



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Sciegen Pharmaceuticals Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	208677
DUNS:	079391286
Proprietary Name (If Applicable) and Established Name:	Pregabalin Capsules, 300 mg 90s per Bottle
Selling Unit NDC:	50228-357-90
Individual Unit NDC:	1 Bottle
UPC:	350228357906
UDI	
CVX Code:	
MVX Code:	
Description:	White to Off white powder filled in size "0" hard gelatin capsules with orange colored cap and white opaque colored body imprinted "SG" on cap and "357" on body with black ink.
Active Ingredient(s):	Pregabalin, USP
URL for Additional Product Information:	
Address:	89 arkay drive
City:	Hauppauge
Key Contact:	Siva Reddy.P.V
Phone Number:	631-434-2723, 631-524-5509
Product Therapeutic Classification:	Anti Epileptic and Fibromyalgia
Application:	ANDA

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	Controlled Room – between 20 and 25 C (68° – 77° F)
Temperature Range	
Other Temperature Range Requirement (write in)	
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:	631-524-5509
Group E-mail:	sivareddyp@sciegenpharm.com
c. Special regulations for product in any states?	No
Special returns requirements for this product?	
d. Store product (unit of sale) upright?	Yes
Protect product (unit of sale) from light?	No
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	Yes
reverse numbered?	No
co-licensed?	Yes
Is the Product... Direct-Ship Only	
Is the Product... Unit of Use	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose NDC, indicate NDC here:	
Country of Origin	USA
Is this product covered under the Trade Agreements Act (TAA)?	Yes

PRODUCT DESCRIPTION INFORMATION	
Size:	21.4 mm
Strength:	300mg
Dosage Form:	Capsule
Product Shape:	Capsule
Product Color:	Orange opaque Cap / white Opaque Body
Product Imprint:	"SG" on cap and "357" on the body in black ink.

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Bottle
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? Yes
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	24 Bottles Each
<input type="checkbox"/> Vial Power Multi	per Case Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In	3 Cases Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Lyrica
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="Bottle"/>	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> 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?	
Has FDA granted waiver/exception/exemption for product?	No
GLN:	350228000000
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	0.16	NA	3.8	2.1	#VALUE!	90 Tablets per Bottle
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	#VALUE!	NA
Case:	4.5	12.1	4.5	8.2	446.49	24 Bottles per Case
Pallet:	375	48	48	40	92160	74 Cases per Pallet
UPC:	Case:	350228357906				
	Carton:					

GTIN PRODUCT INFORMATION								
Serialized?	Yes	Level	Saleable Unit	Quantity	GTIN-14	Item		
If not, when?		<input checked="" type="checkbox"/>	Item	<input checked="" type="checkbox"/>	1	00350228357906	2D	Linear
Items aggregated?	No	<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack				2D	Linear
		<input checked="" type="checkbox"/>	Case		24	20350228357900	2D	Linear
		<input type="checkbox"/>	Pallet				2D	Linear
		<input type="checkbox"/>					2D	Linear
		<input type="checkbox"/>					2D	Linear
		<input type="checkbox"/>					2D	Linear

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)		Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

\*Please provide any additional information on page 2. Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. See new p. 3 for Designated Drop Ship Only. Signature:

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.)                     

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT or IATA?  
 (if yes, answer a-e below and provide SDS) No

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?  
No (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? Yes

Controlled by State(s)? Yes

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic) V N

Controlled Substance Code 2782

Listed Chemical (List I or II) No

If yes, indicate which:                     

Is it a scheduled listed chemical product? No

**CLASS OF TRADE RESTRICTION:**

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No

Restricted to retail pharmacy only: Yes

Restricted to hospital, clinics, and physician offices only: Yes

Restricted from US territories? (explain in comments) No

Comments: Not Applicable

**SDS Hazard Classification**

Organic

Inorganic

Steroid/Androgen

Corrosive

Oxidizer

Contact Hazard

Aerosol Class; Identify NFPA Storage Level:                     

Is the product a NIOSH hazardous drug? No

If yes, indicate which:                     

**Hazardous Waste Identification**

EPA Hazardous Waste Code:                     

**REMS or REGISTRY RESTRICTIONS**

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?                     

Website URL:                     

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

**REMS:**                     

REMS Program Manager Name:                      Phone:                     

Supplier Manages REMS registry exclusively:                     

Wholesale distributor support:                     

Provider Name:                     

Site Enrollment Number assigned by Supplier:                     

DEA #:                     

PCPDP #:                     

NPI #:                     

Comments                     

**Registry:**                     

Registry Program Contact Name:                      Phone:                     

Comments                     

**RETURN INSTRUCTIONS**

Contact tel. # if product received damaged: 1877-671-6307

Is product returnable for credit:                     

URL/Link to returns policy:                     

Special regulations or returns requirements for this product in certain states? No

If so, which states? Other requirements? Comments?                     

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

**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> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #:</p> <p style="margin-left: 20px;">Name: <input type="text"/></p> <p style="margin-left: 20px;">Phone: <input type="text"/></p> <p style="margin-left: 20px;">Fax Number: <input type="text"/></p> <p style="margin-left: 20px;">Fax Number: <input type="text"/></p> <p style="margin-left: 20px;">Phone No.: <input type="text"/></p> <p style="margin-left: 20px;">Site Address: <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 style="width: 100%; height: 80px;" 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> <p style="margin-left: 20px;"><input type="checkbox"/> Monday</p> <p style="margin-left: 20px;"><input type="checkbox"/> Tuesday</p> <p style="margin-left: 20px;"><input type="checkbox"/> Wednesday</p> <p style="margin-left: 20px;"><input type="checkbox"/> Thursday</p> <p style="margin-left: 20px;"><input type="checkbox"/> Friday</p> <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="checkbox"/></p> <p style="margin-left: 20px;">Phone: <input type="text"/> Phone #: <input type="text"/></p> <p style="margin-left: 20px;">Fax: <input type="text"/> Fax #: <input type="text"/></p> <p style="margin-left: 20px;">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:	Return Instructions
<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 style="width: 100%; height: 80px;" type="text"/></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 style="margin-left: 20px;">If so, which states? Other requirements? Comments?</p> <p style="margin-left: 20px;"><input style="width: 100%; height: 40px;" type="text"/></p>
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
<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>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>
Miscellaneous Notes:	
<p><input style="width: 100%; height: 100px;" type="text"/></p>	