

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

PRODUCT INFORMATION SPECIAL HANDLING AND STORAGE R		
PRODUCT INFORMATION SPECIAL HANDLING AND STORAGE N	REQUIREMENTS*	
Company Name: Camber Pharmaceuticals Application: ANDA a. Temperature – Indicate the USP temperature range for this pr	product.	
		n 20 and 25 C (68° – 77°
DUNS: 826774775 Other Temperature Range Requirement		
Proprietary Name (If Applicable) and Established Name: Hydrocodone Bitartrate and Acetaminophen Tablets, USP 5mg/325mg-500ct (write in)		
Selling Unit NDC: 31722-996-05 Individual Unit NDC: UPC: 331722996051		
UDI CVX Code: MVX Code: Is this product to be shipped to customers on ice?		No
Description: Off white to white capsule shaped tablet debossed 'T 257' on sone side and plain on the other side with bisect line.	ce?	No
Active Ingredient(s): Hydrocodone Bitartrate and Acetalminophen b. Contact for temperature excursion questions:		
Name: Soma Ri		
URL for Additional Product Information: www.camberpharma.com Number: 732-529		
Address:         1031 Centennial Avenue         Address 2:         Group E-mail:         somaraju           City:         Piscataway         State:         NJ         Zip:         08854         08854	raju@heterousa.com	
Key Contact: Customer Service Small: customer service@camberpharma.com c. Special regulations for product in any states?		No
Phone Number: 732-529-0430 Fax: 732-562-8788 Special returns requirements for this product?	_	No
Product Therapeutic Classification:	_	
d. Store product (unit of sale) upright?		No
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION Protect product (unit of sale) from light?		No
Is the Product e. Shelf life:		24 Months
a legend device? No Size: 500 Initial shelf life at launch (if different):		Months
reverse numbered? No No		
co-licensed? No Strength: 5mg/325mg ORDER INFORMATION	ON	
is the Product	is the NDC selling un	
Dosage Form:   Oral Solid Tablet	le of 500 count	nitr
Boy/Carton (Write-in	e-in, e.g. 1 Box of 10 V	Vials)
If Unit Dose, is item bar coded to unit dose for hospital scanning?	,g	,
Product Shape: Capsule	num order quantity?	Yes
If full Dose NDC, indicate NDC here:	num order quantity?	
Product Color: Off white to white	num order quantity?	
Country of Origin  United States  Product Color:  Off white to white  Tube Vial Liquid Sgl		h
Country of Origin United States Product Color: Off white to white Vial Liquid Sgl Vial Liquid Multi If Yes, h	s, how many of which	h package type?
Country of Origin United States Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  Product Color: Off white to white  Tube Vial Liquid Sgl Vial Liquid Multi If Yes, h Vial Powder Sql 12	s, how many of which	
Country of Origin United States Product Color: Off white to white Vial Liquid Sgl Vial Liquid Multi If Yes, h	s, how many of which	
Country of Origin  Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  Off white to white  Tube  Vial Liquid Sgl  Vial Liquid Multi  If Yes, h  Vial Powder Sgl  Vial Powder Sgl  Vial Powder Multi  Vial Powder Multi  Tube	s, how many of which 2 Each Inner/Carton/Pa	
Country of Origin Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  Tube  Vial Liquid Sgl  Vial Powder Sgl  Vial Powder Multi  Other: Write In	s, how many of which 2 Each Inner/Carton/Pa	
Country of Origin Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Powder Multi Other: Write In  Authorized Generic  Authorized Generic  Tube Vial Liquid Multi If Yes, h Vial Powder Sql Vial Powder Multi Other: Write In	i, how many of which  2	Pack
Country of Origin  Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  T 257'    Vial Liquid Multi   If Yes, h   Vial Power Sql   Vial Power Sql   Vial Power Multi   Other: Write In	is, how many of which   2	Pack
Country of Origin  Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  Tube  Vial Liquid Sgl  Vial Liquid Multi  If Yes, h  Vial Powder Sql  Vial Powder Multi  Other: Write In  I. Orange Book Rating:  II. Generic Equivalent to What Brand?:  Norco  Product Color:  Off white to white  Tube  Vial Powder  Vial Liquid Multi  If Yes, h  Authorized Generic, other section  fields are not applicable  Rec. sell unit to customer?  Rx billing	s, how many of which  2	Pack
