

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

Version 2024						Introduction T	ype: New Item		x Final Version			Date:	7/17/	2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUI	EMENTS*		
Company Name:	Camber Pharmac	ceuticals, Inc.				Applicat	ion: ANDA	a. Temperature -	Indicate the USP temper	rature range for th	nis product.			
Application Number for NDA/AN	IDA/BLA; PMA/510	0(k): 204316	6			NDA 505(b) Type:	NOT APPLICABLE		mperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applical	ble:													
DUNS:	11-856-3719							Oti	her Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Quetian	apine Tablets, USP 300 mg						(write in)					
Selling Unit NDC:	31722-768-60		Unit of Use NDC:		31722-768-60		331722768603	No	ites					
UDI			CVX Code:			MVX Code:								
Description:	Quetiapine Table	ts, USP 300 mg							this product to be shipped				No	
										No				
Active Ingredient(s):		Quetiapine fumarate	e, USP											
URL for Additional Product Information: www.camberpharma.com							b. Contact for temperature excursion questions:  Name: Soma Raju							
Address:	800 Centennial A		<u>a.com</u>			Address 2:	I	-	ime: imber:		732-529-042	3		
City:	Piscataway	.,			State:	NJ	Zip: 08854		oup E-mail:			eterousa.con	n	
Key Contact:	Customer Service				Email:	customerservice (	camberpharma.com							
Phone Number:	1-866-827-3647				Fax:				tions for product in any	states?	No			
Product Therapeutic Classificatio	on:	Atypical antipsychot	otic					Sp	ecial returns requirement	s for this product?			No	
					_							1		
	ADDITI	IONAL PRODUCT INF	FORMATION			PRODUCT	DESCRIPTION INFORMATION	d. Store product	(unit of sale) upright?			I	No	
The product is?			Is the Product	Direct-Ship C	Only			Pro	otect product (unit of sa	le) from light?		i	No	
a legend device?		No	Is the Product	Unit of Use		Size:	60 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			0.20.		Ini	tial shelf life at launch (i	f different):				Months
a product kit?		No				Strength:	300 mg			ORDER INFORM	ATION			
if yes, list NDCs of			FDA Approval Status				Eller as attacked			ORDER INFORM	ATION			
component parts reverse numbered?		No				Dosage Forn	n: Film-coated tablet	Un	it of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 6			
latex-free?		Yes					Capsule, biconvex		Box/Carton			g. 1 Box of 10	0 Vials)	
preservative-free?		Yes	Dairy, Lactose,	Animai Produc	cts	Product Sha	pe:		Ampule					
correctional institution block?		No				Product Cold	White		Glass		Minimum or	der quantity	?	Yes
opioid?		No				1 Todact Con			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imp	rint: Debossed with '45' on one side and 'l' on the other side		Vial Liquid Sgl					_
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for		In this was don't account to	and a settle a			and 1 artino datal state	_	Vial Liquid Multi Vial Powder Sql			many of which	ich package t	type?
If Unit Dose, indicate NDC here:			Is this product covered u Trade Agreements Act (1		No				Vial Powder Sgi Vial Powder Multi		24	Inner/Carton	/Pack	
ii Offit Dose, indicate NDC fiere.			Trade Agreements Act (	70191	140				Other: Write In			Case	/I duk	
			FOR GENERIC DRUG PR	ODUCTS										
											I			
					Au	thorized Generic	*If Authorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section fields are not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:					acy:	
II. Generic Equivalent to What Bra	and?:	Seroquel						Each						
								(Write-in, e.g. 1 V	ial)			Gram		
		DRUG SUPPL	LY CHAIN SECURITY ACT (	DSCSA) INFO	RMATION			HCPCS J-Code:		1		Milliliter		
Does supplier meet DSCSA defini	ition of manufactu													
Does supplier friedt Dood A defini		ror?	Yes	_	GI N:	0331722498975			ITEN	AND PACKING IN	IFORMATION			
Is product exempt from DSCSA?		rer?	Yes No	7	GLN:	0331722498975			ITEN	AND PACKING IN	IFORMATION			
· ·		irer?				0331722498975							Volume	Saleable #
If yes, select exemption:		irer?			GLN: GCP:	0331722498975			ITEN Weight Lbs.	Dimensio	ons (US msm	its.)		Saleable #
If yes, select exemption: Other exemption - Write in:		irer?			GCP:			Item/Each:	Weight Lbs.	Dimensio Depth	ons (US msm Width	nts.) Height	(Cube)	Pieces
If yes, select exemption:			No	- -	GCP:	0331722498975  iginal product rect from mfr?		Item/Each:		Dimensio	ons (US msm	its.)		
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	s exclusive distrib on/exemption for p	utor?	No No	- - -	GCP: If yes, was or purchased di	iginal product	r repackaged product	Box/Carton/Bund	Weight Lbs.	Dimensio Depth	ons (US msm Width	nts.) Height	(Cube)	Pieces
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	s exclusive distrib on/exemption for p	utor?	No No Yes		GCP: If yes, was or purchased di	iginal product	r repackaged product	Box/Carton/Bund	Weight Lbs.	Dimensio Depth	ons (US msm Width	nts.) Height	(Cube)	Pieces
