

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014							Intro	duction Type:	New Item		Final Version			Date:	4/19	/2017
				PRODUCT INFORM	IATION						SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	*	
Company Name: Camber Pharmaceuticals					Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.								
Application Number for ND	A/ANDA/BLA (drug);	PMA/510(k)(med	d device):		2	07419			•	Tempera	ature Range		Controlled R	loom – betwe	en 20 and 25	C (68° $-$ 77° F
DUNS:	82-667-4775									Other Te	emperature Range Re	equirement				
Proprietary Name (If Applica	ble) and Established	Name:	Oxycodone	and Acetaminophen Ta						(wr	ite in)]
Selling Unit NDC:	31722-949-05			Individual Unit NDC	:	31722-949-05		UPC: 33172294	9057							
UDI				CVX Code:			MVX	Code:		Is this pr	oduct to be shipped t	to customers	on ice?		No	-
Description: White, round, biconvex tablets with break line on one side and debossed with 'T 192' on other							Is this product to be shipped to customers on dry ice? No									
Active Ingredient(s): Oxycodone and Acetaminophen						b. Contact for temperature excursion questions: Name: Soma Raju										
URL for Additional Product Information: www.camberpharma.com								Number	:		732-529-042	23				
Address:					Address 2:				Group E			somaraju@h	neterousa.com	n		
City:	Piscataway				State: NJ Zip: 08854											
Key Contact:	Customer Service 732-529-0430					Email: customerservice@camberpharma.com			c. Special regulations for product in any states? No Special returns requirements for this product? No				-			
Phone Number: Product Therapeutic Classifi						Fax: 732-562-8788							-			
Product Therapeutic Classifi	ication:									d. Store product (unit of sale) upright? No						
ADDITIONA	L PRODUCT INFORM						PRODUCT	DESCRIPTION INFO	RMATION	d. Store product (unit of sale) upright? No Protect product (unit of sale) from light? No						
Is the Product							e. Shelf life:				24	Months				
a legend device?			No				ſ				helf life at launch (if	different):			24	Months
reverse numbered?			No			Size:	E	500				-				1
co-licensed?		1	No			Strength:	F	5MG/325MG			C	ORDER INFO	RMATION			
Is the Product		Direct-Ship Onl	ly			ou chigan.		MIG/0201110								
Is the Product		Unit of Use				Dosage Form:	: t	ablet		Unit of S				NDC selling	unit?	
							L			x	Bottle Box/Carton		1 box of 12 l	g. 1 Box of 1	0 \/iale)	
If Unit Dose, is item bar code	ed to unit dose for hosp	bital scanning?					Г				Ampule		(White hi, e.	g. 1 Dox 01 1	0 100)	
If Unit Dose NDC, indicate N	DC here:					Product Shape: round				Glass Minimum order quantity?			Yes			
		,				Product Color	r: V	White to Off White			Tube					
Country of Origin		United States					-			Vial Liquid Sgl Vial Liquid Multi If Yes, how many of which package type?						
Is this product covered under	r the Trade Agreement	ts Act (TAA)?				Product Imprint: T 192'			Vial Equid Walth Vial Powder Sql Each				type :			
		-								Vial Power Multi 12 Inner/Carton/Pack						
-											Other: Write In	_		Case		
			, F	FOR GENERIC DRUG F	PRODUCTS					-						
						Auth	orized Gene	eric *If Author	ized Generic, other section	PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating:	L Orange Book Rating: AB				fields are not applicable				Rec. sell unit to customer? Rx billing unit to pharmacy:				acv.			
II. Generic Equivalent to What Brand?: Percocet												Each				
								(Write-in, e.g. 1 Vial)		_		Gram				
		DRUG	G SUPPLY	CHAIN SECURITY AC	T (DSCSA) IN	IFORMATION								Milliliter		
Does supplier meet DSCSA	definition of manufac	turer?		Yes	G	LN:					ITEM A	ND PACKING	G INFORMATI	ON		
Is product exempt from DSC			No	0												
If yes, select exemption:											Weight Lbs.		nsions (US m		Volume	# Pieces:
Other exemption - Write in: Is product repackaged?			No	0	14	Ves was origin	al product	purchased direct		Item:		Depth	Height	Width	(Cube)	
Is product sold by manufact	urer's exclusive distri	ibutor?	140	No		om mfr?		purchased unect		item.	0.58		5.56	3.1		
Has FDA granted waiver/exc				No	lf	yes, attach doci	umentation	from FDA.		Box/Carton/Bundle/	14.8	13	6.5	9.8	0.479	12
					DMATION					Inner Pack:						
				GTIN PRODUCT INFO	Saleable					Case:						
				Level	Unit			Quantity	GTIN-14	Pallet:						
Serialized?	Yes	Г	X Ite	em		X 2D	1	Linear 1	00331722949057							
If not, when?				ox/Carton/Bundle/Inner Pack	x	X 2D		Linear 12	10331722949054	UPC:	Case:					
Items aggregated?	No	_ [ase		2D		Linear			Carton:					
Pallet 2D Linear						COST INFORMATION WHOLESALER USE ONLY:										
		ŀ				2D 2D		Linear			IN ORMATION			MIOLEGAL	LR OSL ONL	
		ŀ				2D 2D		Linear		Regular Cost			Vendor #:			
			2D			Linear					5 Whsl. Code #:					
		-								Federal Excise Tax Pe	r Unit of Sale		Fineline Co	de:		
										As of date:						
							and latter D				400005		<u> </u>			
*Please provide any addition	al information on no	no 2	Att	acti copy of SAFETY D	ATA SHEET	ອບອ) or non haza				ODUCT PACKAGING and B						
*Please provide any addition	ai mormation on pag	ye 2.					See new	p. 3 for Designated	a brop Ship Only.	Signatu	ie.					