Country of Origin Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  Tube Vial Liquid Sgl Vial Liquid Multi If Yes, h Vial Powder Sql Vial Powder Multi Other: Write In  Authorized Generic  Authorized Generic, other section fields are not applicable II. Generic Equivalent to What Brand?: Norco  Norco  Product Color: Off white to white  Vial Liquid Multi If Yes, h Vial Powder Sql Vial Powder Sql Vial Powder Multi Other: Write In  PHARMACY ORDER / BILL Rec. sell unit to customer? Rx billin  (Write-in, e.g. 1 Vial)	is, how many of which  2	Pack
Country of Origin  Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  Tube  Vial Liquid Sgl  Vial Liquid Multi  If Yes, h  Vial Powder Sql  Vial Powder Multi  Other: Write In  I. Orange Book Rating:  II. Generic Equivalent to What Brand?:  Norco  Product Color:  Off white to white  Tube  Vial Powder  Vial Liquid Multi  If Yes, h  Authorized Generic, other section  fields are not applicable  Rec. sell unit to customer?  Rx billing	s, how many of which  2	Pack
Country of Origin Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  Tube Vial Liquid Sgl Vial Liquid Multi If Yes, h Vial Powder Sql Vial Powder Multi Other: Write In  Authorized Generic  Authorized Generic, other section fields are not applicable II. Generic Equivalent to What Brand?: Norco  Norco  Product Color: Off white to white  Vial Liquid Multi If Yes, h Vial Powder Sql Vial Powder Sql Vial Powder Multi Other: Write In  PHARMACY ORDER / BILL Rec. sell unit to customer? Rx billin  (Write-in, e.g. 1 Vial)	In the second se	Pack
Country of Origin  Is this product covered under the Trade Agreements Act (TAA)?  FOR GENERIC DRUG PRODUCTS  Authorized Generic  I. Orange Book Rating:  II. Generic Equivalent to What Brand?:    Drug Supply Chain Security Act (DSCSA) INFORMATION    Drug Supply Chain Security Act (DSCSA) INFORMATION    Does supplier meet DSCSA definition of manufacturer?   Security Act (DSCSA) INFORMATION    Drug Supply Chain Security Act (DSCSA) INFORMATION    Does supplier meet DSCSA definition of manufacturer?   Security Act (DSCSA) INFORMATION    Does supplier meet DSCSA definition of manufacturer?   Security Act (DSCSA) INFORMATION    Drug Supplier meet DSCSA definition of manufacturer?   Security Act (DSCSA) INFORMATION    Drug Supplier meet DSCSA definition of manufacturer?   Security Act (DSCSA) INFORMATION    Drug Supplier meet DSCSA definition of manufacturer?   Security Act (DSCSA) INFORMATION    Drug Supplier meet DSCSA definition of manufacturer?   Security Act (DSCSA) INFORMATION    Drug Supplier meet DSCSA definition of manufacturer?   Security Act (DSCSA) INFORMATION    Drug Supplier meet DSCSA definition of manufacturer?   Security Act (DSCSA) INFORMATION    Drug Supplier meet DSCSA definition of manufacturer?   Security Act (DSCSA) INFORMATION    Security Act (DSCSA) INFORMATION	is, how many of which  2	cy:
Country of Origin  Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  Tube  Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Liquid Multi Vial Powder Multi Other: Write In  I. Orange Book Rating: II. Generic Equivalent to What Brand?:  Norco  DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION  Does supplier meet DSCSA definition of manufacturer?  Yes  GLN:  G33172200000  ITEM AND PACKING INFORM IDENTITY AND PACKING INFORM ITEM AND PACKING INFORM ITEM AND PACKING INFORM IDENTITY AND PACKING INFORM ITEM AND PACKING INFORM ITEM AND PACKING INFORM IDENTITY AND PACKING INFORM ITEM AND PACKING INFORM ITEM AND PACKING INFORM IDENTITY AND PACKING INFORM ITEM AND PAC	is, how many of which  2	Pack  Cy:  Volume # Pieces.
Country of Origin  Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  FOR GENERIC DRUG PRODUCTS  Tube Product Imprint:  T 257'    Vial Liquid Sgl Vial Power Sql Vial Power Multi Other: Write In    Vial Power Multi   Vial Power Mul	s, how many of which  2	cy:
Country of Origin  Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  Tube  Vial Liquid Sgl Vial Powder Sql Vial Powder Sql Vial Powder Sql Vial Powder Sql Vial Powder Multi Other: Write In  PHARMACY ORDER / BILL  Rec. sell unit to customer?  Rx billin  Broduct exempt from DSCSA? If yes, select exemption: Other exe	s, how many of which  2	Pack  Cy:  Volume # Pieces.
