



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Final VersionDate:

PRODUCT INFORMATION	
Company Name:	Sciegen Pharmaceuticals Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	209635
DUNS:	079391286
Proprietary Name (If Applicable) and Established Name:	Quetiapine Extended Release Tablets, USP 200mg ,60s per Bottle
Selling Unit NDC:	50228-382-60
Individual Unit NDC:	1 Bottle
UPC:	350228382601
UDI	
CVX Code:	
MVX Code:	
Description:	Yellow, film coated, capsule shaped biconvex tablet embossing with 382 on one side and plain on the other side
Active Ingredient(s):	Quetiapine Fumarate
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:	Multi -Acting Receptor Targeted (MARTA) Antipsychotic

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:	sivareddyp@sciegenpharm.com
c. Special regulations for product in any states?	
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
e. Shelf life:	
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	
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:	0.6800" X0.2750"
Strength:	200mg
Dosage Form:	Tablets
Product Shape:	Capsule Shape
Product Color:	Yellow
Product Imprint:	"382" on one side and plain on the other side

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> yes 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	
<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 Power 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
	3 Cases Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Seroquel XR
<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:
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:	0.11	NA	3	1.73	#VALUE!	60 Tablets per Bottle
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	NA	NA
Case:	4	12.2	4.5	8.4	461.16	24 Bottle per Case
Pallet:	680	48	54	40	103680	160 Cases per Pallet
UPC:	Case:	350228382601				
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Yes	Level	Saleable Unit	Quantity	GTIN-14	
If not, when?		<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	1	00350228382601	
Items aggregated?	No	<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack				
		<input checked="" type="checkbox"/> Case		24	20350228382605	
		<input type="checkbox"/> Pallet				
		<input type="checkbox"/>				
		<input type="checkbox"/>				
		<input type="checkbox"/>				
		<input type="checkbox"/>				
		<input type="checkbox"/>				
		<input type="checkbox"/>				
		<input type="checkbox"/>				

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:			

