

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

Version 2024						Introduction T	ype: New Item		x Final Version			Date:	10/23/	/2025
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharma	ceuticals, Inc.				Applicat	ion: ANDA	a. Temperature -	Indicate the USP temper	erature range for t	his product.			
Application Number for NDA/AN	IDA/BLA; PMA/51	0(k): 214956	3			NDA 505(b) Type:	NOT APPLICABLE		mperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applica	ble:													
DUNS:	11-856-3719							Otl	ner Temperature Range F	Requirement		permitted bety	ween 15°C to	30°C (59°F
Proprietary Name (If Applicable) a		ame: Gabape	entin Capsules, USP 300 m						(write in)		to 86°F)			
Selling Unit NDC:	31722-149-05		Unit of Use NDC:			UPC: MVX Code:	331722149051	No	tes					
UDI			CVX Code:			MVX Code:								
Description:	Gabapentin Cap	sules, USP 300 mg							this product to be shipped				No	
Active Ingredient(s): Gabapentin, USP					Is this product to be shipped to customers on dry ice?									
		www.camberpharma							nperature excursion que	estions:	O D - !			
URL for Additional Product Inform Address:	800 Centennial A		i.com		1	Address 2:	I		me:		Soma Raju 732-529-042	12		
City:	Piscataway	ve, Suite 1			State:	NJ	Zip: 08854	Number: 732-529-0423				n		
Key Contact:	Customer Service	e			Email:	-	camberpharma.com	Stoup E-mail.			<u>oomaraja(e)</u>	101010404.001		
Phone Number:	1-866-827-3647				Fax:	732-562-8788	-	c. Special regulat	tions for product in any	states?			*Yes	
Product Therapeutic Classification	on:	Anticonvulsant			1			Sp	ecial returns requirement	s for this product?			No	
					1									
	ADDIT	IONAL PRODUCT INF	FORMATION			PRODUCT D	DESCRIPTION INFORMATION	d. Store product	(unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	nly			Pro	otect product (unit of sa	ale) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	500 ct	e. Shelf life:		. •			24	Months
if yes, enter class #			Orphan Drug Status			Size:		Ini	tial shelf life at launch (	if different):				Months
a product kit?		No				Strength:	300 mg							
if yes, list NDCs of			FDA Approval Status							ORDER INFORM	MATION			
component parts reverse numbered?		N.				Dosage Forn	n: Hard gelatin capsule		it of Sale		What is the	NDC selling	unit?	
co-licensed?		No No	Allergens Present					Un Un	x Bottle		1 Bottle of 5		unitr	
latex-free?		Yes					Capsule		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Corn, Alcohol, A	nimal, Wheat, I	Oye	Product Shap	pe:		Ampule		(	g	,	
correctional institution block?		No				Product Cold	Yellow opaque cap and		Glass		Minimum o	der quantity	?	Yes
opioid?		No				Product Cold	yellow opaque body		Tube				L	
Cannabinoid?		No	Country of Origin	India		Product Impr	Imprinted with 'A' on cap and		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					i roduct impi	'Int: '470' on body in black ink		Vial Liquid Multi				ch package t	ype?
hospital scanning?			Is this product covered u		-				Vial Powder Sgl		12	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	IAA)?	No				Vial Powder Multi Other: Write In			Inner/Carton	/Pack	
			FOR GENERIC DRUG PR	ODUOTO					Other: write in			Case		
			FOR GENERIC DRUG PR	ODUCIS										
					Au	uthorized Generic	*If Authorized Generic, other		PH	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section fields are not applicable	Rec. sell unit to d				nit to pharma	acv.	
