



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

Version 2021 Introduction Type:   Final Version Date:

**PRODUCT INFORMATION** **SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

**Company Name:** Camber Pharmaceuticals, Inc. **Application:** ANDA  
**Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):** 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 **Unit of Use NDC:**  **UPC:** 331722949057  
**UDI**  **CVX Code:**  **MVX Code:**   
**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](http://www.camberpharma.com)  
**Address:** 800 Centennial Ave, Suite 1 **Address 2:**   
**City:** Piscataway **State:** NJ **Zip:** 08854  
**Key Contact:** Customer Service **Email:** [customerservice@camberpharma.com](mailto:customerservice@camberpharma.com)  
**Phone Number:** 1-866-827-3647 **Fax:** 732-562-8788  
**Product Therapeutic Classification:**  Combination full opioid agonist, and non-opioid, non-salicylate analgesic and antipyretic

**a. Temperature – Indicate the USP temperature range for this product.**  
 Temperature Range:   
 Other Temperature Range Requirement (write in):   
 Notes:   
 Is this product to be shipped to customers on ice?   
 Is this product to be shipped to customers on dry ice?   
**b. Contact for temperature excursion questions:**  
**Name:** Soma Raju  
**Number:** 732-529-0423  
**Group E-mail:** [somaraju@heterousa.com](mailto:somaraju@heterousa.com)  
**c. Special regulations for product in any states?**   
 Special returns requirements for this product?   
**d. Store product (unit of sale) upright?**   
 Protect product (unit of sale) from light?   
**e. Shelf life:**  Months  
 Initial shelf life at launch (if different):  Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class #	<input type="text" value="No"/>	Is the Product... Direct-Ship Only	<input type="text" value="Neither"/>
a product kit? if yes, list NDCs of component parts reverse numbered?	<input type="text" value="No"/>	Is the Product... Orphan Drug Status	<input type="text"/>
co-licensed?	<input type="text" value="No"/>	FDA Approval Status	<input type="text"/>
latex-free?	<input type="text" value="No"/>	Allergens Present	<input type="text" value="Dye, Corn, Alcohol, Animal"/>
preservative-free?	<input type="text" value="Yes"/>	Country of Origin	<input type="text" value="USA"/>
correctional institution block? opioid?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="Yes"/>
Cannabinoid?	<input type="text" value="No"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>		
If Unit Dose, indicate NDC here:	<input type="text"/>		
		Size:	<input type="text" value="500 ct"/>
		Strength:	<input type="text" value="5 mg/325 mg"/>
		Dosage Form:	<input type="text" value="Tablet"/>
		Product Shape:	<input type="text" value="Round, biconvex"/>
		Product Color:	<input type="text" value="White to off-white"/>
		Product Imprint:	<input type="text" value="Break line on one side and debossed with T 192 on other side"/>

**ORDER INFORMATION**

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="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	
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	
<input type="checkbox"/> Vial Powder Multi	
<input type="checkbox"/> Other: Write In	

Minimum order quantity?   
 If Yes, how many of which package type?  
 Each  
 Inner/ Carton/ Pack  
 Case

**FOR GENERIC DRUG PRODUCTS**

I. Orange Book Rating:   Authorized Generic \*If Authorized Generic, other section fields are not applicable  
 II. Generic Equivalent to What Brand?:

**PHARMACY ORDER / BILL UNIT**

Rec. sell unit to customer?   
 (Write-in, e.g. 1 Vial)  
 Rx billing unit to pharmacy:  
 Each  
 Gram  
 Milliliter

**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

Does supplier meet DSCSA definition of manufacturer?   
 Is product exempt from DSCSA?   
 If yes, select exemption:   
 Other exemption - Write in:   
 Is product repackaged?   
 Is product sold by manufacturer's exclusive distributor?   
 Has FDA granted waiver/exemption/exemption for product?   
 If yes, attach documentation from FDA.   
 GLN:   
 GCP:   
 If yes, was original product purchased direct from mfr?   
 Provide source manufacturer for repackaged product:

