

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014						Intro	oduction Typ	pe:	New Item			Final Version			Date:	1/18	3/2018
PRODUCT INFORMATION										SPECIAL HANDLING AND STORAGE REQUIREMENTS*							
Company Name: Camber Pharmaceuticals Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.									
Application Number for ND	DA/ANDA/BLA (drug); PMA/510(k)(med device):			07418			Temperature Range Co				Controlled Room – between 20 and 25 C (68° – 77° F						
DUNS:	82-667-4775			_						Other Te	mperature Range Re	auirement					
Proprietary Name (If Applica	Applicable) and Established Name: Oxycodone Hydrochloride Tablets 15MG 100CT			MG 100CT							ite in)						
Selling Unit NDC:	31722-917-01		Individual Unit NDC:					317229170	018		·						_
UDI CVX Code:					MVX	Code:				Is this pr	oduct to be shipped to	o customers o	n ice?		No	_	
Description: Light yellow, round biconvex, beveled edge tablets debossed with 'T' and break line on					one side and '188' on other				Is this product to be shipped to customers on dry ice?				No	_			
Constant Indiana												_					
Active Ingredient(s): Oxycodone Hydrochloride								b. Contact for tempera Name:	Soma Raiu								
URL for Additional Product Information: www.camberpharma.com			om							Number	732-529-0423						
Address:					Address 2:					Group E-mail:				somaraju@heterousa.com			
City:	Piscataway				State: NJ Zip: 08854												
Key Contact:	Customer Service				Email: customerservice@camberpharma.com						c. Special regulations for product in any states?						
Phone Number:	732-529-0430				Fax: 732-562-8788						Special returns requirements for this product						_
Product Therapeutic Classifi	ication:																
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION									MATION		d. Store product (unit of sale) upright?						_
				FRODUCT DESCRIPTION INFORMATION					Protect product (unit of sale) from light?				24 Month				
Is the Product a legend device?		No				ſ					e. Shelf life:	olf life at launch (if a	different).			24	Months Months
reverse numbered?	No			Size: 100				Initial shelf life at launch (if different):						WOILLIS			
co-licensed?	No				Strength: 15MG						ORDER INFORMATION						
Is the Product		Direct-Ship Only			Strength:		TOIVIG										
Is the Product		Unit Dose			Dosage Form:		Tablets				Unit of S				NDC selling	unit?	
										Bottle		1 box of 24	.g. 1 Box of 1	O Viele)			
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?								- 111	x	Box/Carton Ampule		(vviite-iii, e	.g. 1 box 01 1	U VIAIS)	
If Unit Dose NDC, indicate N	IDC here:				Product Shape: Round							Glass		Minimum o	rder quantity	/?	
					Product Color: Yellow							Tube					
Country of Origin		United States	-			-				_		Vial Liquid Sgl		W. W			
Is this product covered under the Trade Agreements Act (TAA)?					Product Imprint: T'/188'				Vial Liquid Multi If Yes, how many of which package type? Vial Powder Sql Each					type?			
									Vial Power Multi			Inner/Cartor	n/Pack				
												Other: Write In		1	Case		
FOR GENERIC DRUG PRODUCTS																	
Authorized Generic *If Authorized Generic, other section PHARMACY ORDER / BILL UNIT																	
10 0 10 11				Authorized Generic *If Authorized Generic, other section fields are not applicable			on										
I. Orange Book Rating: II. Generic Equivalent to What Brand?: Roxicodone				noted are not approache					Rec. sell unit to customer?			Rx billing unit to pharmacy: Each					
II. Control Equitation to What Brand I.										(Write-in, e.g. 1 Vial)			Gram				
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION									(" , " , " , " , " , " , " , " , " , "				Milliliter				
													ID D 4 0 (1) 10				
Does supplier meet DSCSA (Is product exempt from DSC		urer?	Yes No	GL	.N:							IIEM AF	ND PACKING	INFORMAT	ION		
If yes, select exemption:	SAY		INU										Dimer	sions (US n	nsmts.)	Volume	
Other exemption - Write in:									1			Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:
Is product repackaged?			No		Yes, was origina	al product	purchased	direct			Item:	0.06		2.935	1.562		
Is product sold by manufact			No		om mfr?		FD.4				D101011-1						
Has FDA granted waiver/exc	eption/exemption for	product?	No	IT)	es, attach docu	umentation	n from FDA.				Box/Carton/Bundle/ Inner Pack:					0	
			GTIN PRODUCT INFORM	MATION							Case:	4.0	40.0	7	0.0	0.11	0.4
				Saleable								1.9	10.8	/	3.2	0.14	24
			Level	Unit			_	Quantity	GTIN-14		Pallet:						
Serialized?	Yes	X	Item Box/Carton/Bundle/Inner Pack	V	X 2D 2D		Linear	1	00331722917018 10331722917015	_	upo	C				<u> </u>	
If not, when? Items aggregated?	No	х	Case	Х	X 2D 2D		Linear	24	10331722917015	-	UPC:	Case: Carton:					
	Pallet 2D Linear																
]]	2D Linear							COST	WHOLESALER USE ONLY:								
					2D		Linear										
				2D 2D	-	Linear			-	Regular Cost			Vendor #: Whsl. Code #:				
]]		<u> </u>			2D	igsquare	ruesi			-	Invoice Cost (WAC) (\$) Federal Excise Tax Pe		\$15.4U	Fineline Co			
											As of date:	Jill Of Jale					
			Attach copy of SAFETY DAT	A SHEET (S	SDS) or non haza	ard letter, F	PACKAGE IN	ISERT, LAI	BEL AND PHOTO OF	PROD	OUCT PACKAGING and B	ARCODE.					
*Please provide any addition	nal information on pag	e 2.				See new	v p. 3 for Des	signated D	Orop Ship Only.		Signatur	re:					



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? Yes Controlled by State(s)? Yes Registry: ARCOS Reportable? Yes Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code CII-Oxycodone 9143 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: No 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) No Comments:	Saturday Overnight receipt available: No PO Receipt Cut off time: Phone: No Phone: Phone #: Fax #: Fax: Yes Fax #: Formight Fees apply: Yes Other fees apply: 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								