Country of Origin   United States   Product Color: Off white to white   Tube   Vial Liquid Sql   Vial Liquid Sql   Vial Powder Sql   12   Vial Powder Sql	s, how many of which  2	Pack  Cy:  Volume # Pieces.
Country of Origin  Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  T 257'    Vial Liquid Multi   HYes, h   Vial Power Sql   12   Vial Power Multi   Via	s, how many of which  2	Pack  Cy:  Volume # Pieces.
Country of Origin  Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  T 257'  Authorized Generic, other section fields are not applicable  I. Orange Book Rating:  II. Generic Equivalent to What Brand?:    Norco	LL UNIT  Illing unit to pharmacy Each Gram Milliliter  RMATION  (US msmts.) ight Width 22 2.895	cy:  Volume (Cube) #Pieces:
Country of Origin Is this product covered under the Trade Agreements Act (TAA)?    Product Imprint:   T257'   Tube   Vial Liquid Sgl   Vial Liquid Multi   Vial Powder Sql   12   Vial Powder Sql	LL UNIT  Illing unit to pharmacy Each Gram Milliliter  RMATION  (US msmts.) ight Width 22 2.895	Pack  Cy:  Volume # Pieces.
Country of Origin  Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  T 257'  Authorized Generic "If Authorized Generic, other section fields are not applicable  I. Orange Book Rating:  AA  I. Orange Book Rating:  AA  I. Orange Book Rating:  AA  DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION  Does supplier meet DSCSA definition of manufacturer?  Yes  GLN:  G33172200000  If yes, select exemption:  Other exemption:  Other exemption:  Other exemption wire in:  Is product odd by manufacturer's exclusive distributor?  No  If yes, was original product purchased direct  Is product odd by manufacturer's exclusive distributor?  No  If yes, was original product purchased direct  Is product odd by manufacturer's exclusive distributor?  No  If yes, attach documentation from FDA.  GTIN PRODUCT INFORMATION  Saleable  Level  Unit Quantity GTIN-14  Tube  Vial Liquid Sgl  Vial Liquid Multi  Vial Power Nulti  Other verite in:  Vial Cupid Sgl  Vial Cupid Sgl  Vial Cupid Sgl  Vial Cupid Sgl  Vial Cupid Multi  Vial Powder Sgl  Item  Welpha Los  Dimensions (U  Depth Height  Item:  0.573  5.22  Box/Carton/Bundle/ Inner Pack:  Case:  7.5  12.1  5.5	LL UNIT  Illing unit to pharmacy Each Gram Milliliter  RMATION  (US msmts.) ight Width 22 2.895	cy:  Volume (Cube) #Pieces:
Country of Origin  Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  Tube  Vial Liquid Sgl  Vial Liquid Multi Vial Ciquid Multi Vial Liquid Multi Vial Ciquid Multi Vial Liquid Multi Vial Liquid Multi Vial Ciquid Multi Vial Ciquid Multi Vial Liquid Multi Vial Ciquid Multi Vial Liquid Mul	LL UNIT  Illing unit to pharmacy Each Gram Milliliter  RMATION  (US msmts.) ight Width 22 2.895	Volume (Cube) #Pieces:
Country of Origin  Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  T 257  Authorized Generic  Authorized Generic  Authorized Generic  If Authorized Generic, other section fields are not applicable  II. Generic Equivalent to What Brand?:  Norco  DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION  Does supplier meet DSCSA definition of manufacturer?  Yes  GLN:  G33172200000  If Yes, was original product purchased direct from mf?  Is product sold by manufacturer's exclusive distributor?  Has FDA granted waiver/exception/exemption for product?  Serialized?  Yes  Serializ	LL UNIT  Illing unit to pharmacy Each Gram Milliliter  RMATION  (US msmts.) ight Width 22 2.895	Volume (Cube) #Pieces:
Country of Origin  Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  T 257    Product Imprint:   T 257	LL UNIT  LIIIng unit to pharmacy Gram Milliliter  RMATION  (US msmts.) ight Width 22 2.895	Volume (Cube) #Pieces:
Country of Origin United States   Product Color: Off white to white   Fish product covered under the Trade Agreements Act (TAA)?   Product Imprint:   T 257   Fish product covered under the Trade Agreements Act (TAA)?   Product Imprint:   T 257   Fish pro	LL UNIT  Illing unit to pharmacy Each Gram Milliliter  RMATION  (US msmts.) ight Width 22 2.895	Volume (Cube) #Pieces:
