

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

						Introduction Type:	New Item]	x Final Version			Date:	08-14	-2024
			PRODUCT INFORMAT	TION					SPECIAL HAND	LING AND STOP	RAGE REQUIR	EMENTS*		
Company Name:	CREEKWOOD PHAR		10			Application:	ANDA	a Tomporatu	re – Indicate the USP temp	araturo rango for	this product			
Application Number for NDA/AN				20	04989	Application.	,	a. remperatur	Temperature Range	Controlled Room		and 25 C (6	8° – 77° F)	
Medical Device Class, if applica			5 ,.						remperature range			(-	,	
DUNS:	118582565								Other Temperature Range	Requirement				
Proprietary Name (If Applicable)		: Gabape	entin capsules, USP 300 m	a .1000's per B	lottle			1	(write in)					
Selling Unit NDC:	82619-143-03		Unit of Use NDC:		82619-143-03	UPC: N38	2619143034		Notes					
UDI	NA		CVX Code:			MVX Code: NA								
Description:	White to off white nov	wder filled in size "	1" hard gelatin cansules w	ith oneque Vella	ow colored car	and onaque Yellow cold	red body imprinted "SG" on	i	Is this product to be shipped	d to customers on	ice?		No	1
Description.	cap and "180" on body		i nara gelatin capsules wi	un opaque rend	Sw colored cap	and opaque renow cold	red body implified bod off		Is this product to be shipped				No	
Active Ingredient(s):		abapentin						-	io ano produce to be emppo		ury 100 .		110	1
								b. Contact for	r temperature excursion qu	estions:				
URL for Additional Product Infor	mation:								Name:		SUJIT SAKE	AL		
Address:	1130 US 46 W					Address 2: Suit	e 21	1	Number:		551-303-933	0		
City:	Parsippany				State:	NJ Zip	: 07054		Group E-mail:		sujit@cree	kwoodpha	rma.com	
Key Contact:	Paul Thomas				Email:	paul@creekwoodp	<u>harma.com</u>							
Phone Number:	1-732-344-022				Fax:			c. Special reg	ulations for product in any	states?			No	
Product Therapeutic Classification	on: An	nticonvulsant							Special returns requirement	s for this product	?		No	
														1
	ADDITIONA	L PRODUCT INFO	ORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store produ	uct (unit of sale) upright?				Yes	1
The product is?			Is the Product	Direct-Ship C	Only				Protect product (unit of sa	ale) from light?			No	1
a legend device?	No	,	Is the Product	Unit of Use			19mm -Size '1'	e. Shelf life:	· · · · · · · · · · · · · · · · · · ·	, .			36	Months
if yes, enter class #			Orphan Drug Status			Size:			Initial shelf life at launch (if different):				Months
a product kit?	No)				a	300 mg							1
if yes, list NDCs of			FDA Approval Status			Strength:	U U			ORDER INFORM	IATION			
component parts						Decese Form	capsule							
reverse numbered?	No					Dosage Form:			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?	No	,	Allergens Present						x Bottle		1 Bottle of 1	000 Capsule	s	
latex-free?	Ye	/S				Product Shape:	CAPSULE		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?	Ye	/S				i roudet onape.			Ampule					
correctional institution block?	No	j				Product Color:	Yellow color cap/Yellow		Glass		Minimum or	der quantity	?	Yes
opioid?	No)				Froduct Color.	color body		Tube					
Cannabinoid?	No	,	Country of Origin	INDIA		Product Imprint:	SG on Cap and 180 on		Vial Liquid Sgl					
If Unit Dose, is item bar coded to						r roudet imprint.	Body		Vial Liquid Multi		If Yes, how	many of wh	ich package	type?
hospital scanning?	No	J	Is this product covered u						Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	No				Vial Power Multi		per cases	Inner/Cartor	/Pack	
									Other: Write In		3	Case		
		F	FOR GENERIC DRUG PRO	DDUCTS	[
					A	the anima of O and a size with A	uthorized Generic, other							
I. Orange Book Rating:									PH/	ARMACY ORDER	/ BILL UNIT			
II. Generic Equivalent to What Brand?: Neurontin (gabapentin) Capsules								Rec. sell unit		ARMACY ORDER	/ BILL UNIT Rx billing u	nit to pharm	acy:	
II. Generic Equivalent to What Br	and?: Ne	urontin (gabapent	in) Capsules		Au			Rec. sell unit		ARMACY ORDER		nit to pharm Each	acy:	
II. Generic Equivalent to What Br	and?: Ne							Rec. sell unit	to customer? Bottle	ARMACY ORDER	Rx billing u	Each Gram	acy:	
II. Generic Equivalent to What Br	rand?: Ne		tin) Capsules CHAIN SECURITY ACT (I	DSCSA) INFOR					to customer? Bottle	ARMACY ORDER	Rx billing u	Each	acy:	
		DRUG SUPPLY	CHAIN SECURITY ACT (DSCSA) INFOR	RMATION	sect			to customer? Bottle 1 Vial)		Rx billing u	Each Gram Milliliter	acy:	
Does supplier meet DSCSA defin	nition of manufacturer?	DRUG SUPPLY		DSCSA) INFOR					to customer? Bottle 1 Vial)	ARMACY ORDER	Rx billing u	Each Gram Milliliter	acy:	
Does supplier meet DSCSA defin Is product exempt from DSCSA?	nition of manufacturer?	DRUG SUPPLY	CHAIN SECURITY ACT (DSCSA) INFOR	RMATION GLN:	sect 850045940003			to customer? Bottle 1 Vial)	AND PACKING I	Rx billing u	Each Gram Milliliter		
Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption:	nition of manufacturer?	DRUG SUPPLY	CHAIN SECURITY ACT (DSCSA) INFOR	RMATION	sect			to customer? Bottle 1 Vial) ITEM	AND PACKING I	Rx billing un x NFORMATION	Each Gram Milliliter ts.)	Volume	Saleable #
Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	nition of manufacturer?	DRUG SUPPLY	CHAIN SECURITY ACT (I Yes		RMATION GLN: GCP:	850045940003 850045940		(Write-in, e.g.	to customer? Bottle 1 Vial)	AND PACKING I	Rx billing u	Each Gram Milliliter		Pieces
Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	nition of manufacturer?	DRUG SUPPLY	CHAIN SECURITY ACT (L Yes No	DSCSA) INFOR	GLN: GCP: If yes, was or	850045940003 850045940 iginal product			to customer? Bottle 1 Vial) ITEM	AND PACKING I	Rx billing un x NFORMATION	Each Gram Milliliter ts.)	Volume	Pieces 1000 Caps
Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer'	nition of manufacturer?	DRUG SUPPLY	CHAIN SECURITY ACT (L Yes No No	DSCSA) INFOR	GLN: GCP: If yes, was or purchased di	sect 850045940003 850045940 riginal product rect from mfr?	ion fields are not applicable	(Write-in, e.g.	to customer? Bottle 1 Vial) ITEM Weight Lbs. 2.75	AND PACKING I Dimensi Depth	Rx billing un x NFORMATION ions (US msrr Width	Each Gram Milliliter ts.) Height	Volume (Cube)	Pieces 1000 Caps per Bottle
Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exceptio	hition of manufacturer? '' ''s exclusive distributor on/exemption for produ	DRUG SUPPLY	CHAIN SECURITY ACT (L Yes No	DSCSA) INFOR	GLN: GCP: If yes, was or purchased di	850045940003 850045940 iginal product	ion fields are not applicable	(Write-in, e.g.	to customer? Bottle 1 Vial) ITEM Weight Lbs. 2.75	AND PACKING I Dimensi Depth	Rx billing un x NFORMATION ions (US msrr Width	Each Gram Milliliter ts.) Height	Volume (Cube)	Pieces 1000 Caps
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Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exception If yes, attach documentation from	nition of manufacturer? 's exclusive distributor on/exemption for produ om FDA.	DRUG SUPPLY 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	CHAIN SECURITY ACT (D Yes No No No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased di Provide source	850045940003 850045940 850045940 riginal product rect from mfr? cc manufacturer for rep	on fields are not applicable	(Write-in, e.g.	to customer? Bottle 1 Vial) ITEM Weight Lbs. 2.75 undle/	AND PACKING I Dimensi Depth NA	Rx billing un x NFORMATION ions (US msrr Width 7.9	Each Gram Milliliter ts.) Height 4.275	Volume (Cube) #VALUE!	Pieces 1000 Caps per Bottle NA 12 Bottles per case 40 cases
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HDA