II. Generic Equivalent to What Brand?:		Neurontin						rece. Sen unit to dustomer i			Each			
								(Write-in, e.g. 1 V	ial)	_		Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT (	DSCSA) INFOR	RMATION			HCPCS J-Code:	,			Milliliter		
				_										
Does supplier meet DSCSA defin		irer?	Yes No	-	GLN:		ts to non-controlled substance states ts to controlled substance states		İTEN	AND PACKING I	NFORMATIO	V		
Is product exempt from DSCSA?			INO			,								
													Volume	Saleable #
If yes, select exemption:					GCP:				Weight Lbs.		ons (US msn	•		Pieces
Other exemption - Write in:			No			ululual muadost	abassal .	Mam/Fach		Depth	ons (US msn Width	nts.) Height	(Cube)	1
Other exemption - Write in: Is product repackaged?	e avelucive dietrib	uutor?	No Yes		If yes, was o	riginal product pure	chased	Item/Each:	Weight Lbs.		•	•		
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's			No Yes No		If yes, was o	nfr?	<u> </u>	'	0.75	Depth	Width	Height	(Cube)	
Other exemption - Write in: Is product repackaged?	on/exemption for p		Yes		If yes, was o	nfr?	r repackaged product	Item/Each:  Box/Carton/Bund Inner Pack:	0.75	Depth	Width	Height	(Cube)	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	on/exemption for p	product?	Yes No		If yes, was o	nfr?	<u> </u>	Box/Carton/Bund	0.75	<b>Depth</b> 3.36	Width 3.36	Height 6	(Cube) 67.74	12
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	on/exemption for p	product?	Yes	NFORMATION	If yes, was o	nfr?	<u> </u>	Box/Carton/Bund Inner Pack: Case:	0.75	Depth	Width	Height	(Cube)	12
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptic If yes, attach documentation fro	on/exemption for point FDA.	eroduct?	Yes No N AND HIBCC PRODUCT I	NFORMATION	If yes, was o direct from n Provide sour	nfr? ce manufacturer fo	r repackaged product	Box/Carton/Bund	0.75	<b>Depth</b> 3.36	Width 3.36	Height 6	(Cube) 67.74	12
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	on/exemption for p	GTIN	Yes No	NFORMATION	If yes, was o direct from n Provide sour	nfr?	<u> </u>	Box/Carton/Bund Inner Pack: Case:	0.75	<b>Depth</b> 3.36	Width 3.36	Height 6	(Cube) 67.74	12
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro  Saleable Unit of Measure	on/exemption for point FDA.  RFID tag(Y/N)	GTIN Saleable Quantity	Yes No N AND HIBCC PRODUCT I	NFORMATION	If yes, was or direct from n Provide sour	nfr? ree manufacturer fo	r repackaged product	Box/Carton/Bund Inner Pack: Case:	0.75	<b>Depth</b> 3.36	Width 3.36	Height 6	(Cube) 67.74	12
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro  Saleable Unit of Measure  x Item/Each	on/exemption for point FDA.	GTIN	Yes No N AND HIBCC PRODUCT I	NFORMATION	If yes, was or direct from n Provide sour	nfr? ce manufacturer fo	r repackaged product	Box/Carton/Bund Inner Pack: Case:	0.75	<b>Depth</b> 3.36	Width 3.36	Height 6 7.5	(Cube) 67.74	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro  Saleable Unit of Measure	on/exemption for point FDA.  RFID tag(Y/N)	GTIN Saleable Quantity	Yes No N AND HIBCC PRODUCT I	NFORMATION	If yes, was ordirect from n Provide sour	nfr? ree manufacturer fo	r repackaged product	Box/Carton/Bund Inner Pack: Case:	0.75	<b>Depth</b> 3.36	Width 3.36	Height 6 7.5	(Cube) 67.74 1229.06	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptic If yes, attach documentation fro  Saleable Unit of Measure  X Item/Each Box/Carton/Bundle/Inner Pack	on/exemption for point FDA.  RFID tag(Y/N)	GTIN Saleable Quantity	Yes No N AND HIBCC PRODUCT I	NFORMATION	If yes, was ordirect from n Provide sour	nfr? ce manufacturer fo	r repackaged product	Box/Carton/Bund Inner Pack: Case:	0.75	Depth 3.36 14.25	Width 3.36 11.5	Height 6 7.5	(Cube) 67.74 1229.06	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro  Saleable Unit of Measure  X	on/exemption for point FDA.  RFID tag(Y/N)	GTIN Saleable Quantity	Yes No N AND HIBCC PRODUCT I	NFORMATION	If yes, was ordirect from n Provide sour	nfr? ce manufacturer fo	r repackaged product	Box/Carton/Bund Inner Pack: Case: Pallet:	0.75  9.75  COST INFORMATION	Depth 3.36 14.25	Width 3.36  11.5  Vendor #: Whsl. Code	Height 6 7.5 WHOLESAL	(Cube) 67.74 1229.06	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro  Saleable Unit of Measure  X	on/exemption for point FDA.  RFID tag(Y/N)	GTIN Saleable Quantity	Yes No N AND HIBCC PRODUCT I	NFORMATION	If yes, was ordirect from n Provide sour	nfr? ce manufacturer fo	r repackaged product	Box/Carton/Bund Inner Pack: Case: Pallet:  Regular Cost Invoice Cost (WA	0.75  9.75  COST INFORMATION  C) (\$)	Depth 3.36 14.25	Width 3.36 11.5	Height 6 7.5 WHOLESAL	(Cube) 67.74 1229.06	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro  Saleable Unit of Measure  X	on/exemption for point FDA.  