

Anna D'Ascanio

Approved By: Anna D'Ascanio, Manager, QC Raw Materials

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A. Cross

Approved By: Alexandra Cross, Project Leader, QA Lab Review

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Version: 2
Effective date: 23-May-2013

Specification and Certificate of Analysis

Material: ROSUVASTATIN CALCIUM
Material #: 258872
Batch No.: KY6017
Storage Precautions: Store in a tight container, under nitrogen, protected from light at 2°C to 8°C
Manufacturer: Changzhou Pharmaceutical Factory
Manufacturing Plant: CHANGZHOU PHARMACEUTICAL FACTORY, Changzhou, Jiangsu, China
Manufacturer Lot No.: ERS130709
Testing Site: Signet

<u>TEST</u>	<u>SPECIFICATION</u>		<u>RESULTS</u>
	<u>METHOD</u>	<u>ACCEPTANCE CRITERIA</u>	
APPEARANCE	G-74	A white to off-white powder.	Conforms
IDENTIFICATION	USP <197K>	IR Spectrum: Corresponds to standard.	Conforms
IDENTIFICATION OF CALCIUM	ROSU-DS-60-SG	Positive for Calcium	Conforms
X-RAY DIFFRACTION	ROSU-DS-61-SG	Conforms to Exhibit A	Conforms
IRON	ROSU-DS-72-SG	NMT 25 ppm	4ppm
HEAVY METALS	G-54 (As per USP)	NMT 20 ppm	Less than 20 ppm
WATER CONTENT	G-18 (As per USP/EP)	NMT 3.0%	0.9%

RELATED COMPOUNDS	ROSU-DS-20-SG	ROU RC2: NMT 0.15% ROU RC3: NMT 0.15% ROU RC5: NMT 0.15% ROU RC6: NMT 0.15% ROU RC7: NMT 0.15% ROU RC9: NMT 0.15% Unidentified Impurity: NMT 0.10% each Total Impurities: NMT 0.5%	BRT BRT BRT BRT ND BRT BRT BRT
ASSAY	ROSU-DS-10-SG	98.0 to 102.0% (anhydrous basis)	100.3%
RESIDUAL SOLVENTS	ROSU-DS-30-SG	Methanol: NMT 300 ppm Ethyl Ether: NMT 300 ppm Acetone: NMT 300 ppm Acetonitrile: NMT 200 ppm t-Butylmethyl ether: NMT 500 ppm Hexane: NMT 150 ppm Isopropyl Ether: NMT 200 ppm Ethyl Acetate: NMT 300 ppm Tetrahydrofuran: NMT 200 ppm Cyclohexane: NMT 100 ppm DMF: NMT 200 ppm	3ppm 2ppm 5ppm 18ppm 0ppm 0ppm ND 0ppm 0ppm ND ND
RESIDUAL SOLVENTS	ROSU-DS-31-SG	Acetic acid: NMT 300 ppm	21ppm
ISOPENTYL BROMIDE	ROSU-DS-32-SG	NMT 1 ppm	ND
SPECIFIC ROTATION	G-20 (As per USP/EP)	[alpha] _{25, D} : +15° to +21°	+17°
PARTICLE SIZE (LASER)	ROSU-DS-71-SG	D(v,0.9): NMT 425 µm	293microns

Legend:

BRT: Below Reporting Threshold

ND: None Detected

Reporting Threshold: 0.05%

ROU RC2:

Calciumbis((3R*,5R*,6E)-7-{4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl}-3,5-dihydroxyhept-6-enoate). (Anti-Rosuvastatin) (Synthetic Impurity/Degradation Product)

ROU RC3:

N-{4-(4-fluorophenyl)-5-[(E)-2-(4-hydroxy-6-oxotetrahydro-2H-pyran-2-yl)vinyl]-6-isopropyl-pyrimidin-2-yl}-N-methylmethanesulphonamide. (Rosuvastatin Lactone) (Synthetic Impurity/Degradation Product)(Metabolite).

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ROU RC5:

(3R,5S)-5-{8-fluoro-4-isopropyl-2-[methyl(methylsulfonyl)amino]-5,6-dihydrobenzo[h]quinazolin-6-yl}-3,5-dihydroxypentanoic acid. (Degradation Product)

ROU RC6:

(3R,5R)-5-{8-fluoro-4-isopropyl-2-[methyl(methylsulfonyl)amino]-5,6-dihydrobenzo[h]quinazolin-6-yl}-3,5-dihydroxypentanoic acid. (Degradation Product)

ROU RC7:

Methyl(3R,5S,6E)-7-{4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl}-3,5-dihydroxyhept-6-enoate. (Rosuvastatin Methyl Ester)(Synthetic Impurity)

ROU RC9:

7-[4-(4-Fluorophenyl)-6-(1-methylethyl)-2-[methyl(methylsulfonyl)amino]-5-pyrimidinyl]-3-hydroxy-5-oxo-6-heptenoic acid (5-keto-Rosuvastatin) (Degradation Product)

Approved By:



Thomas Pallikaras, Associate, QC Central Lab Support

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