



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2024

Introduction Type: New Item☒ Final VersionDate: 3/16/2026

PRODUCT INFORMATION	
Company Name:	Camber Pharmaceuticals, Inc.
Application Number for NDA/ANDA/BLA; PMA/510(k):	207419
Medical Device Class, if applicable:	
DUNS:	11-856-3719
Proprietary Name (If Applicable) and Established Name:	Oxycodone and Acetaminophen Tablets, USP 5 mg/325 mg
Selling Unit NDC:	31722-949-05
UDI	
Description:	Oxycodone and Acetaminophen Tablets, USP 5 mg/325 mg
Active Ingredient(s):	Oxycodone hydrochloride, USP, acetaminophen, USP
URL for Additional Product Information:	www.camberpharma.com
Address:	800 Centennial Ave, Suite 1
City:	Piscataway
Key Contact:	Customer Service
Phone Number:	1-866-827-3647
Product Therapeutic Classification:	Combination full opioid agonist, and non-opioid, non-salicylate analgesic and antipyretic

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product...	Direct-Ship Only
a legend device?	No	Is the Product...	Neither
if yes, enter class #		Orphan Drug Status	
a product kit?	No	FDA Approval Status	
if yes, list NDCs of component parts		Allergens Present	Dye, Corn, Alcohol, Animal
reverse numbered?	No	Country of Origin	USA
co-licensed?	No	Is this product covered under the Trade Agreements Act (TAA)?	Yes
latex-free?	Yes		
preservative-free?	Yes		
correctional institution block?	No		
opioid?	Yes		
Cannabinoid?	No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?			
If Unit Dose, indicate NDC here:			

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AA
II. Generic Equivalent to What Brand?:	Percocet
	☐ Authorized Generic
	*If Authorized Generic, other section fields are not applicable

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	Yes
Has FDA granted waiver/exception/exemption for product?	No
If yes, attach documentation from FDA.	

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14
X Item/Each	N	1		00331722949057
Box/ Carton/ Bundle/ Inner Pack				
X Case	N	12		10331722949054
Pallet				

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature - Indicate the USP temperature range for this product.	
Temperature Range	Controlled Room - between 20 and 25 C (68° - 77° F)
Other Temperature Range Requirement (write in)	
Notes	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
b. Contact for temperature excursion questions:	
Name:	Soma Raju
Number:	732-529-0423
Group E-mail:	somaraju@heterousa.com
c. Special regulations for product in any states?	*Yes
Special returns requirements for this product?	*Yes
d. Store product (unit of sale) upright?	No
Protect product (unit of sale) from light?	No
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	Months

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
x Bottle	1 Bottle of 500 Tablets
Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
Ampule	
Glass	
Tube	
Vial Liquid Sgl	
Vial Liquid Multi	
Vial Powder Sgl	
Vial Powder Multi	
Other: Write In	
	Minimum order quantity? Yes
	If Yes, how many of which package type?
	12 Each
	Inner/ Carton/ Pack
	Case

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
(Write-in, e.g. 1 Vial)	Each
HCP/CS J-Code:	Gram
	Milliliter

ITEM AND PACKING INFORMATION						
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
	Depth	Width	Height			
Item/Each:	0.58	3.1	3.1	5.56	53.43	1
Box/ Carton/ Bundle/ Inner Pack:						
Case:	7.4	13	9.8	6.5	828.1	12
Pallet:						

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$50.35	Whsl. Code #:	
As of date:	3/14/2019	Fineline Code:	

