

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

© August 2014							Intro	duction Typ	e:	New Item		Final Version			Date:	4/19	/2017
				PRODUCT INFORM	MATION							SPECIAL HANDLI	NG 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)(me	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	quirement				_
Proprietary Name (If Applica		Name:	Oxycodone	and Acetaminophen T							(w	rite in)					]
Selling Unit NDC:	31722-949-01			Individual Unit NDC	>:	31722-949-01			3172294901	9	- II						
UDI				CVX Code:	_		WVX	Code:				oduct to be shipped to				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 I	nformation:	www.camberph	arma.com								Number	:		732-529-042	23		
Address:					Address 2:				Group E				neterousa.cor	n			
City:	Piscataway			State: NJ Zip: 08854													
Key Contact:	Customer Service				Email: customerservice@camberpharma.com Fax: 732-562-8788			c. Special regulations for product in any states?         No           Special returns requirements for this product?         No				-					
Phone Number:	732-529-0430				Fax: 732-562-8788							-					
Product Therapeutic Classifi	ication:										d Stave weeduct (unit of cale) unviews?						
ADDITIONA	L PRODUCT INFOR	MATION					PRODUCT	DESCRIPTIC		ATION	d. Store product (unit of sale) upright? No Protect product (unit of sale) from light? No						
Is the Product											e. Shelf life:	product (unit of Sale	/ nom ngm.		i	24	Months
a legend device?			No				Г					nelf life at launch (if o	different).			24	Months
reverse numbered?			No			Size:		100									
co-licensed?			No			Strength:	Ī	5MG/325MG				0	RDER INFO	RMATION			
Is the Product		Direct-Ship On	ly			ou engin.	Ĺ	0110/020110									
Is the Product		Unit of Use				Dosage Form	<b>:</b>	tablet			Unit of S				NDC selling	unit?	
							L				x	Bottle Box/Carton		1 box of 24 I	g. 1 Box of 1	0 \/iale)	
If Unit Dose, is item bar code	ed to unit dose for hos	pital scanning?					Г					Ampule		(winte-in, e.	g. i box oi ii	0 viais)	
If Unit Dose NDC, indicate N	DC here:					Product Shap	be:	round				Glass		Minimum o	rder quantity	?	Yes
						Product Colo	r:	White to Off V	Nhite			Tube					
Country of Origin		United States					-					Vial Liquid Sgl Vial Liquid Multi		K Vee herr		-h	
Is this product covered under	r the Trade Agreemen	ts Act (TAA)?				Product Imprint: T 192'			Vial Liquid Multi If Yes, how many of which package type? Vial Powder Sql Each			type?					
							L					Vial Power Multi		24	Inner/Carton	/Pack	
												Other: Write In	_		Case		
			F	FOR GENERIC DRUG	PRODUCTS						_						
						Auth	orized Gen	eric *If		Generic, other section		PHAR	MACY ORD	FR/BILLUNI	т		
L Orongo Book Pating	AB				-	////			elds are not		PHARMACY ORDER / BILL UNIT Rec. sell unit to customer? Rx billing unit to pharmacy:						
	I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: Percocet			_					Rec. seit unit to custo		1	KX billing u	Each	acy.			
									(Write-in, e.g. 1 Vial)		_		Gram				
		DRU	G SUPPLY	CHAIN SECURITY AC	T (DSCSA) IN	IFORMATION									Milliliter		
D				Yes		iLN:					-				ON		
Does supplier meet DSCSA of Is product exempt from DSC		turer?	No		_ 0	LN:					ITEM AND PACKING INFORMATION						
If yes, select exemption:				-								Weight   he	Dime	ensions (US m	ismts.)	Volume	# Pieces:
Other exemption - Write in:												Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:
Is product repackaged?			No			Yes, was origin	al product	purchased of	lirect		Item:	0.14		3.225	1.835		
Is product sold by manufactu Has FDA granted waiver/exc				No No		om mfr? yes, attach doc	umentation	n from FDA			Box/Carton/Bundle/						
Thas I by granted warver/exe	ephoniexemption for	product:		110	- "	yes, attach 400	amentation	in noin i bA.			Inner Pack:	3.11	12.3	3.8	8.3	0.225	24
				GTIN PRODUCT INFO	RMATION						Case:	1					
					Saleable												
			<u> </u>	Level	Unit	<b>x</b> 2D				GTIN-14	Pallet:						
Serialized? If not, when?	Yes	-	x Ite	em ox/Carton/Bundle/Inner Pack	x	x 2D x 2D		Linear		00331722949019 10331722949016	UPC:	Case:					
Items aggregated?	No	_		ase	^	2D 2D		Linear	24	10331722343010	UFC.	Carton:					
		-		allet		2D		Linear			<sup></sup>						
						2D		Linear			COST	INFORMATION			WHOLESAL	ER USE ONI	.Y:
						2D		Linear									
					-	2D 2D		Linear			Regular Cost		£10.07	Vendor #:	<i>#</i> .		
				20 Lr			Linear			Invoice Cost (WAC) (\$ Federal Excise Tax Pe		\$10.07	Whsl. Code Fineline Co				
											As of date:						
			Att	ach copy of SAFETY D	ATA SHEET	(SDS) or non haz	ard letter, F	PACKAGE IN	SERT, LAB	EL AND PHOTO OF PRO	ODUCT PACKAGING and B	ARCODE.					
*Please provide any addition	al information on pa	ge 2.					See new	v p. 3 for Des	ignated Dr	op Ship Only.	Signatu	re:					



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

	ated Drop Ship Only Products, Please Use Page 3						
MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS Hazard Classification						
Is the product a CA Prop 65 carcinogen? No Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning?	Organic     Corrosive       Inorganic     Oxidizer       Steroid/Androgen     Contact Hazard						
c. Contact Hazard? No d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No	Aerosol Class; Identify NFPA Storage Level:						
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						
SF#							
	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						
	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:							
Comments.							
	NEOUS NOTES and/or Image of Product Barcode:						
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	<b>Order Receipt and Proces</b>	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