



# 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 5 mg, 500's count per bottle  
 Selling Unit NDC: 50228-116-05 Unit of Use NDC: 1 bottle UPC: 350228116053  
 UDI: [ ] CVX Code: [ ] MVX Code: [ ]  
 Description: Pink colored, oval shaped, biconvex, film coated tablets, debossed with SG on one side and 116 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?  
 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... Unit of Use [ ]  
 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: 0.1740 x 0.3000  
 Strength: 5 mg  
 Dosage Form: Tablet  
 Product Shape: Oval  
 Product Color: Pink  
 Product Imprint: "SG" on one side and "116" 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  
 II. Generic Equivalent to What Brand?: Crestor  
 [ ] Authorized Generic \*If Authorized Generic, other section fields are not applicable

**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  
 If yes, select exemption:  
 Other exemption - Write in: [ ]  
 Is product repackaged? [ ] No  
 Is product sold by manufacturer's exclusive distributor? [ ] No  
 Has FDA granted waiver/exception/exemption for product? [ ] No  
 If yes, attach documentation from FDA. [ ]

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
X Item/Each	1	[ ]	00350228116053	[ ]
X Box/Carton/Bundle/Inner Pack	24	[ ]	20350228116057	[ ]
X Case	[ ]	[ ]	[ ]	[ ]
X Pallet	[ ]	[ ]	[ ]	[ ]

**COST INFORMATION**

Regular Cost [ ]  
 Invoice Cost (WAC) (\$) \$33.57  
 As of date: [ ]

**WHOLESALE USE ONLY:**  
 Vendor #: [ ]  
 Whsl. Code #: [ ]  
 Fineline Code: [ ]



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For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic?  No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
  - Is the product a CA Prop 65 carcinogen?  No
  - Is the product a CA Prop 65 reproductive toxicant?  No
  - Does the product label bear a CA Prop 65 warning?  No

- c. Contact Hazard?  No
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)  No
- e. Does the product contain DEHP?  No

Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?  No

Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?  No

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger
- Cargo
- Passenger & Cargo

Is this a reportable quantity?

RQ Threshold:

Is this a marine pollutant?  No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

- (if yes, identify method below)
  - Limited Quantity
  - Consumer Commodity, ORM-D
  - Small Quantity (49 CFR 173.4)
  - Special Permit; DOT-SP
  - Special Provision (listed in Column 7 of 49 CFR 172.101); SP#

### ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance?  No      Controlled Substance Code
- Controlled by State(s)?       Listed Chemical (List I or II)
- ARCOS Reportable?       If yes, indicate which:
- Schedule No.       Is it a scheduled listed chemical product?:

### CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices
- Restricted to retail pharmacy only:
- Restricted to hospital, clinics, and physician offices only:
- Restricted from US territories? (explain in comments)
- Comments:

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

### SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:

NFPA Storage Level:

Is the product a NIOSH hazardous drug?  No

If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:       Waste Characteristics:

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required

Limited Distribution Requirement

Comments / Details: (For example, iPledge program?)

**REMS:**

REMS Program Manager Name:       Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:       DEA #:

Site Enrollment Number assigned by Supplier:       NCPDP#:

NPI #:

Comments

**Registry:**

Registry Program Contact Name:       Phone:

Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  6315245509

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?



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Version 2021

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
<p>Purchase orders may be accepted by:</p> <ul style="list-style-type: none"> <li>a. EDI <input type="checkbox"/></li> <li>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></li> <li>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></li> <li>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></li> <li>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></li> </ul> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Monday</li> <li><input type="checkbox"/> Tuesday</li> <li><input type="checkbox"/> Wednesday</li> <li><input type="checkbox"/> Thursday</li> <li><input type="checkbox"/> Friday</li> </ul> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	<p><b>Return Instructions</b></p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p> <p><b>ADDITIONAL INFORMATION</b></p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>
Other Data Information Required to Process PO:	
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	
Miscellaneous Notes:	
<p><input type="text"/></p>	