

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014					Introduction Type	: New Item			Final Version			Date:	3/19	9/2019
			PRODUCT INFORMATION						SPECIAL HANDL	ING AND ST	RAGE REQ	UIREMENTS	*	
Company Name:	Camber Pharmaceuti	cale			Applicat	ion: ANDA		a. Temperature – Indica	to the LICE temper	oturo rongo	or this prod	unt		
Application Number for ND) -	209908	Аррисан	70070		Temperature – indica		ature range			en 20 and 25	5 C (68° – 77° F
		mAro ro(k)(med device)	<i>y</i> .	200000				· ·	=		Controlled		011 20 4114 20	0 (00 11 1
DUNS:	82-667-4775								perature Range Re	quirement				-
Proprietary Name (If Applical		Name: Tadalafil	Tablets 5mg 30ct		UPC: 33	1722644303		(writ	e in)					1
Selling Unit NDC:	31722-644-30		Individual Unit NDC:			1/22644303		La di Carana	Access to a Maria de					
UDI			CVX Code:		MVX Code:			· ·	duct to be shipped to				No	_
Description:	Round shape concav	e punches embossed with	i 'H' on lower punch and 'T17' on t	ipper punch.				Is this pro	duct to be shipped to	o customers o	n dry ice?		No	_
Active Ingredient(s):		Tadalafil						b. Contact for temperat	ure excursion que	stions:				
UDL for Additional Box book by								Name:			Soma Raju 732-529-04	22		
URL for Additional Product In Address:				Address 2:			Number: Group E-mail:			732-529-0423 somaraju@heterousa.com				
City:	1031 Centennial Avenue Piscataway State:							Group E-	maii:		somaraju@r	ieterousa.coi	11	
Key Contact:	Customer Service				Email: customerservice@camberpharma.com Fax: 732-562-8788			c Special regulations for	or product in any s	tatos?			No	No
Phone Number:	732-529-0430							c. Special regulations for product in any states? Special returns requirements for this produ						
Product Therapeutic Classifi					02 002 0.00			oposiai re	tarrio roquirornonio i	ioi uno produc	••			-
Product Therapeutic Classiii	ication.							d Ctara mandered (comit a	f a a l a \				Ne	
ADDITIONA	AL PRODUCT INFORM	ATION	1	DD	ODUCT DESCRIPTIO	NINEORMATION		d. Store product (unit o	r sale) uprignt? roduct (unit of sale	a) from liabt?			No No	_
	AL PRODUCT IN ORW	ATION		r ix	ODOCT DESCRIPTIO	N IN ORMATION			roduct (unit or sale	e) iroin light?			INU	=
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a legend device?		No		Size:	30CT			Initial she	If life at launch (if o	different):			L	Months
reverse numbered?		No No								ORDER INFO	MATION			
co-licensed?		Direct-Ship Only		Strength:	5MG					JRDER INFO	RIMATION			
Is the Product Is the Product		Unit Dose						Unit of Sa	ulo.		What is the	NDC selling	unit?	
is the Froduct		Offit DOSC		Dosage Form:	Tablet				Bottle		1 box of 24		unit.	
									Box/Carton			g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar code	ed to unit dose for hosp	tal scanning?							Ampule		(g	,	
If Unit Dose NDC, indicate NI	DC here:			Product Shape:	Round				Glass		Minimum o	rder quantity	1?	Yes
				Product Color:	White				Tube					-
Country of Origin		India		Product Color:	vvnite				Vial Liquid Sgl					
Is this product covered under	r the Trade Agreements	Act (TAA)2		Product Imprint:	T17 / H				Vial Liquid Multi		If Yes, how	many of whi	ich package	type?
is this product covered under	i the fraue Agreements	ACI (IAA):		1 Todact Imprint.	117711				Vial Powder Sql			Each		
]						Vial Power Multi		24	Inner/Cartor	/Pack	
									Other: Write In	_		Case		
			FOR GENERIC DRUG PRODU	318				ļ						
									DHAD	MACY ORDE	D / DILL LINI	,		
				Authoriz		Authorized Generic, other sect	ction			RMACY ORDE				
I. Orange Book Rating:	AB	Tax		Authoriz		Authorized Generic, other sect ds are not applicable	ction	Rec. sell unit to custom		RMACY ORDE		nit to pharm	асу:	
I. Orange Book Rating: II. Generic Equivalent to Wha		Cialis		Authoriz			ction			RMACY ORDE		nit to pharm Each	асу:	
			V CHAIN SECURITY ACT /DSC				ction	Rec. sell unit to custom (Write-in, e.g. 1 Vial)		RMACY ORDE		nit to pharm Each Gram	асу:	
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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			