



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

Version 2024

Introduction Type: New Item☒ Final VersionDate: 5/17/2025**PRODUCT INFORMATION**

Company Name:	Camber Pharmaceuticals, Inc.	Application:	ANDA
Application Number for NDA/ANDA/BLA; PMA/510(k):	207419	NDA 505(b) Type:	NOT APPLICABLE
Medical Device Class, if applicable:			
DUNS:	11-856-3719		
Proprietary Name (If Applicable) and Established Name:	Oxycodone and Acetaminophen Tablets, USP 10 mg/325 mg		
Selling Unit NDC:	31722-951-05	Unit of Use NDC:	331722951050
UDI		CVX Code:	
		MVX Code:	
Description:	Oxycodone and Acetaminophen Tablets, USP 10 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	Address 2:	
City:	Piscataway	State:	NJ
Key Contact:	Customer Service	Zip:	08854
Phone Number:	1-866-827-3647	Email:	customerservice@camberpharma.com
		Fax:	732-562-8788
Product Therapeutic Classification:	Combination full opioid agonist, and non-opioid, non-salicylate analgesic and antipyretic		

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?	<input type="text"/> No
Is this product to be shipped to customers on dry ice?	<input type="text"/> 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?	
Special returns requirements for this product?	<input type="text"/> *Yes
	<input type="text"/> *Yes
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="text"/> No
e. Shelf life:	<input type="text"/> No
Initial shelf life at launch (if different):	<input type="text"/> 24 Months

ADDITIONAL PRODUCT INFORMATION

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

PRODUCT DESCRIPTION INFORMATION

Size:	500 ct
Strength:	10 mg/325 mg
Dosage Form:	Tablet
Product Shape:	Capsule
Product Color:	White to off-white
Product Imprint:	Debossed with 'T 194' on one side and plain on other side

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating:	AA	<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable
II. Generic Equivalent to What Brand?:	Percocet		

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	<input type="text"/> Yes	GLN:	0843368117603
Is product exempt from DSCSA?	<input type="text"/> No	GCP:	
If yes, select exemption:		If yes, was original product purchased direct from mfr?	<input type="text"/>
Other exemption - Write in:		Provide source manufacturer for repackaged product	
Is product repackaged?	<input type="text"/> No		
Is product sold by manufacturer's exclusive distributor?	<input type="text"/> Yes		
Has FDA granted waiver/exception/exemption for product?	<input type="text"/> 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	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	N	1		00331722951050	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack					
<input checked="" type="checkbox"/> Case	N	12		10331722951057	
<input type="checkbox"/> Pallet					

ORDER INFORMATION

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

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text"/>	<input type="text"/> Each
(Write-in, e.g. 1 Vial)	<input type="text"/> Gram
HCP/CS J-Code:	<input type="text"/> Milliliter

ITEM AND PACKING INFORMATION

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

COST INFORMATION

Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$100.70	Whsl. Code #:	
As of date:	3/14/2019	Fineline Code:	

WHOLESALE USE ONLY:

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?	<input type="checkbox"/> No		
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	<input type="checkbox"/> No		
Is the product a CA Prop 65 carcinogen?	<input type="checkbox"/> No		
Is the product a CA Prop 65 reproductive toxicant?	<input type="checkbox"/> No		
Does the product label bear a CA Prop 65 warning?	<input type="checkbox"/> No		
c. Contact Hazard?	<input type="checkbox"/> No		
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	<input type="checkbox"/> No		
e. Does the product contain DEHP?	<input type="checkbox"/> No		
Is this product regulated for shipment by DOT? (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?	<input type="checkbox"/> No		
Is this product regulated for shipment by IATA? (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?	<input type="checkbox"/> No		
Is the product restricted for air shipment? If so, indicate restriction:			
<input type="checkbox"/> Passenger			
<input type="checkbox"/> Cargo			
<input type="checkbox"/> Passenger & Cargo			
Is this a reportable quantity? <input type="checkbox"/> No			
RQ Threshold: <input type="text"/>			
Is this a marine pollutant? <input type="checkbox"/> No			
Is this product shipped utilizing an authorized DOT exception or Special Permit?			
<input type="checkbox"/> No (if yes, identify method below)			
<input type="checkbox"/> Limited Quantity			
<input type="checkbox"/> Consumer Commodity, ORM-D			
<input type="checkbox"/> Small Quantity (49 CFR 173.4)			
<input type="checkbox"/> Special Permit; DOT-SP			
<input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);			
SP# <input type="text"/>			
ADD'L STORAGE INFORMATION			
Is the Product...			
Controlled Substance?	<input type="checkbox"/> Yes	Controlled Substance Code	9143
Controlled by State(s)?	<input type="checkbox"/> Yes	Listed Chemical (List I or II)	<input type="checkbox"/> No
ARCOS Reportable?	<input type="checkbox"/> Yes	If yes, indicate which:	
Schedule No.	2	Is it a scheduled listed chemical product?:	<input type="checkbox"/> No
CLASS OF TRADE RESTRICTION:			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		<input type="checkbox"/> Yes	
Restricted to retail pharmacy only:		<input type="checkbox"/> No	
Restricted to hospital, clinics, and physician offices only:		<input type="checkbox"/> No	
Restricted from US territories? (explain in comments)		<input type="checkbox"/> No	
Comments: <input type="text"/>			
SDS Hazard Classification			
<input checked="" type="checkbox"/> Organic	<input type="checkbox"/> Corrosive		
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer		
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard		
Does the product have an Aerosol class? If yes, identify NFPA Storage Level:		<input type="checkbox"/> No	
NFPA Storage Level: <input type="text"/>			
Is the product a NIOSH hazardous drug?		<input type="checkbox"/> No	
If yes, indicate which: <input type="text"/>			
Hazardous Waste Identification			
EPA Hazardous Waste Code: <input type="text"/>		Waste Characteristics <input type="text"/>	
REMS or REGISTRY RESTRICTIONS			
Is there a REMS on this product?		<input type="checkbox"/> Yes	
If Yes, is it managed with a pharmacy registry?		<input type="checkbox"/> No	
Website URL:		https://opioidanalgesicrems.com/home.html	
Med Guide Required		<input type="checkbox"/> Yes	
Limited Distribution Requirement		<input type="checkbox"/> No	
Comments / Details: (For example, iPledge program?)		<input type="text"/>	
REMS:		<input type="checkbox"/> Yes	
REMS Program Manager Name:		Murali Kuraku	Phone: 631-851-0550 Ext. 1433
Supplier Manages REMS registry exclusively:		<input type="checkbox"/>	
Wholesale distributor support:		<input type="checkbox"/>	
Provider Name:		<input type="text"/>	DEA #: <input type="text"/>
Site Enrollment Number assigned by Supplier:		<input type="text"/>	NCPDP#: <input type="text"/>
Comments		Arpitha Teegala is included as an additional responsible person for Opioid REMS administration.	
Registry:		<input type="checkbox"/> No	
Registry Program Contact Name:		<input type="text"/>	Phone: <input type="text"/>
Comments		<input type="text"/>	
RETURN INSTRUCTIONS			
Contact tel. # if product received damaged:		1-866-827-3647	
Is product returnable for credit:		<input type="checkbox"/> Yes	
URL/Link to returns policy:		contact - customerservice@camberpharma.com	
Special regulations or returns requirements for this product in certain states?		<input type="checkbox"/> Yes	
If so, which states? Other requirements? Comments?		<input type="text"/>	
DEA Form 222 or its electronic equivalent is required for all returns in all states.		<input type="text"/>	
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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="text"/></p> <p>b. Autofax <input type="text"/></p> <p>c. Fax <input type="text"/></p> <p>d. Phone only <input type="text"/></p> <p>e. Supplier Web Site only <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p>
<p>Expedited Freight Charges or Other Designated Drop Ship Fees:</p> <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p>Overnight and Priority Overnight PO Processing</p> <p>Overnight receipt available: <input type="text"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p>
<p>Class of Trade Restriction:</p> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input type="text"/></p>	
<p>Other Data Information Required to Process PO:</p> <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Return Instructions</p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
<p>Miscellaneous Notes:</p> <p><input type="text"/></p>	<p>ADDITIONAL INFORMATION</p> <p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>