Standard Pharmaceutical Product Information (Page 2)

	nated Drop Ship Only Products, Please Use Page 3 HAZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply):						
a. Cytotoxic? No	SDS Hazard Classification					
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?						
Is the product a CA Prop 65 carcinogen? No	Organic Corrosive					
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?						
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS					
Passenger	Is there a REMS on this product? No					
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? No						
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					
	NPI #: No					
ADD'L STORAGE INFORMATION						
Is the Product	Comments					
Controlled Substance? Yes						
Controlled by State(s)? Yes	Registry: No					
ARCOS Reportable? Yes	Registry Program Contact Name: Phone:					
Schedule No. (inc. N for non-narcotic) n/a	Comments					
Controlled Substance Code CII- Oxycodone 9143						
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: Yes					
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:						
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:					



Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRO	DUCT ONLY - if n	ot a designated drop ship, do not con	nplete.	
Order Method for Designated Drop Ship Product		Standard	Order Receipt and Proces	sing
Purchase orders may be accepted by: a. EDI Yes b. Autofax No Fax Number:		Purchase order daily receipt cut off Cut off time:	time by supplier 2:30PM	Eastern
No Par Number. c. Fax Yes d. Phone only No e. Supplier Web Site only No Site Address:		Shipping lead time of PO: Ships same day for next day receipt:	24/48 Hours	Days
Minimum Order Quantity: case pack Supplier's Customer Service Number: 732-529-0430 x466 x465 x467 x470 Contracted 3PL company / contact #: Name: Phone:		Ships for second day receipt: Ships regular ground for 3-10 days red		No Yes
Expedited Freight Charges or Other Designated Drop Ship Fees:		Overnight and	Priority Overnight PO Pro	ocessing
Expedited freight fees billed with each order: No		Overnight receipt available:		Yes
Drop Ship service fee billed with each order: No		PO Receipt cut off time:	2:30PM	Eastern
Drop Ship miscellaneous fees billed: No Comments:		Days of week overnight is availal		xMondayxTuesdayxWednesdayxThursdayxFriday
		Priority Overnight receipt available:		Yes
Class of Trade Restriction: 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:	Yes Yes No No	PO Receipt C Saturday Overnight receipt availabl PO Receipt C Phone: Fax: EDI: Overnight Fees apply: Other fees apply:	e: ut off time: Yes Phone #: Yes Fax #: Yes 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 damage Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirer If so, which states? Other requirem	nents for this product in certa	732-529-0430 Yes ain states? Yes
		ADI	DITIONAL INFORMATION	
	Is product order for scheduled patient Is product order for restocking purpose	No No		