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



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For Designated 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? Is the product a CA Prop 65 carcinogen? ☐ No Is the product a CA Prop 65 reproductive toxicant? ☐ No Does the product label bear a CA Prop 65 warning? ☐ No 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 Is this product regulated for shipment by DOT? ☐ No (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? ☐ Is this product regulated for shipment by IATA? ☐ No (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? ☐ Is the product restricted for air shipment? If so, indicate restriction: ☐ No ☐ Passenger ☐ Cargo ☐ Passenger & Cargo Is this a reportable quantity? ☐ No RQ Threshold: Is this a marine pollutant? ☐ No Is this product shipped utilizing an authorized DOT exception or Special Permit? ☐ No (if yes, identify method below) ☐ Limited Quantity ☐ Consumer Commodity, ORM-D ☐ Small Quantity (49 CFR 173.4) ☐ Special Permit; DOT-SP ☐ Special Provision (listed in Column 7 of 49 CFR 172.101); SP#		SDS Hazard Classification <table style="width: 100%;"><tr><td>☒ Organic</td><td>☐ Corrosive</td></tr><tr><td>☐ Inorganic</td><td>☐ Oxidizer</td></tr><tr><td>☐ Steroid/Androgen</td><td>☐ Contact Hazard</td></tr></table> Does the product have an Aerosol class? If yes, identify NFPA Storage Level: ☐ No NFPA Storage Level: Is the product a NIOSH hazardous drug? ☐ No If yes, indicate which: Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? ☐ Yes If Yes, is it managed with a pharmacy registry? ☐ No Website URL: www.OpioidAnalgesicREMS.com Med Guide Required ☐ Yes Limited Distribution Requirement ☐ No Comments / Details: (For example, iPledge program?) REMS: REMS Program Manager Name: Syneos Health Phone: 800-503-0784 Supplier Manages REMS registry exclusively: ☐ No Wholesale distributor support: ☐ No Provider Name: DEA #: Site Enrollment Number assigned by Supplier: NCPDP#: NPI #: Comments Registry: Registry Program Contact Name: No Phone: Comments		☒ Organic	☐ Corrosive	☐ Inorganic	☐ Oxidizer	☐ Steroid/Androgen	☐ Contact Hazard										
☒ Organic	☐ Corrosive																		
☐ Inorganic	☐ Oxidizer																		
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ADD'L STORAGE INFORMATION																			
Is the Product... <table style="width: 100%;"><tr><td>Controlled Substance?</td><td>☐ Yes</td><td>Controlled Substance Code</td><td> 9143</td></tr><tr><td>Controlled by State(s)?</td><td>☐ Yes</td><td>Listed Chemical (List I or II)</td><td>☐ No</td></tr><tr><td>ARCOS Reportable?</td><td>☐ Yes</td><td>If yes, indicate which:</td><td> </td></tr><tr><td>Schedule No.</td><td> 2</td><td>Is it a scheduled listed chemical product?:</td><td>☐ No</td></tr></table>		Controlled Substance?	☐ Yes	Controlled Substance Code	9143	Controlled by State(s)?	☐ Yes	Listed Chemical (List I or II)	☐ No	ARCOS Reportable?	☐ Yes	If yes, indicate which:		Schedule No.	2	Is it a scheduled listed chemical product?:	☐ No	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: ☐ Yes URL/Link to returns policy: contact - customerservice@camberpharma.com Special regulations or returns requirements for this product in certain states? ☐ Yes If so, which states? Other requirements? Comments? DEA Form 222 or its electronic equivalent is required for all returns in all states.	
Controlled Substance?	☐ Yes	Controlled Substance Code	9143																
Controlled by State(s)?	☐ Yes	Listed Chemical (List I or II)	☐ No																
ARCOS Reportable?	☐ Yes	If yes, indicate which:																	
Schedule No.	2	Is it a scheduled listed chemical product?:	☐ No																
CLASS OF TRADE RESTRICTION:																			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices ☐ Yes Restricted to retail pharmacy only: ☐ No Restricted to hospital, clinics, and physician offices only: ☐ No Restricted from US territories? (explain in comments) ☐ No Comments:																			
MISCELLANEOUS NOTES and/or Image of Product Barcode:																			
*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part 1301.72.																			

Release DATE



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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: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone: Fax Number: Fax Number: Phone No.: Site Address:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight and Priority Overnight PO Processing Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday Priority Overnight receipt available: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Phone #: Fax: Fax #: EDI: Overnight Fees apply: Other fees apply:
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:	
Other Data Information Required to Process PO: Patient Procedure Date: Physician Name: Physician/Clinic Phone #: Physician State License #: Physician/Clinic DEA #: Physician/Clinic Specialty:	Return Instructions 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?