



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:  Final VersionDate: 

PRODUCT INFORMATION	
Company Name:	Sciegen Pharmaceuticals Inc
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	214092
DUNS:	0793912286
Proprietary Name (if Applicable) and Established Name:	Carbidopa and Levodopa Tablets USP 10 mg / 100 mg, 500s
Selling Unit NDC:	50228-457-05
UDI	Individual Unit NDC: 1 Bottle CVX Code: <input type="text"/> MVX Code: <input type="text"/>
UPC:	350228457057
Description:	Light blue, Mottled, round, uncoated tablets debossed with "SG" on one side and "457" on the other
Active Ingredient(s):	Carbidopa USP & Levodopa USP
URL for Additional Product Information:	
Address:	89 Arkay Drive
City:	Hauppauge
Key Contact:	Siva Reddy, P.V.
Phone Number:	631-424-2727 XT 107, 631-524-5509
Product Therapeutic Classification:	Used in the treatment of Parkinson's disease

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	<input type="text"/>
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
<b>b. Contact for temperature excursion questions:</b>	
Name:	Siva Reddy, P.V.
Number:	631-424-2723 XT 107, 631-524-5509
Group E-mail:	sivareddy@sciegenpharm.com
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	No
<b>e. Shelf life:</b>	
Initial shelf life at launch (if different):	24 Months

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

PRODUCT DESCRIPTION INFORMATION	
Size:	0.3150"
Strength:	10 mg / 100 mg
Dosage Form:	Tablet
Product Shape:	Round
Product Color:	Light blue
Product Imprint:	SG' on one side and '457' on other

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	1 Bottle of 500 Tablets
<input type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	
<input type="checkbox"/> Vial Powder Multi	
<input type="checkbox"/> Other: Write In	
	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?:	Sinemet
<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"/>	<input 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:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
GLN:	035022800000
If Yes, was original product purchased direct from mfr?	<input type="checkbox"/>
If yes, attach documentation from FDA.	<input type="text"/>

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.25	NA	3	1.74	#VALUE!	500 Tablets per Bottle
Box/ Carton/ Bundle/ Inner Pack:	NA	NA	NA	NA	#VALUE!	NA
Case:	6	13.9	5	9.2	639.4	24 Bottles per Case
Pallet:	960	48	48	40	92160	160 Cases per Pallet
UPC:	Case:	350228457057				
	Carton:	<input type="text"/>				

GTIN PRODUCT INFORMATION						
Serialized?	Level	Item	Saleable Unit	Quantity	GTIN-14	If not, when?
Yes		Box/ Carton/ Bundle/ Inner Pack		1	00350228457057	
No		Case		24	20350228457051	
		Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	<input type="text"/>	Whsl. Code #:	<input type="text"/>
Federal Excise Tax Per Unit of Sale	<input type="text"/>	Fineline Code:	<input type="text"/>
As of date:	<input type="text"/>		

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? No  
 (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?  
 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? No

Controlled by State(s)? No

ARCOS Reportable? \_\_\_\_\_

Schedule No. (inc. N for non-narcotic) \_\_\_\_\_

Controlled Substance Code \_\_\_\_\_

Listed Chemical (List I or II) \_\_\_\_\_

If yes, indicate which: \_\_\_\_\_

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: \_\_\_\_\_

SDS Hazard Classification	
<input checked="" type="checkbox"/> Organic <input type="checkbox"/> Inorganic <input type="checkbox"/> Steroid/Androgen  <input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <span style="float: right;">_____</span>	<input type="checkbox"/> Corrosive <input type="checkbox"/> Oxidizer <input type="checkbox"/> Contact Hazard  Is the product a NIOSH hazardous drug? <span style="float: right;">No</span> If yes, indicate which: <span style="float: right;">_____</span>

Hazardous Waste Identification
EPA Hazardous Waste Code: <span style="float: right;">_____</span>

REMS or REGISTRY RESTRICTIONS
Is there a REMS on this product? <span style="float: right;">_____</span> If Yes, is it managed with a pharmacy registry? <span style="float: right;">_____</span> Website URL: <span style="float: right;">_____</span>
Comments / Details: (For example, iPledge program?) <span style="float: right;">_____</span>
<b>REMS:</b> <span style="float: right;">_____</span> REMS Program Manager Name: <span style="float: right;">_____</span> Phone: <span style="float: right;">_____</span> Supplier Manages REMS registry exclusively: <span style="float: right;">_____</span> Wholesale distributor support: Provider Name: <span style="float: right;">_____</span> Site Enrollment Number assigned by Supplier: <span style="float: right;">_____</span>
DEA #: <span style="float: right;">_____</span> PCPDP #: <span style="float: right;">_____</span> NPI #: <span style="float: right;">_____</span>

Comments <span style="float: right;">_____</span>
<b>Registry:</b> <span style="float: right;">_____</span> Registry Program Contact Name: <span style="float: right;">_____</span> Phone: <span style="float: right;">_____</span>
Comments <span style="float: right;">_____</span>

RETURN INSTRUCTIONS
Contact tel. # if product received damaged: <span style="float: right;">1877-671-4307</span>
Is product returnable for credit: <span style="float: right;">_____</span> URL/Link to returns policy: <span style="float: right;">_____</span>
Special regulations or returns requirements for this product in certain states? <span style="float: right;">No</span>
If so, which states? Other requirements? Comments? <span style="float: right;">_____</span>

### 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"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> 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="checkbox"/></p> <p>Drop Ship service fee billed with each order: <input type="checkbox"/></p> <p>Drop Ship miscellaneous fees billed: <input type="checkbox"/></p> <p>Comments: <input style="width: 100%; height: 50px;" 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><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><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: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> 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: 50px;" 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>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 50px;" type="text"/></p>
Other Data Information Required to Process PO:	Miscellaneous Notes:
<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><input style="width: 100%; height: 100px;" type="text"/></p>
ADDITIONAL INFORMATION	
<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>	