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	s exclusive distrib on/exemption for p	utor? product?	No No Yes No	TORMATION.	GCP: If yes, was or purchased di	iginal product	r repackaged product	Box/Carton/Bund	Weight Lbs.	Dimensio Depth	ons (US msm Width	nts.) Height	(Cube)	Pieces
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	s exclusive distrib on/exemption for p	utor? product?	No No Yes	IFORMATION	GCP: If yes, was or purchased di	iginal product	r repackaged product	Box/Carton/Bund Inner Pack: Case:	Weight Lbs. 0.19	Dimension Depth 1.87	ons (US msm Width 1.87	Height	(Cube) 13.99	Pieces 1
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	s exclusive distribi orlexemption for p m FDA.	utor? product?	No Yes No IN AND HIBCC PRODUCT II	NFORMATION	GCP: If yes, was or purchased di Provide source	iginal product rect from mfr? ce manufacturer fo		Box/Carton/Bund	Weight Lbs. 0.19	Dimension Depth 1.87	ons (US msm Width 1.87	Height	(Cube) 13.99	Pieces 1
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation from	s exclusive distrib on/exemption for p	utor? product?	No No Yes No	NFORMATION	GCP:  If yes, was or purchased di Provide source	iginal product rect from mfr? se manufacturer fo	r repackaged product  Unit of Use GTIN-14	Box/Carton/Bund Inner Pack: Case:	Weight Lbs. 0.19	Dimension Depth 1.87	ons (US msm Width 1.87	Height	(Cube) 13.99	Pieces 1
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation from	s exclusive distribi orlexemption for p m FDA.	utor? roduct?  GTIN	No Yes No IN AND HIBCC PRODUCT II	NFORMATION	GCP:  If yes, was or purchased di Provide source	iginal product rect from mfr? ce manufacturer fo		Box/Carton/Bund Inner Pack: Case:	Weight Lbs. 0.19 4.95	Dimension Depth 1.87	ons (US msm Width 1.87	Height 4 5	(Cube) 13.99 484.69	Pieces 1 24
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation from Saleable Unit of Measure  X	s exclusive distribution for pile m FDA.  RFID tag(Y/N)	saleable Quantity	No Yes No IN AND HIBCC PRODUCT II	NFORMATION	GCP:  If yes, was or purchased di Provide source  GTII	iginal product rect from mfr? se manufacturer fo	Unit of Use GTIN-14	Box/Carton/Bund Inner Pack: Case:	Weight Lbs. 0.19	Dimension Depth 1.87	ons (US msm Width 1.87	Height 4 5	(Cube) 13.99	Pieces 1 24
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If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation froi  Saleable Unit of Measure  X	s exclusive distribution for pile m FDA.  RFID tag(Y/N)	saleable Quantity	No Yes No IN AND HIBCC PRODUCT II	NFORMATION	GCP:  If yes, was or purchased di Provide source  GTII	iginal product rect from mfr? se manufacturer fo	Unit of Use GTIN-14	Box/Carton/Bund Inner Pack: Case: Pallet:	Weight Lbs.  0.19  4.95  COST INFORMATION	Dimension Depth 1.87 11.75	vendor #:	Height 4 5	(Cube) 13.99 484.69	Pieces 1 24
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation froi  Saleable Unit of Measure  X	s exclusive distribution for pile m FDA.  RFID tag(Y/N)	saleable Quantity	No Yes No IN AND HIBCC PRODUCT II	NFORMATION	GCP:  If yes, was or purchased di Provide source  GTII	iginal product rect from mfr? se manufacturer fo	Unit of Use GTIN-14	Box/Carton/Bund Inner Pack: Case: Pallet:	Weight Lbs.  0.19  4.95  COST INFORMATION	Dimension Depth 1.87 11.75	Nons (US msm Width 1.87 8.25	Height 4 5	(Cube) 13.99 484.69	Pieces 1 24
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation froi  Saleable Unit of Measure  X	s exclusive distribution for pile m FDA.  RFID tag(Y/N)	saleable Quantity	No Yes No IN AND HIBCC PRODUCT II	NFORMATION	GCP:  If yes, was or purchased di Provide source  GTII	iginal product rect from mfr? se manufacturer fo	Unit of Use GTIN-14	Box/Carton/Bund Inner Pack: Case: Pallet:  Regular Invoice Cost (WA	Weight Lbs.  0.19  4.95  COST INFORMATION  C) (\$)	Dimension Depth 1.87 11.75	vendor #:	Height 4 5	(Cube) 13.99 484.69	Pieces 1 24
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation froi  Saleable Unit of Measure  X	s exclusive distribution for pile m FDA.  RFID tag(Y/N)	Saleable Quantity  1  24	No Yes No IN AND HIBCC PRODUCT II HIBCC		GCP: If yes, was or purchased di Provide source GTII	iginal product rect from mfr? se manufacturer fo N-14 31722768603 31722768607	Unit of Use GTIN-14  00331722768603	Box/Carton/Bund Inner Pack: Case: Pallet:  Regular Invoice Cost (WA As of date:	Weight Lbs. 0.19 4.95  COST INFORMATION C) (\$) 3/18/2024	Dimension Depth 1.87 11.75	vendor #:	Height 4 5	(Cube) 13.99 484.69	Pieces 1 24
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation froi  Saleable Unit of Measure  X	s exclusive distribution for pile m FDA.  RFID tag(Y/N)	Saleable Quantity  1  24	No Yes No IN AND HIBCC PRODUCT II HIBCC		GCP: If yes, was or purchased di Provide source GTII	iginal product rect from mfr? se manufacturer fo N-14 31722768603 31722768607	Unit of Use GTIN-14	Box/Carton/Bund Inner Pack: Case: Pallet:  Regular Invoice Cost (WA As of date:	Weight Lbs. 0.19 4.95  COST INFORMATION C) (\$) 3/18/2024	Dimension Depth 1.87 11.75	vendor #:	Height 4 5	(Cube) 13.99 484.69	Pieces 1 24



