Hangzhou Huarong Pharm Co.,Limited

No. 5 Yongfuqiao Road, Gongshu District, Hangzhou, Zhejiang Province, China.
TEL: 0086-571-86758373 FAX: 0086-571-81131109

CERTIFICATE OF ANALYSIS

Product : ROSUVASTATIN CALCIUM
Quantity : 207.5Kg
Batch NO. : RS-703-230707-B

Manufacturing Date : Jun.24.2023
Retest Date : Jun.24.2025

Tests	Specifications		Results
Appearance	A white or off-white powder		White powder
Optical rotation	+17°～+21°		+18°
Identification	A. The retention time of the major peak of the Sample solution corresponds to that of the reference substance, as obtained in the test for Enantiomeric Purity. B. UV: λ_{max}=242nm±2nm C. IR: similar to Reference Substance D. Calcium: Meets the requirements E.X-Ray Powder Diffraction spectrum is similar to reference spectrum		Complies Complies Complies Complies Complies
Chlorides	≤0.1%		0.05%
Sulphates	≤0.1%		Complies
Calcium	3.9%～4.3%（on the anhydrous basis）		4.0%
Enantiomer	≤0.15%		Not Detected
Related substances	Rosuvastatin related compound A	≤0.2%	Not Detected
	Diastereoisomer	≤0.15%	Not Detected
	Light degradation impurity 1	≤0.15%	Not Detected
	TP-13 Impurity 1	≤0.15%	Not Detected
	Light degradation impurity 2	≤0.15%	Not Detected
	Rosuvastatin methyl ester	≤0.15%	Not Detected
	Rosuvastatin lactone	≤0.15%	Not Detected
	Rosuvastatin dehydro analog	≤0.15%	Not Detected
	Rosuvastatin isoamyl ester	≤0.15%	Not Detected
	Any unknown impurity	≤0.10%	Not Detected
	Total impurities	≤0.75%	Not Detected
Water	≤3.0%		1.27%
*Acetates	≤3000ppm		Complies
Residual solvents	Ethyl ether ≤300ppm		Not Detected
	Acetonitrile ≤410ppm		Not Detected
	Isoamyl alcohol≤5000ppm		Not Detected
	DMF≤880ppm		Not Detected
	*Benzene≤2ppm		Complies
Isoamyl bromide	≤37.5ppm		Not Detected
Assay	98.5%～102.0%（Calculated on the anhydrous and solvent-free basis）		101.2%

Note: *: skip testing item which is not routinely tested.
The results above meet all requirements under **ROSUVASTATIN CALCIUM** in **USP and In-House Standard.**

HANGZHOU HUARONG PHARMACEUTICAL CO., LTD. QC