

## **Standard Pharmaceutical Product Information (Rx Product Only)**

© August 2014					Introduction	Type:	New Item		Final Version			Date:		5/2020	
			PRODUCT INFORMATION						SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	S*		
Company Name: Camber Pharmaceuticals Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.							
Application Number for ND	n Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 204793							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F							
DUNS:	82-667-4775							<del>-,</del>	emperature Range Re	equirement	-			=	
Proprietary Name (If Applica Selling Unit NDC:	31722-636-90	Name: Silodos	in Capsules 8MG 90CT Individual Unit NDC:		UPC:	3317226	38902	- (w	rite in)						
UDI	01122 000 00		CVX Code:		MVX Code:	0017220		Is this p	roduct to be shipped t	o customers	on ice?		No		
Description: White cap/white body size '1' hard gelatin capsules imprinted with 'H' on cap and '52' on body filled with white to off white powder.								Is this product to be shipped to customers on dry ice? No							
			· · · · · · · · · · · · · · · · · · ·								•			_	
Active Ingredient(s): Silodosin								b. Contact for temper Name:	ature excursion ques	stions:	Cama Daiu	Soma Raju			
URL for Additional Product Information: www.camberpharma.com								Numbe	r:		732-529-0423				
Address:	1031 Centennial Avenue Address 2:						Group				heterousa.co	m			
City:	Piscataway  State: NJ Zip: 08854  Customer Service Email: customerservice@camberpharma.com									0			N1-		
Key Contact: Phone Number:	Customer Service 732-529-0430			Fax:	732-562-8788	@camberpr	narma.com	c. Special regulations	returns requirements		ıct?		No No	_	
Product Therapeutic Classif														_	
								d. Store product (unit of sale) upright?							
	AL PRODUCT INFORI	MATION			PRODUCT DESCR	IPTION INF	ORMATION	<b>-</b>	product (unit of sale	e) from light?	?		No	=	
Is the Product		N.						e. Shelf life:	h -16 116 1 1 h - 616				24	Months Months	
a legend device? reverse numbered?		No No	-	Size:	90			initial s	helf life at launch (if	airrerent):				Wonths	
co-licensed?		No	-	Strength:	8 MG				C	ORDER INFO	RMATION				
Is the Product		Direct-Ship Only Unit Dose	-	Ou engin.	O MIC						140	NDC selling			
Is the Product		Unit Dose	-	Dosage Fo	orm: Gelatin o	capsules		Unit of	Bottle		1 box of 24		j unit?		
If Unit Dose, is item bar code	ad to unit does for hos	nital scanning?						x	Box/Carton			.g. 1 Box of 1	10 Vials)		
III '		pital scalling:		Product S	hape: N/A				Ampule				_		
If Unit Dose NDC, indicate N	IDC here:		1						Glass Tube		Minimum o	rder quantity	y?	Yes	
Country of Origin		India		Product C	olor: White				Vial Liquid Sgl						
Is this product covered unde	er the Trade Agreemen	ts Act (TAA)?		Product In	nprint: H/S2			Vial Liquid Multi If Yes, how many of which package type? Vial Powder Sql Each							
							Vial Powder Sql Each Vial Power Multi 24 Inner/Carton/Pack								
				L					Other: Write In	_		Case	#1 don		
			FOR GENERIC DRUG PRODU	CTS											
Authorized Generic *If Authorized 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:				
	eric Equivalent to What Brand?: Rapafio									Each					
		DRUG SUPE	PLY CHAIN SECURITY ACT (DSC	SA) INFORMATION	J			(Write-in, e.g. 1 Vial)				Gram Milliliter			
					wiiiiiitei										
Does supplier meet DSCSA		cturer?	Yes	GLN:					ITEM A	ND PACKING	G INFORMAT	ION			
Is product exempt from DSC If yes, select exemption:	SA?		No							Dime	ensions (US n	nsmts )	Volume		
Other exemption - Write in:	:								Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:	
Is product repackaged?			No		ginal product purcha	sed direct		Item:	0.15		4	2			
Is product sold by manufact Has FDA granted waiver/exc			No No	from mfr?	documentation from F	DΛ		Box/Carton/Bundle/							
rias i DA granted warver/exc	zeption/exemption to	product:	110	ii yes, allacii t	documentation from f	DA.		Inner Pack:							
			GTIN PRODUCT INFORMAT					Case:	4.3	11.5	5	8	0.266	24	
			Sale Level Ur			Quantity	GTIN-14	Pallet:	_						
Serialized?	Yes	х	Item	x 20	Linear	1	00331722636902	Pallet:							
If not, when?			Box/Carton/Bundle/Inner Pack	20				UPC:	Case:		· I		ı	· I	
Items aggregated?	No	х	Case			24	30331722636903		Carton:						
	Pallet 2D Linear						COST INFORMATION WHOLESA					LER USE ONLY:			
				20	Linear										
	2D Linear 2D Linear							Regular Cost				Vendor #:			
		<u> </u>		2E	Linear			Invoice Cost (WAC) (\$ Federal Excise Tax Po		\$90.00	Whsl. Code Fineline Co				
-								As of date:	. Sint or Suite	1					
*Please provide any addition	nal information as se	ao 3	Attach copy of SAFETY DATA SI	HEET (SDS) or non			LABEL AND PHOTO OF PROPERTY CONTROL PROPERTY OF PROPER	ODUCT PACKAGING and E Signatu							
r rease provide any addition	нат плотпаноп оп ра	y <del>c</del> 4.			3ee new p. 3 101	Pesignate	a brop only only.	Signati	nc.						