**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:						

**GTIN AND HIBCC PRODUCT INFORMATION**

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	<input type="text" value="1"/>	<input type="text"/>	<input type="text" value="00331722949057"/>	<input type="text"/>
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input checked="" type="checkbox"/> Case	<input type="text" value="12"/>	<input type="text"/>	<input type="text" value="10331722949054"/>	<input type="text"/>
<input type="checkbox"/> Pallet	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**COST INFORMATION** **WHOLESALE USE ONLY:**

Regular Cost   
 Invoice Cost (WAC) (\$)   
 As of date:   
 Vendor #:   
 Whsl. Code #:   
 Finline Code:

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?            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</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions?            (If yes, attach SDS with special instructions.) <input type="checkbox"/> No</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT?            (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/></p> <p>Is this product regulated for shipment by IATA?            (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/></p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger  <input type="checkbox"/> Cargo  <input type="checkbox"/> Passenger &amp; Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No            RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit?  <input type="checkbox"/> No (if yes, identify method below)</p> <p><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"/></p>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; margin: 0;"><b>SDS Hazard Classification</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input checked="" type="checkbox"/> Organic</td> <td style="width: 50%; border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p>Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text"/> No</p> <p>NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? <input type="checkbox"/> No            If yes, indicate which: <input type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; margin: 0;"><b>Hazardous Waste Identification</b></p> <p>EPA Hazardous Waste Code: <input type="text"/> Waste Characteristics: <input type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; margin: 0;"><b>REMS or REGISTRY RESTRICTIONS</b></p> <p>Is there a REMS on this product? <input type="checkbox"/> Yes <input type="checkbox"/> No            If Yes, is it managed with a pharmacy registry? <input type="checkbox"/> No            Website URL: <input type="text" value="https://opioidanalgesicrems.com/home.html"/></p> <p>Med Guide Required <input type="checkbox"/> Yes <input type="checkbox"/> No            Limited Distribution Requirement <input type="checkbox"/> No <input type="checkbox"/> Yes            Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p><b>REMS:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>REMS Program Manager Name: <input type="text" value="Prathima Arrabally"/> Phone: <input type="text" value="(631) 881-4614 Ext. 1412"/>            Supplier Manages REMS registry exclusively: <input type="text"/>            Wholesale distributor support: <input type="text"/>            Provider Name: <input type="text"/> DEA #: <input type="text"/>            Site Enrollment Number assigned by Supplier: <input type="text"/> NCPDP#: <input type="text"/>            NPI #: <input type="text"/></p> <p>Comments <input type="text"/></p> <p><b>Registry:</b> <input type="checkbox"/> No <input type="checkbox"/> Yes            Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/>            Comments <input type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center; margin: 0;"><b>RETURN INSTRUCTIONS</b></p> <p>Contact tel. # if product received damaged: <input type="text" value="1-866-827-3647"/>            Is product returnable for credit: <input type="checkbox"/> Yes <input type="checkbox"/> No            URL/Link to returns policy: <input type="text" value="contact - customerservice@camberpharma.com"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> Yes <input type="checkbox"/> No            If so, which states? Other requirements? Comments? <input type="text"/></p> <p>DEA Form 222 or its electronic equivalent is required for all returns in all states.</p> </div>	<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
<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						
ADD'L STORAGE INFORMATION							
<p>Is the Product...</p> <p>Controlled Substance? <input type="checkbox"/> Yes <input type="checkbox"/> No      Controlled Substance Code <input type="text" value="9143"/></p> <p>Controlled by State(s)? <input type="checkbox"/> Yes <input type="checkbox"/> No      Listed Chemical (List I or II) <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>ARCOS Reportable? <input type="checkbox"/> Yes <input type="checkbox"/> No      If yes, indicate which: <input type="text"/></p> <p>Schedule No. <input type="text" value="2"/>      Is it a scheduled listed chemical product?: <input type="checkbox"/> No <input type="checkbox"/> Yes</p>							
CLASS OF TRADE RESTRICTION:							
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Comments: <input type="text"/></p>							
MISCELLANEOUS NOTES and/or Image of Product Barcode:							
<p>*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part 1301.72.</p>							



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

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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 <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/> Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <input type="text"/>	<b>Purchase order daily receipt cut off time by supplier</b> Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	<b>Overnight receipt available:</b> <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday <b>Priority Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> <b>Saturday Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>