

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014						Introduction	Type:	New Item	<u> </u>	Final Version			Date:	5/24	1/2018
			PRODUCT INFORM	ATION						SPECIAL HANDL	NG AND STO	ORAGE REQ	UIREMENTS*		
Company Name:	Camber Pharmaceuti	cals				Ap	plication:	ANDA	a. Temperature – Indi	cate the USP tempera	ature range	for this prod	uct.		
Application Number for ND			e):							ature Range	ataro rango		Room – betwe	en 20 and 25	C (68° – 77° I
DUNS:	82-667-4775	***	•	_					-	emperature Range Red	uirement				
Proprietary Name (If Applical		Name: Sildena	fil Tablet 50MG 100CT						-	rite in)	quirement				1
Selling Unit NDC:	31722-710-01		Individual Unit NDC:	:		UPC:	3317227	710015		,					
UDI			CVX Code:			MVX Code:			Is this p	roduct to be shipped to	customers of	on ice?		No	_
Description:	Tablet press with 9.0	Omm. round shape bi cor	ncave punches embossed w	rith '36' on lower	r punch and 'I' o	n upper punch.			Is this p	roduct to be shipped to	customers of	on dry ice?		No	
		, ,				.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,							•		-
Active Ingredient(s):		Sildenafil							b. Contact for temper	ature excursion ques	stions:				
									Name:			Soma Raju			
URL for Additional Product II Address:		www.camberpharma.co	m			Address 2:	_		Numbe			732-529-04			
City:	1031 Centennial Avenue Piscataway				State: NJ Zip: 08854			Group	=-maii:		somaraju@r	neterousa.com	л		
Key Contact:	Piscataway Customer Service				Email: customerservice@camberpharma.com			c. Special regulations	for product in any st	ates?			No		
Phone Number:	732-529-0430				Fax: 732-562-8788			Special returns requirements for this product?				-			
Product Therapeutic Classifi	ication:					•			"				•		-
									d. Store product (unit of sale) upright?						
ADDITIONA	AL PRODUCT INFORM	IATION			F	PRODUCT DESCR	IPTION INF	ORMATION		product (unit of sale) from light?	•	•	No	_
Is the Product			1						e. Shelf life:				ļ	24	Months
a legend device?		No			Size:	100CT			Initial s	nelf life at launch (if d	ifferent):				Months
reverse numbered?		No	<u>.</u>		OLC.	10001									
co-licensed?		No No	-		Strength:	50MG				0	RDER INFO	RMATION			
Is the Product		Direct-Ship Only Unit Dose							Unit of	Cala		What is the	NDC selling	unit?	
is the Floduct		Onit Dooc	•		Dosage Form:	Tablet			Onk of	Bottle		1 box of 12		uiik.	
		9-1							х	Box/Carton			.g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar code	ed to unit dose for nosp	ital scanning?			Product Shape	e: Round				Ampule			-		
If Unit Dose NDC, indicate NI	DC here:		j		Froduct Snape	e. Itouria				Glass		Minimum o	rder quantity	?	Yes
		1. 2.	1		Product Color	: White				Tube					
Country of Origin		India	1							Vial Liquid Sgl Vial Liquid Multi		If Voc how	many of whi	ch nackago	tuno?
Is this product covered under	r the Trade Agreements	Act (TAA)?			Product Imprir	nt: 1 / 36			Vial Liquid Multi If Yes, how many of which package type? Vial Powder Sql Each						
			•							Vial Power Multi		12	Inner/Carton	/Pack	
										Other: Write In	_		Case		
			FOR GENERIC DRUG P	RODUCTS											
							*** * **			DUAD	MACY ORDE	ED / DILL LINI	Ŧ		
	1			_	Autho	rized Generic		orized Generic, other section	PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating: AB					fields are not applicable			Rec. sell unit to customer?			Rx billing unit to pharmacy:				
II. Generic Equivalent to What Brand?: Viagra								(Write-in, e.g. 1 Vial)			Each X Gram				
		DRUG SUPI	PLY CHAIN SECURITY ACT	(DSCSA) INFO	ORMATION				(vviite-iii, e.g. i viai)				Milliliter		
				<u> </u>									1		
Does supplier meet DSCSA		turer?	Yes	GLI	N:					ITEM A	ND PACKING	INFORMATI	ON		
Is product exempt from DSC	CSA?		No	_							B*			V-1	
If yes, select exemption:	_									Weight Lbs.		nsions (US m		Volume (Cube)	# Pieces:
Other exemption - Write in: Is product repackaged?	•		No	If Y	es was origina	I product purchas	sed direct		Item:		Depth	Height	Width	(Cube)	
Is product sold by manufact	turer's exclusive distr	ibutor?	No		n mfr?	ii product parena	ocu uncot		ikem.	0.15		3.75	1.5		
Has FDA granted waiver/exc			No	_ If ye	es, attach docu	umentation from F	DA.		Box/Carton/Bundle/	1.6	6.6	3.75	4.875	0.06	12
		-							Inner Pack:	1.0	0.0	3.73	4.073	0.00	12
			GTIN PRODUCT INFOR						Case:	15.75	14.3	9.125	10.5	0.79	96
			Level	Saleable Unit			0	CTIN 44	Pallet:						
Serialized?	Yes	х	ltem	Offic	x 2D	Linear	Quantity 1	GTIN-14 00331722710015	Pallet:						3168
If not, when?	165		Box/Carton/Bundle/Inner Pack	x	x 2D	Linear	12	10331722710012	UPC:	Case:		<u> </u>			1
Items aggregated?	Yes	x	Case		x 2D	Linear	96	30331722710016		Carton:					
			Pallet		2D	Linear				•					
					2D	Linear			cos	INFORMATION			WHOLESAL	ER USE ONL	_Y:
			(_	2D	Linear			December Over						
		<u> </u>		 	2D 2D	Linear			Regular Cost Invoice Cost (WAC) (.	\$60.00	Vendor #: Whsl. Code	. #.		
			ı L		20	Lilical			Federal Excise Tax Po		ΦΟ.00	Fineline Co			
-									As of date:			1			
		<u> </u>	Attach copy of SAFETY [DATA SHEET (S	SDS) or non haz	ard letter, PACKAC	GE INSERT	, LABEL AND PHOTO OF PR	ODUCT PACKAGING and B	ARCODE.					
*Please provide any addition	nal information on page	qe 2.						ed Drop Ship Only.	Signatu						



