

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014					li	ntroduction T	уре:	New Item		Final Version			Date:	6/13	/2019	
PRODUCT INFORMATION									SPECIAL HANDLING AND STORAGE REQUIREMENTS*							
Company Name:	: Camber Pharmaceuticals Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.							
Application Number for ND	DA/ANDA/BLA (drug); PMA/510(k)(med device):				11009			Tempera	Temperature Range Controlled Room – between 20 and 25 C (68)				C (68° - 77° I			
DUNS:	82-667-4775							Other Te	emperature Range Re	quirement						
Proprietary Name (If Applica	cable) and Established Name: Methylphenidate HCL ER Tablets 54MG 100CT								rite in)							
Selling Unit NDC:	31722-955-01		Individual Unit NDC:			UPC:	3317229550	010							-	
UDI CVX Code:				N	//VX Code:			Is this p	oduct to be shipped t	o customers o	n ice?		No	_		
Description:	215 in black ink.	ck ink.			Is this product to be shipped to customers on dry ice? No					_						
Active Ingredient(s): Methylphenidate								b. Contact for tempera	Soma Raju							
URL for Additional Product I	Information:	www.camberpharma.com						— I	Number:			732-529-0423				
Address:	1031 Centennial Ave				Address 2:			Group E-mail:			somaraju@heterousa.com					
City:	Piscataway			Sta	State: NJ Zip: 08854 Email: customerservice@camberpharma.com							,				
Key Contact:	Customer Service									c. Special regulations for product in any states?				No		
Phone Number:	732-529-0430			Fa	Fax: 732-562-8788			Special returns requirements for this product? No					_			
Product Therapeutic Classifi																
										d. Store product (unit of sale) upright? No						
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION				Protect product (unit of sale) from light?					-			
Is the Product													Months			
a legend device? reverse numbered?		No	No No			Size: 100CT			Initiai si	neir lite at launch (if	airrerent):			24	Months	
co-licensed?			No No						ORDER INFORMATION							
Is the Product	I			Strengt	h:	54MG										
Is the Product	Unit Dose		Dosage	Dosage Form: Tablet				Unit of Sale What is the NDC selling				unit?				
				Dosago		Tablet]	Bottle		1 box of 24				
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?							, <u>×</u>	Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)		
If Unit Dose NDC, indicate N	IDC here:			Produc	Product Shape: Cylindrical Biconvex					Ampule Glass		Minimum o	order quantity	12	Yes	
II Oliit Dose NDC, ilidicate N	IDO Here.				Product Online			†	Tube		William C	ruer quantity	•	163		
Country of Origin		USA		Produc	Product Color: Light to dark brown				Vial Liquid Sgl							
Is this product covered under the Trade Agreements Act (TAA)?				Produc	Product Imprint: 215			Vial Liquid Multi If Yes, how many of which package type?								
is this product covered under the made rigicoments rice (1704):								<u> </u>	Vial Powder Sql			Each				
										Vial Power Multi Other: Write In		24	Inner/Carton Case	/Pack		
FOR GENERIC DRUG PRODUCTS													Case			
Authorized Generic **If Authorized Generic, ott							PHARMACY ORDER / BILL UNIT									
I. Orange Book Rating:	AB	<u>.</u>			fields are not applicable			Rec. sell unit to customer?			Rx billing unit to pharmacy:					
II. Generic Equivalent to What Brand?: Concerta							(Write-in, e.g. 1 Vial)			Each						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION													Gram Milliliter			
			(,								<u> </u>	J Williams			
Does supplier meet DSCSA			Yes	GLN:						ITEM A	ND PACKING	INFORMAT	ION			
Is product exempt from DSC																
If yes, select exemption: Other exemption - Write in:	-									Weight Lbs.	Dimer	nsions (US n Height	nsmts.) Width	Volume (Cube)	# Pieces:	
Is product repackaged?	•		No	If Yes, was	original prod	duct purchased	d direct	_	Item:		Deptil	_		(Oubc)		
Is product sold by manufactu	urer's exclusive distri		No	from mfr?	3				· [[0.18		3.4	2.015			
Has FDA granted waiver/exc	ception/exemption for	product?	No	If yes, attac	h documenta	ation from FDA	۸.		Box/Carton/Bundle/							
l			GTIN PRODUCT INFORMA	TION					Inner Pack:							
				eable					Case:	4.7	12.3	8.3	3.8		24	
				Init			Quantity	GTIN-14	Pallet:							
Serialized?	Yes	х	Item	х	2D	Linear	1	00331722955010	1111							
If not, when?			Box/Carton/Bundle/Inner Pack		2D	Linear			UPC:	Case:						
Items aggregated?							Carton:									
	Pallet 2D Linear 2D Linear					_cost	WHOLESALER USE ONLY:									
]]	2D Linear Linear Linear Linear							COST INFORMATION			MISEES/IEER OOL ONET.					
								Regular Cost			Vendor #:					
				2D	Linear			Invoice Cost (WAC) (\$) \$223.9		\$223.90	Whsl. Code					
									Federal Excise Tax Pe	r Unit of Sale		Fineline Co	de:			
									As of date:							
 			Attach copy of SAFETY DATA S	SHEET (SDS) or no	on hazard lette	or DACKAGE	INSEPT I A	REI AND PHOTO OF P	CODUCT PACKAGING and B	ARCODE						
*Please provide any addition	nal information on pag		rador dopy of OALLTT DATA	5.1.E.E.T (5.D.S) 01 110				Drop Ship Only.	Signatu							



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. Cytotoxic? 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? 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? REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? Cargo If Yes, is it managed with a pharmacy registry? Passenger & Cargo Website URL: Is this a reportable quantity? RQ Threshold: Comments / Details: (For example, iPledge program?) Is this a marine pollutant? Nο 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 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: No SP# PCPDP #: NPI#: No ADD'L STORAGE INFORMATION Is the Product.. Comments 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 1724 Listed Chemical (List I or II) No RETURN INSTRUCTIONS If ves. indicate which: 732-529-0430 Is it a scheduled listed chemical product?: No Contact tel. # if product received damaged: 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: 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? 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: a. EDI Yes	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern							
b. Autofax No Fax Number: c. Fax Yes Fax Number: d. Phone only No Phone No.:	Shipping lead time of PO: 24/48 Hours Days							
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt: No Yes							
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: No	Overnight receipt available: PO Receipt cut off time: 2:30PM Eastern							
Drop Ship miscellaneous fees billed: Comments:	Days of week overnight is available:							
	Priority Overnight receipt available: Yes							
Class of Trade Restriction:	PO Receipt Cut off time: 2:30PM EST							
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) No Comments:	Saturday Overnight receipt available: No PO Receipt Cut off time: Phone: Yes Phone #: Fax #: 732-562-8788 Fax #: Yes Overnight Fees apply: Yes No							
Other Data Information Required to Process PO:	Return Instructions							
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician/Clinic DEA #: Physician/Clinic Specialty:	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?							
Miscellaneous Notes:								
	ADDITIONAL INFORMATION							
	Is product order for scheduled patient procedure? Is product order for restocking purposes? No							