RFID tag(Y/N)	GTIN Saleable Quantity	Yes No N AND HIBCC PRODUCT I	NFORMATION	If yes, was ordirect from n Provide sour	nfr? ce manufacturer fo	r repackaged product	Box/Carton/Bund Inner Pack: Case: Pallet:  Regular Cost	0.75  9.75  COST INFORMATION	Depth 3.36 14.25	Width 3.36  11.5  Vendor #: Whsl. Code	Height 6 7.5 WHOLESAL	(Cube) 67.74 1229.06	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro  Saleable Unit of Measure  X	on/exemption for point FDA.  RFID tag(Y/N)	GTIN Saleable Quantity	Yes No N AND HIBCC PRODUCT I	NFORMATION	If yes, was ordirect from n Provide sour	nfr? ce manufacturer fo	r repackaged product	Box/Carton/Bund Inner Pack: Case: Pallet:  Regular Cost Invoice Cost (WA	0.75  9.75  COST INFORMATION  C) (\$)	Depth 3.36 14.25	Width 3.36  11.5  Vendor #: Whsl. Code	Height 6 7.5 WHOLESAL	(Cube) 67.74 1229.06	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro  Saleable Unit of Measure  X	on/exemption for point FDA.  RFID tag(Y/N)	Saleable Quantity 1 1 12	Yes No NAND HIBCC PRODUCT I HIBCC		If yes, was ordirect from n Provide sour	in-14 331722149051 331722149055	r repackaged product	Box/Carton/Bund Inner Pack: Case:  Pallet:  Regular Cost Invoice Cost (WA As of date:	0.75  9.75  COST INFORMATION  C) (\$)	Depth 3.36 14.25	Width 3.36  11.5  Vendor #: Whsl. Code	Height 6 7.5 WHOLESAL	(Cube) 67.74 1229.06	



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

#### Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply):  a. Cytotoxic?  b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS Hazard Classification					
Is the product a CA Prop 65 carcinogen?  Is the product a CA Prop 65 reproductive toxicant?  Does the product label bear a CA Prop 65 warning?  No	x     Organic     Corrosive       Inorganic     Oxidizer       Steroid/Androgen     Contact Hazard					
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?	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  NFPA Storage Level:  Is the product a NIOSH hazardous drug?  No					
(if yes, answer a-e below and provide SDS)  a. UN/dentification Number  b. Proper Shipping Name	If yes, indicate which:					
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification  EPA Hazardous Waste Code:  Waste Characteristics					
	El 711 IZZI GOLG VIGLE GOLG.					
Is this product regulated for shipment by IATA?  (if yes, answer a-e below and provide SDS)	REMS or 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:					
Is the product restricted for air shipment? If so, indicate restriction:  Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)					
Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit?  No (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4)	REMS:  REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier:  No Phone:  Phone:  DEA #: NCPDP#: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments					
SP#	Registry:  Registry Program Contact Name:  No  Phone:					
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: Comments					
Is the Product						
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS					
Controlled by State(s)? Yes 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:	Special regulations or returns requirements for this					
Restricted to hospital, clinics, and physician offices only:  Restricted from US territories? (explain in comments)  No	product in certain states?  If so, which states? Other requirements? Comments?					
Comments:	This product is classified as a Schedule V controlled substance in Alabama, Kentucky, Montana, North Dakota, Tennessee, Utah, Virginia, and West Virginia.					
MISCELLANEC	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:		Purchase order daily receipt cut off time by supplier
a. EDI		Cut off time:
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 #:	Name:	
	Phone:	
Expedited Freight Cha	arges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each orde	er:	Overnight receipt available:
Drop Ship service fee billed with each orde	er:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed:		Days of week overnight is available:
Comments:		Tuesday
		Wednesday
		Thursday
		Friday
		Priority Overnight receipt available:
Cla	ss of Trade Restriction:	PO Receipt Cut off time:
Restricted to retail pharmacy only:	harmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:  PO Receipt Cut off time:
Restricted to retail priarriacy only.  Restricted to hospital, clinics, and physiciar	n offices only:	Phone: Phone #:
Restricted from US territories? (explain in c	-	Order receipt method: Fax: Fax #:
Comments:	oniments)	EDI:
		Overnight Fees apply:
		Other fees apply:
Other Data Inf	formation Required to Process PO:	Return Instructions
Patient Procedure Date:	1	Contact # if product is received damaged:
Physician Name:		Is product returnable for credit:
Physician/Clinic Phone #		URL/Link to returns policy:
Physician State License #		ONE Ellik to retains policy.
Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certain states?
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?
	Miscellaneous Notes:	·
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure?
		Is product order for restocking purposes?