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL H	HAZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):		,					
a. Cytotoxic?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	ODO HAZARA GRADANIONI						
Is the product a CA Prop 65 carcinogen?	Organic Corrosive						
Is the product a CA Prop 65 carcinogen?	Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard						
- O-st-st-H10	Associated Characteristic NETPA Characteristics						
c. Contact Hazard?	Aerosol Class; Identify NFPA Storage Level:						
d. Does this product require special clean-up instructions? No							
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug?						
e. Does the product contain DEHP? No	If yes, indicate which:						
Is this product regulated for shipment by DOT or IATA?							
(if yes, answer a-e below and provide SDS)							
a. UN/Identification Number							
b. Proper Shipping Name	Hazardous Waste Identification						
c. DOT Hazard Class	EPA Hazardous Waste Code:						
d. Packing Group							
e. Inhalation Hazard?							
	DELIA DEGLETA DESTRUCTIONA						
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS						
Passenger	Is there a REMS on this product?						
Cargo	If Yes, is it managed with a pharmacy registry?						
Passenger & Cargo	Website URL:						
Is this a reportable quantity? No							
RQ Threshold:	Comments / Details: (For example, iPledge program?)						
Is this a marine pollutant?							
Is this product shipped utilizing an authorized DOT exception or Special Permit?							
No (if yes, identify method below)	REMS:						
Limited Quantity	REMS Program Manager Name: Phone:						
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively: No						
Small Quantity (49 CFR 173.4)	Wholesale distributor support: No						
Special Permit; DOT-SP	Provider Name:						
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #: No						
SP#	by Supplier: PCPDP #: No						
01 #							
ADD'L STORAGE INFORMATION	NPI #: No						
Is the Product	Comments						
	Comments						
	Pariety, No.						
Controlled by State(s)? ARCOS Reportable? No	Registry: No						
·	Registry Program Contact Name: Phone:						
Schedule No. (inc. N for non-narcotic)	Comments						
Controlled Substance Code	RETURN INSTRUCTIONS						
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS						
If yes, indicate which:							
Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 732-529-0430						
CLASS OF TRADE RESTRICTION:	Is product returnable for credit:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	URL/Link to returns policy: contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only: Yes	Special regulations or returns requirements for this product in certain states?						
Restricted to hospital, clinics, and physician offices only:	If so, which states? Other requirements? Comments?						
Restricted from US territories? (explain in comments) No							
Comments:							
Comments.							
MISCELLAN	NEOUS NOTES and/or Image of Product Barcode:						



Standard Pharmaceutical Product Information (Page 3)

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				
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Case pack Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone: Yes Fax Number: 732-562-8788 No Phone No.: No Site Address: 732-529-0430 x466 x465 x467 x470 Name: Phone:	Shipping lead time of PO: Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:	Eastern Days No No Yes			
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Process				
Expedited freight fees billed with each order: No	Overnight receipt available:	Yes			
Drop Ship service fee billed with each order: No		Eastern			
Drop Ship miscellaneous fees billed: Comments:		x Monday x Tuesday x Wednesday x Thursday Friday			
	Priority Overnight receipt available:	Yes			
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) No Comments:	EDI: Yes Overnight Fees apply: Yes Other fees apply: No	2:30PM EST No 732-562-8788			
Other Data Information Required to Process PO:	Return Instructions				
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain s If so, which states? Other requirements? Comments?	732-529-0430 Yes states? Yes			
	ADDITIONAL INFORMATION				
	Is product order for scheduled patient procedure? Is product order for restocking purposes?	No No			