## **Standard Pharmaceutical Product Information (Page 2)**

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): **SDS Hazard Classification** a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Organic Corrosive No Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard c. Contact Hazard? No 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? No (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? REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: 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? RQ Threshold: Comments / Details: (For example, iPledge program?) Is this a marine pollutant? Nο Is this product shipped utilizing an authorized DOT exception or Special Permit? (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 by Supplier: No SP# PCPDP #: NPI#: No ADD'L STORAGE INFORMATION Is the Product.. Comments Controlled Substance? No Controlled by State(s)? No Registry: ARCOS Reportable? No Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code Listed Chemical (List I or II) No RETURN INSTRUCTIONS If ves. indicate which: 732-529-0430 Is it a scheduled listed chemical product?: No Contact tel. # if product received damaged: CLASS OF TRADE RESTRICTION: Is product returnable for credit: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No 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? No Restricted to hospital, clinics, and physician offices only: No If so, which states? Other requirements? Comments? Restricted from US territories? (explain in comments) No Comments: MISCELLANEOUS 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 Yes	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern							
b. Autofax         No         Fax Number:           c. Fax         Yes         Fax Number:           d. Phone only         No         Phone No.:	Shipping lead time of PO: 24/48 Hours Days							
e. Supplier Web Site only  Minimum Order Quantity:  Supplier's Customer Service Number:  Contracted 3PL company / contact #:  Phone:	Ships same day for next day receipt:  Ships for second day receipt:  Ships regular ground for 3-10 days receipt:  Yes							
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing							
Expedited freight fees billed with each order:  Drop Ship service fee billed with each order:  No	Overnight receipt available:  PO Receipt cut off time:  2:30PM  Eastern							
Drop Ship miscellaneous fees billed:  Comments:	Days of week overnight is available:							
	Priority Overnight receipt available: Yes							
Class of Trade Restriction:	PO Receipt Cut off time: 2:30PM EST							
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:	Saturday Overnight receipt available:         No           PO Receipt Cut off time:         Phone #:           Order receipt method:         Yes         Phone #:         Fax #:         732-562-8788           EDI:         Yes         Yes         Overnight Fees apply:         Yes         No							
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:	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 states?  If so, which states? Other requirements? Comments?							
Miscellaneous Notes:								
	ADDITIONAL INFORMATION							
	Is product order for scheduled patient procedure?  Is product order for restocking purposes?  No							