



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):	203855
Application:	ANDA
DUNS:	079391286
Proprietary Name (if Applicable) and Established Name:	Pramipexole Dihydrochloride Tablets 1.5mg, 1000s per Bottle
Selling Unit NDC:	50228-131-10
Individual Unit NDC:	
UPC:	350228131100
UDI	
CVX Code:	
MVX Code:	
Description:	White to off white, oval, flat, beveled edge un coated tablets debossed on one side with 'S' on the left side of bisect and 'G' on the right side of bisect and other side '1' on the left side and '31' on the right side of the bisect.
Active Ingredient(s):	Pramipexole Dihydrochloride Monohydrate USP
URL for Additional Product Information:	
Address:	89 arday drive
City:	Hauppauge
Key Contact:	Siva Reddy,P.V
Phone Number:	631-434-2723, 631-524-5509
Product Therapeutic Classification:	Anti Parkinsons - Dopamine Agonist
Address 2:	
State:	NY
Zip:	11788
Email:	sivareddy@sciengenpharm.com
Fax:	631-357-3178

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)	
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:	sivareddy@sciengenpharm.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:	
Initial shelf life at launch (if different):	21 Months

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: Authorized Generic *If Authorized Generic, other section fields are not applicable

II. Generic Equivalent to What Brand?:

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
yes	1 Bottle of 1000 Tablets
Bottle	(Write-in, e.g. 1 Box of 10 Vials)
Box/Carton	
Ampule	
Glass	
Tube	
Vial Liquid Sgl	
Vial Liquid Multi	
Vial Powder Sgl	
Vial Powder Multi	
Other: Write In	
	Minimum order quantity? Yes
	If Yes, how many of which package type?
	12 Bottles Each
	per Case Inner/Carton/Pack
	3 Cases Case

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? GLN:

Is product exempt from DSCSA?

If yes, select exemption:
Other exemption - Write in:

Is product repackaged?

If Yes, was original product purchased direct from mfr?

Is product sold by manufacturer's exclusive distributor?

If yes, attach documentation from FDA.

Has FDA granted waiver/exception/exemption for product?

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
bottle	X Each
(Write-in, e.g. 1 Vial)	Gram
	Milliliter

GTIN PRODUCT INFORMATION

	Serialized?		Level		Quantity	GTIN-14
	Yes	No	Item	Saleable Unit		
If not, when?			X	X	1	00350228131100
Items aggregated?			X	X	12	20350228131104
				X		
				X		
				X		
				X		
				X		
				X		
				X		
				X		
				X		

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/Carton/Bundle/Inner Pack:	0.9	NA	6.2	3.3	#VALUE!	1000 Tabs per Bottle
Case:	11.5	12.9	8.5	9.75	1069.0875	12 Bottles per Case
Pallet:	145	48	48	40	92160	9 Cases per Pallet
UPC:	Case:	350228131100				
	Carton:					

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:	

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"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
<input type="checkbox"/> 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"/> 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>Purchase order daily receipt cut off time by supplier</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>Overnight receipt available: <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>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <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:	
<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>	
Other Data Information Required to Process PO:	Return Instructions
<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>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>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input style="width: 100%; height: 100px;" type="text"/>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>