APOTEX

Innovating for
patient affordability

Certificate of Manufacture

Apotex Product Name: ROSUVASTATIN FCT 10MG 30 BLS RFF

Importing Country: CHILE

Marketing Authorization Number: F-22.189

Strength/Potency: 10MG

Package Size/Type: 30'S/BLISTER PACK-BOX

Dosage form: Film Coated Tablets

Packaged Batch/Lot No.: NW5674

Mfg. Batch No.: NV9347

Date of Manufacture: June 17, 2018

Expiry Date: JUN-20

Name, address of Fabricator(s)/ Manufacturer(s) – Manufacturing site(s) & Number of Manufacturing Authorization / License or Certificate of GMP Compliance of a manufacturer/fabricator.

APOTEX INC. – Head Office 150 Signet Dr Toronto, ON, CANADA #100375-A ☒	APOTEX INC. – Etobicoke Site 50 Steinway Blvd Etobicoke, ON, CANADA #100375-F ☐	APOTEX INC. – Richmond Hill Site 380 Elgin Mills Rd Richmond Hill, ON, CANADA #100375-G ☐	ARPL Plot No 1 Bommasandra Industrial Area, 4th Phase Bangalore, INDIA #100375-B ☐	APOTEX INC. 4100 Weston Rd Weston, ON, CANADA #100375-B ☒
APOTEX INC. 3701 Weston Rd Weston, ON, CANADA #100375-E ☐	APOTEX INC. – Barmac 200 Barmac Dr Weston, ON, CANADA #100375-I ☐	APOTEX INC.- Anti Biotics 20 Kenhar Dr Weston, ON, CANADA #100375-C ☐	APOTEX INC. – S.P. Facility 285 Gary Ray Dr Weston, ON, CANADA #100375-H ☐	APOTEX INC. 400 Ormont Dr Weston, ON, CANADA #100375-D ☐

Results of analysis:
A Certificate of Analysis approved by SHAMIM AKHTAR on July 11, 2018 is attached.

Comments/remarks:

We hereby certify that the above information is authentic and accurate. This batch of product has been fabricated/manufactured, including packaging and quality control at the above-mentioned site(s) in full compliance with the Good Manufacturing Practices requirements of the local importing country and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Ela Senguttuvan, QA Product Release Coordinator

Date: 9/7/2018

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Version: 3
Effective date: 09-Apr-2018

Approved By: Margaret Chong, Manager, QC Dosage Signet
Date: 04/09/2018 09:58:43

Approved By: Elena Doubova, Project Leader, QA Approver
Date: 04/09/2018 10:55:06

Specification and Certificate of Analysis

Material: ROSUVASTATIN FCT 10 MG APO
Material #: 100021495
Batch No.: NV9347
Storage Precautions: Store at controlled room temperature, in tight containers.
Date Manufactured: 06/17/2018
Testing Site: Apotex Inc., 150 Signet.Dr., Toronto, ON, Canada

TEST	SPECIFICATION		RESULTS
	METHOD	ACCEPTANCE CRITERIA	
APPEARANCE	VISUAL	Pink, round, biconvex, film-coated tablet, engraved "APO" on one side, "ROS" over "10" on the other side.	Conforms
IDENTIFICATION	ROSU-FCTB-10-SG	HPLC Retention time: Corresponds to standard UV Spectrum: Corresponds to standard	Conforms Conforms
AVERAGE WEIGHT	G-1	149 to 159 mg	154mg
WATER	USP <921> Method Ia	NMT 6.0%	4.9%
DISSOLUTION	ROSU-FCTB-40-SG	As per USP/EP Q = 80% Time = 30 minutes	Mean: 99% %RSD: 2.2% Minimum: 97% Maximum: 102% PASS STAGE1

UNIFORMITY OF DOSAGE UNITS	ROSU-FCTB-10-SG	As per USP/EP	Mean: 101.4% % RSD: 1.9% Minimum: 99.4% Maximum: 104.9% AV: 4.6 PASS STAGE1
DEGRADATION PRODUCTS	ROSU-FCTB-22-SG	ROU RC2: NMT 0.5% ROU RC5: NMT 0.5% ROU RC6: NMT 0.5% ROU RC9: NMT 0.5% Unidentified Impurity: NMT 0.2% each	BRT ND ND BRT BRT
DEGRADATION PRODUCTS	ROSU-FCTB-23-SG	ROU RC3: NMT 0.5%	BRT
TOTAL DEGRADATION PRODUCTS	ROSU-FCTB-22-SG & ROSU-FCTB-23-SG	Total Impurities: NMT 1.0%	Below Reporting Threshold
DEGRADATION PRODUCTS	ROSU-FCTB-24-SG	ROU RC10: NMT 30 ppm	Below Reporting Threshold
ASSAY	ROSU-FCTB-10-SG	95.0 to 105.0% (% of claim)	100.9%

Legend:

The drug product complies with ICH Q3D.

ROU RC10:
N-[4-(4-fluorophenyl)-5-formyl-6-(propan-2-yl)pyrimidin-2-yl]-N-methylmethanesulfonamide. (Synthetic Impurity/Degradation Product)
BRT: Below Reporting Threshold
ND: None Detected
Reporting Threshold: 0.1%
ROU RC2:
(E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methanesulfonyl)amino]pyrimidin-5-yl]
-(3R,5R)-3,5-dihydroxyhept-6-enoic acid. (Anti-Rosuvastatin)(Synthetic Impurity/Degradation Product)

ROU RC3:
(E)-(2S,4R)-N-{4-(4-fluorophenyl)-5-[2-(4-hydroxy-6-oxo-tetrahydropyran-2-yl)-vinyl
]
-6-isopropylpyrimidin-2-yl}-N-methylmethanesulfonamide.
(Rosuvastatin Lactone)(Synthetic Impurity/Degradation product)(Metabolite)
ROU RC5:
(3R,5S)-5-[(6R)-8-fluoro-4-isopropyl-2-(N-methylmethanesulfonamido]-5,6-dihydro
benzo
[h]quinazolin-6-yl]-3,5-dihydroxypentanoic acid. (Degradation Product)
ROU RC6:
(3R,5S)-5-[(6S)-8-fluoro-4-isopropyl-2-(N-methylmethanesulfonamido]-5,6-dihydro
benzo
[h]quinazolin-6-yl]-3,5-dihydroxypentanoic acid. (Degradation Product)
ROU RC9:
(3R,6E)7-[4-(4-fluorophenyl)-6-(1-methylethyl)-2-[methyl(methylsulfonyl)amino]
pyrimidin-5-yl]-3-hydroxy-5-oxo-6-heptenoic acid.
(5-keto-Rosuvastatin). (Degradation Product)

Approved By:

Shamim Akhtar, Associate, QC Central Lab Support

Date: 11-Jul-2018 2:43 pm