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

#### Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZ	ZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply):  a. Cytotoxic?  b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  Is the product a CA Prop 65 carcinogen?  Is the product a CA Prop 65 reproductive toxicant?  No Does the product label bear a CA Prop 65 warning?  c. Contact Hazard?  d. Does this product require special clean-up instructions?  (If yes, attach SDS with special instructions.)  e. Does the product contain DEHP?  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	SDS Hazard Classification  X Organic Oxidizer Oxidizer Steroid/Androgen Oxidizer Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug? If yes, indicate which:  Hazardous Waste Identification
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics
	E. M. azarose Management
Is this product regulated for shipment by IATA?	REMS or REGISTRY RESTRICTIONS
(if yes, answer a-e below and provide SDS)	REMS OF REGISTRY RESTRICTIONS
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product?  If Yes, is it managed with a pharmacy registry?  Website URL:
	W to the control of t
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required No
Passenger	Limited Distribution Requirement
Cargo	Comments / Details: (For example, iPledge program?)
Passenger & Cargo	REMS:  REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: NPI #:
Small Quantity (49 CFR 173.4)	
Special Permit; DOT-SP	Comments
Special Provision (listed in Column 7 of 49 CFR 172.101);	
SP#	Registry: No
	Registry Program Contact Name: Phone:
ADD'L STORAGE INFORMATION	Comments
Is the Product	
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS
Controlled by State(s)?  No Listed Chemical (List I or II)  No	
ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647
Schedule No. Is it a scheduled listed chemical product?: No	Is product returnable for credit:
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	contact - customerservice@camberpharma.com
Restricted to retail pharmacy only: No	Special regulations or returns requirements for this
Restricted to hospital, clinics, and physician offices only:	product in certain states?
Restricted from US territories? (explain in comments)  No	If so, which states? Other requirements? Comments?
Comments:	
Comments.	
MISCELLANE	OUS NOTES and/or Image of Product Barcode:



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

#### Version 2024

#### 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:	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:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:  Drop Ship service fee billed with each order:  Drop Ship miscellaneous fees billed:  Comments:	Overnight receipt available:  PO Receipt cut off time:  Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday
	Priority Overnight receipt available:
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:	PO Receipt Cut off time:  Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
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 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?
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?