



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021 Introduction Type: [] Final Version Date: []

PRODUCT INFORMATION

Company Name: Sciegen Pharmaceuticals Inc **Application:** ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 206381
Medical Device Class, if applicable: []
DUNS: 079391286
Proprietary Name (if Applicable) and Established Name: Rosuvastatin Tablets, USP 10 mg, 500's count per bottle
Selling Unit NDC: 50228-117-05 **Unit of Use NDC:** 1 bottle **UPC:** 350228117050
UDI: [] **CVX Code:** [] **MX Code:** []
Description: Pink colored, round, biconvex, film coated tablets, debossed with SG on one side and 117 on other side.
Active Ingredient(s): Rosuvastatin
URL for Additional Product Information: []
Address: 89 arkay drive **Address 2:** []
City: Hauppauge **State:** NY **Zip:** 11788
Key Contact: Siva Reddy, P.V. **Email:** sivareddy@sciegenpharm.com
Phone Number: 631-424-2723, 631-524-5509 **Fax:** 631-357-3178
Product Therapeutic Classification: Hyperlipidemia

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
 Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F)
 Other Temperature Range Requirement (write in): []
 Notes: []
 Is this product to be shipped to customers on ice? [] No
 Is this product to be shipped to customers on dry ice? [] No
b. Contact for temperature excursion questions:
Name: Siva Reddy, P.V.
Number: 631-424-2727 XT 107, 631-524-5509
Group E-mail: sivareddy@sciegenpharm.com
c. Special regulations for product in any states? [] No
 Special returns requirements for this product? [] No
d. Store product (unit of sale) upright? [] Yes
 Protect product (unit of sale) from light? [] Yes
e. Shelf life: Initial shelf life at launch (if different): [] 24 Months
 [] 24 Months

ADDITIONAL PRODUCT INFORMATION

The product is a legend device? [] No
 if yes, enter class # []
 if yes, list NDCs of component parts reverse numbered? [] No
 co-licensed? [] No
 latex-free? []
 preservative-free? []
 correctional institution block? []
 opioid? []
 Cannabinoid? []
 If Unit Dose, is item bar coded to unit dose for hospital scanning? []
 If Unit Dose, indicate NDC here: []
Is the Product... Direct-Ship Only []
Is the Product... Orphan Drug Status []
FDA Approval Status []
Allergens Present []
Country of Origin USA []
 Is this product covered under the Trade Agreements Act (TAA)? [] Yes

PRODUCT DESCRIPTION INFORMATION

Size: 0.2283
Strength: 10 mg
Dosage Form: Tablet
Product Shape: Round
Product Color: Pink
Product Imprint: "SG" on one side and "117" on other side

ORDER INFORMATION

Unit of Sale
 Yes Bottle
 Box/Carton
 Ampule
 Glass
 Tube
 Vial Liquid Sgl
 Vial Liquid Multi
 Vial Powder Sgl
 Vial Power Multi
 Other: Write In []
What is the NDC selling unit? 1 Bottle of 500 Tablets
 (Write-in, e.g. 1 Box of 10 Vials)
Minimum order quantity? [] Yes
If Yes, how many of which package type?
 24 Bottles Each
 per Case Inner/ Carton/Pack
 1 Cases Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB [] Authorized Generic *If Authorized Generic, other section fields are not applicable
II. Generic Equivalent to What Brand?: Crestor []

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? [] Bottle
 (Write-in, e.g. 1 Vial)
Rx billing unit to pharmacy:
 X Each
 Gram
 Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? [] Yes
Is product exempt from DSCSA? [] No
GLN: 0350228000000
GCP: []
If yes, was original product purchased direct from mfr? []
Provide source manufacturer for repackaged product []

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.14	NA	1.8	3.2	#VALUE!	500 tablets per bottle
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	#VALUE!	NA
Case:	3.9	10.75	7.125	4	306.375	24 bottles per case
Pallet:	460	48	40	54	103680	108 case per pallet

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1	[]	00350228117050	[]
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	[]	[]	[]	[]
<input checked="" type="checkbox"/> Case	24	[]	20350228117054	[]
<input type="checkbox"/> Pallet	[]	[]	[]	[]

COST INFORMATION

Regular Cost []
Invoice Cost (WAC) (\$) \$33.57
As of date: []
WHOLESALE USE ONLY:
Vendor #: []
Whsl. Code #: []
Fineline Code: []

