

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014						Introduction Type:	N	New Item		Final Version			Date:	6/13	/2019
			PRODUCT INFOR	RMATION						SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	*	
Company Name:	Camber Pharmaceut	icals				Application	n:	ANDA	a. Temperature – Indio	ate the USP temper	ature range	for this produ	ict.		
Application Number for ND	DA/ANDA/BLA (drug);	PMA/510(k)(med de	vice):	2110	009		•			ature Range				en 20 and 25	C (68° – 77° F
DUNS:	82-667-4775								Other Te	emperature Range Re	equirement				
Proprietary Name (If Applica	able) and Established	Name:								rite in)					1
Selling Unit NDC:	31722-954-01		Individual Unit N	DC:			22954013								-
UDI			CVX Code:			MVX Code:			Is this p	roduct to be shipped t	to customers	on ice?		No	_
Description:	White to off white film	n coated round cylind	drical biconvex tablets printed	d with '214' in black	ink.				Is this p	roduct to be shipped t	to customers	on dry ice?		No	_
															
Active Ingredient(s):		Methylphenidate							b. Contact for tempera Name:	ature excursion ques	stions:	Soma Raju			
URL for Additional Product I	Information: www.camberpharma.com						Number	732-529-0423							
Address:		ormation: www.camberphanna.com Otal Centennial Avenue Address 2:							Group E-mail: somaraju@heterousa.com						
City:	Piscataway											· · · ·			
Key Contact:	Customer Service	stomer Service Email: customerservice@camberpharma.com							c. Special regulations					No	_
Phone Number:	732-529-0430							Special returns requirements for this product? No							
Product Therapeutic Classif	fication:														
	AL PRODUCT INFORM				PROF	DUCT DESCRIPTION I		N	d. Store product (unit		A farmer Parket			No	-
	ALT RODUCT INFORM	ATION	_		FRO	DOCT DESCRIPTION I		N		product (unit of sale	e) from light	ſ		No	
Is the Product		Ne							e. Shelf life:	half life at launah /if	different).			24	Months Months
a legend device? reverse numbered?		No No	—		Size:	100CT			initial si	helf life at launch (if	unterent):			24	wonths
co-licensed?		No	-							(ORDER INFO	RMATION			
Is the Product		Direct-Ship Only	—		Strength:	36MG									
Is the Product		Unit Dose			Dosage Form:	Tablet			Unit of S				NDC selling	unit?	
										Bottle		1 box of 24			
If Unit Dose, is item bar code	led to unit dose for hosp	bital scanning?	_						x	Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)	
If Unit Dose NDC, indicate N	NDC here:			1	Product Shape:	Cylindrical Bicony	vex			Ampule Glass		Minimumo	rder quantity	0	Yes
In Onic Dose NDC, indicate N	NDC Hele.									Tube		Willington	idei quantity		163
Country of Origin		USA			Product Color:	White to off-white	9			Vial Liquid Sgl					
Is this product covered unde	er the Trade Agreement	s Act (TAA)?			Product Imprint:	214				Vial Liquid Multi		If Yes, how		ich package	type?
										Vial Powder Sql			Each		
									J	Vial Power Multi Other: Write In		24	Inner/Cartor Case	/Pack	
			FOR GENERIC DRUG	G PRODUCTS						Other. White in			Case		
					Authorize			eric, other section		PHAR	RMACY ORD	ER / BILL UN	Π		
I. Orange Book Rating:	AB					fields	are not applica	cable	Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What	nat Brand?:	Concerta											Each		
									(Write-in, e.g. 1 Vial)				Gram		
		DRUG SL	UPPLY CHAIN SECURITY A	ACT (DSCSA) INFO	DRMATION								Milliliter		
Does supplier meet DSCSA	definition of manufac	turer?	Yes	GLN	ı: 🗖					ITEM A	ND PACKIN	G INFORMAT	ION		
Is product exempt from DSC			No												
If yes, select exemption:										Weight Lbs.		ensions (US n		Volume	# Pieces:
Other exemption - Write in:	:		NI-						b .		Depth	Height	Width	(Cube)	
Is product repackaged? Is product sold by manufact	turor'e ovelueivo dietri	ibutor?	No		es, was original pro n mfr?	oduct purchased direct	ct		Item:	0.17		3.4	2.015		
Has FDA granted waiver/exc			No		s, attach documer	ntation from FDA.			Box/Carton/Bundle/						
									Inner Pack:						
			GTIN PRODUCT INF						Case:	4.6	12.3	8.3	3.8		24
				Saleable		_					12.0	0.0	0.0		
Serialized?	Yes		Level	Unit	X 2D	Quant		-14 1722954013	Pallet:						
If not, when?	res		k Item Box/Carton/Bundle/Inner Page	ck	x 2D 2D	Linear 1	00331	1722934013	UPC:	Case:					
Items aggregated?	No		x Case	x	x 2D	Linear 24	10331	1722954010	0.0.	Carton:					
		-	Pallet		2D	Linear									
					2D	Linear			COST	INFORMATION			WHOLESAL	ER USE ONI	LY:
					2D	Linear			II			-l.,			
				I	2D 2D	Linear			Regular Cost	N N	\$005 T	Vendor #:	<i>#</i> .		
		L			20	Linear			Invoice Cost (WAC) (\$ Federal Excise Tax Pe		¢205.75	Whsl. Code Fineline Co			
									As of date:			i incine ou			
			Attach copy of SAFETY	DATA SHEET (SD	OS) or non hazard le	etter, PACKAGE INSER	RT, LABEL AN	ID PHOTO OF PRO	DUCT PACKAGING and B	ARCODE.					
*Please provide any addition	nal information on page	ge 2.		(-		e new p. 3 for Design			Signatu						
L									-						