Country of Origin  Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  T257  Authorized Generic.  I. Orange Book Rating: II. Generic Equivalent to What Brand?:  Norco  Does supplier meet DSCSA definition of manufacturer? If yes, select exemption:  Other exemption white in:  Is product exemption with in:  Is product exemption for product?  No  If Yes, was original product purchased direct from mtr?  If yes, select exemption with in:  Is product exemption for product?  No  If Yes, was original product purchased direct from mtr?  If yes, select exemption:  Other exemption with in:  Is product exemption for product?  No  If Yes, was original product purchased direct from mtr?  If yes, select exemption:  Weight Lbs.  Dimensions (U Depth Height  Item:  0.573  5.22  Box/Carton/Bundle/  Inner Pack:  Item:  0.573  5.22  Items aggregated?  No  GTIN PRODUCT INFORMATION  Case:  7.5 12.1 5.5  Pallet:  UPC:  Case:  Carton:  COST INFORMATION	LL UNIT  LINIT	Volume (Cube) #Pieces:
Country of Crigin Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  T 257  Authorized Generic  T 4 Authorized Generic, other seation fields are not applicable  T 4 Seneric Equivalent to What Brand?:  Does supplier meet DSCSA definition of manufacturer?  If yes, select exemption:  Other exemption of product?  No  If yes, asie original product purchased direct from mfr?  Has FDA granted walver/exception/exemption for product?  No  If yes, as original product purchased direct from mfr?  If yes, attach documentation from FDA.  TOTH PRODUCT INFORMATION  Saleable  Level  Unit  Countly GTIN-14  Case:  T 5.5  T 2.1  Serialized?  Yes  Saleable  Level  Unit  Countly GTIN-14  Case:  T 5.5  T 2.1  T 5.5  T 2.1  T 5.5  T 2.1  T 5.5  T 2.1  T 2.5  T 3.5  T 2.1  T 2.5  T 3.5  T 2.5  T 3.5  T	s, how many of which    2	Volume (Cube) #Pieces:
Country of Origin United States Is this product covered under the Trade Agreements Act (TAA)?    Product Imprint:   T257	s, how many of which  2	Volume (Cube) #Pieces:
Country of Origin  Is this product covered under the Trade Agreements Act (TAA)?  Product Imprint:  T 257  Authorized Generic  I Aut	s, how many of which    2	Volume (Cube) #Pieces:
Country of Origin United States Is this product covered under the Trade Agreements Act (TAA)?    Product Imprint:   T257	s, how many of which  2	Volume (Cube) #Pieces:
Country of Origin Is this product covered under the Trade Agreements Act (TAA)?    Product Imprint:   T 257	s, how many of which  2	Volume (Cube) #Pieces:



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

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification a. Cvtotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Organic Corrosive No Is the product a CA Prop 65 reproductive toxicant? No Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? No Steroid/Androgen Contact Hazard Aerosol Class; Identify NFPA Storage Level: c. Contact Hazard? No 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 Hazardous Waste Identification b. Proper Shipping Name c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? No REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? Yes Cargo If Yes, is it managed with a pharmacy registry? No N/A 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? (if yes, identify method below) REMS: Limited Quantity REMS Program Manager Name: Phone Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: No Wholesale distributor support: Small Quantity (49 CFR 173.4) No Special Permit; DOT-SP Provider Name: Site Enrollment Number assigned Special Provision (listed in Column 7 of 49 CFR 172.101); DEA #: by Supplier: No PCPDP #: SP# NPI#: No ADD'L STORAGE INFORMATION Is the Product... Comments None Controlled Substance? Yes Controlled by State(s)? Yes Registry: ARCOS Reportable? Yes Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code 9193 Listed Chemical (List I or II) No RETURN INSTRUCTIONS If yes, indicate which: 732-529-0430 Is it a scheduled listed chemical product?: Contact tel. # if product received damaged: No CLASS OF TRADE RESTRICTION: Is product returnable for credit: 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: No No Special regulations or returns requirements for this product in certain states? 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: MISCELLANEOUS NOTES and/or Image of Product Barcode:



## **Standard Pharmaceutical Product Information (Page 3)**

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