo-Rosucastatin $\leq$ 0.15%	Undetected
	Photo degradation 1 $\leq$ 0.15%	Undetected
	Photo degradation 2 $\leq$ 0.15%	Undetected
	Rosuvastatin lactone $\leq$ 0.15%	Undetected
	Rosuvastatin methyl ester $\leq$ 0.15%	Undetected
	Rosuvastatin isoamyl ester $\leq$ 0.15%	Undetected
	Any unknown impurity $\leq$ 0.10%	0.05%
	Total impurities $\leq$ 0.75%	0.28%
Water	$\leq$ 3.0%	2.1%
Isoamyl Bromide	$\leq$ 37.5ppm	$\leq$ 37.5ppm
Residual solvents	Ethyl ether $\leq$ 300ppm Undetected	Complies
	Acetonitrile $\leq$ 410ppm Undetected	Undetected
	Isoamyl alcohol $\leq$ 5000ppm Undetected	Undetected
	DMF $\leq$ 880ppm Undetected	Undetected
Assay	98.5%~102.0%( caculated on the anhydrous basis)	99.8%