Standard Pharmaceutical Product Information (Page 2)

	nated Drop Ship Only Products, Please Use Page 3 HAZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):							
a. Cytotoxic? No	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
Is the product a CA Prop 65 carcinogen? No	Organic Corrosive						
Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard						
c. Contact Hazard? No	Aerosol Class; Identify NFPA Storage Level:						
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							
b. Proper Shipping Name	Hazardous Waste Identification						
c. DOT Hazard Class	EPA Hazardous Waste Code:						
d. Packing Group							
e. Inhalation Hazard?							
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS						
Passenger	Is there a REMS on this product? No						
Cargo							
	If Yes, is it managed with a pharmacy registry?						
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?							
No (if yes, identify method below)	REMS:						
Limited Quantity	REMS Program Manager Name: Phone:						
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively: No						
Small Quantity (49 CFR 173.4)	Wholesale distributor support: No						
Special Permit; DOT-SP	Provider Name:						
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #: No						
	by Supplier: PCPDP #: No						
SP#							
	NPI #: No						
ADD'L STORAGE INFORMATION							
Is the Product	Comments						
Controlled Substance? Yes							
Controlled by State(s)? Yes	Registry: No						
ARCOS Reportable? Yes	Registry Program Contact Name: Phone:						
Schedule No. (inc. N for non-narcotic) CII	Comments						
Controlled Substance Code 1724							
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS						
If yes, indicate which:							
Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 732-529-0430						
CLASS OF TRADE RESTRICTION:	Is product returnable for credit: Yes						
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: Yes	Special regulations or returns requirements for this product in certain states? No						
Restricted to hospital, clinics, and physician offices only: No							
	If so, which states? Other requirements? Comments?						
Comments:							
	NEOUS NOTES and/or Image of Product Barcode:						
WISCELLA	INCOUS NOTES and/or Image or 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: a. EDI Yes b. Autofax No Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM
c. Fax Yes Fax Number: 732-562-8788 d. Phone only No Phone No.: e. Supplier Web Site only No Site Address:	Shipping lead time of PO: 24/48 Hours Days Ships same day for next day receipt: No
Minimum Order Quantity: case pack Supplier's Customer Service Number: 732-529-0430 x466 x465 x467 x470 Contracted 3PL company / contact #: Name: Phone: Phone:	Ships for second day receipt: No Ships regular ground for 3-10 days receipt: Yes
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: No	Overnight receipt available: Yes
Drop Ship service fee billed with each order: No	PO Receipt cut off time: 2:30PM Eastern
Drop Ship miscellaneous fees billed: No Comments:	Days of week overnight is available: X Monday X Tuesday X Wednesday X Thursday X Friday
	Priority Overnight receipt available: Yes
Class of Trade Restriction: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No Restricted to retail pharmacy only: Yes Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No Comments: O	PO Receipt Cut off time: 2:30PM EST Saturday Overnight receipt available: No PO Receipt Cut off time: No Order receipt method: Phone: Yes Phone: Yes Fax: Yes EDI: Yes Overnight Fees apply: Yes Other fees apply: No
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	Contact # if product is received damaged: 732-529-0430 Is product returnable for credit: Yes URL/Link to returns policy:
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? No Is product order for restocking purposes? No