



# 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):	78420
DUNS:	079391286
Proprietary Name (If Applicable) and Established Name:	Nabumetone Tablets, USP 500 mg, 100's per Bottle
Selling Unit NDC:	50228-465-01
UDI	
Individual Unit NDC:	
UPC:	350228465014
CVX Code:	
MVX Code:	
Description:	White colored, Oval shaped, Biconvex, film coated tablets, debossed with 'SG' on one side '465' on other side.
Active Ingredient(s):	
URL for Additional Product Information:	
Address:	89 arkay drive
City:	Hauppauge
Key Contact:	Siva Reddy.P.V
Phone Number:	6314342723, 6315245509
Product Therapeutic Classification:	Anti Inflammatory
Application:	ANDA
State:	NY
Zip:	11788
Email:	sivareddyp@sciegenpharm.com
Fax:	6313573178

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:	6315245509
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?	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:	0.3386" X 0.6142"
Strength:	500mg
Dosage Form:	Tablets
Product Shape:	Oval
Product Color:	White
Product Imprint:	'SG' on one side '465' on other side.

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> yes Bottle	1 Bottle of 10 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
	3 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Relafen
<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:	0.18	NA	3.4	2	#VALUE!	100 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:	940	48	48	40	92160	200 Cases per Pallet
UPC:	Case:	350228465014				
	Carton:					

GTIN PRODUCT INFORMATION							
Serialized?	Level	Saleable Unit	Quantity	GTIN-14			
Yes	<input checked="" type="checkbox"/>	Item	<input checked="" type="checkbox"/>	2D	<input checked="" type="checkbox"/>	1	00350228465014
If not, when?		Box/Carton/Bundle/Inner Pack		2D			
Items aggregated?	No	Case	<input checked="" type="checkbox"/>	2D	<input checked="" type="checkbox"/>	24	20350228465018
		Pallet		2D			
				2D			
				2D			
				2D			
				2D			
				2D			

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:			