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

Version 2021	For Designate	d 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? 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 No No	SDS Hazard Classification 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?	No No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:	No				
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	No	Is the product a NIOSH hazardous drug? No If yes, indicate which: Hazardous Waste Identification					
c. DOT Hazard Class							
d. Packing Group e. Inhalation Hazard?	No	EPA Hazardous Waste Code:		Waste Characteristics			
Is this product regulated for shipment by IATA?	No						
(if yes, answer a-e below and provide SDS)	INU		REGISTRY RESTRICTIONS				
a. UN/Identification Number							
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group		Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:	No				
e. Inhalation Hazard?	No						
Is the product restricted for air shipment? If so, indicate restriction:	No	Med Guide Required	No				
Passenger Cargo Passenger & Cargo		Limited Distribution Requirement Comments / Details: (For example, iPledge program?)	No				
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:				
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);		Comments IT IS NOT A REMS					
SP#		Registry:	No				
ADD'L STORAGE INFORMATION		Registry Program Contact Name:	DRODUCT	Phone:			
		Comments IT IS NOT A REMS	PRODUCI				
Is the Product Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) ARCOS Reportable? No If yes, indicate which:	No	RI Contact tel. # if product received damaged:					
Schedule No. Is it a scheduled listed chemical product?:	No	Is product returnable for credit:					
CLASS OF TRADE RESTRICTION:		URL/Link to returns policy: https://creekwoo	odpharma.com/wp-content,	/uploads/2023/07/Return-Goods-			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes	Policy.pdf					
Restricted to retail pharmacy only:	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)	If so, which states? Other requirements? Comments?						
Comments:							
		DUS NOTES and/or Image of Product Barcode:					
	MISCELLANEC	TOS NOTES and/or image of Product Barcode:					



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

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete. Version 2021 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 Yes Cut off time: Fax Number: b. Autofax Fax Number: Days c. Fax Shipping lead time of PO: Hours d. Phone only Phone No.: e. Supplier Web Site only Site Address: Ships same day for next day receipt: Minimum Order Quantity: Units Ships for second day receipt: Supplier's Customer Service Number: Ships regular ground for 3-10 days receipt: Contracted 3PL company / contact #: Name: Direct customer solutions (R & S) 1-800-655-7556 Phone: Expedited Freight Charges or Other Designated Drop Ship Fees: **Overnight and Priority Overnight PO Processing** 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: Monday Days of week overnight is available: Comments: Tuesday Wednesday Thursday Fridav Priority Overnight receipt available: **Class of Trade Restriction:** PO Receipt Cut off time: No restriction: Select YES if sold to retail pharmacy, 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 offices only: Phone: Phone #: Order receipt method: Fax: Restricted from US territories? (explain in comments) Fax #: Comments: EDI: Overnight Fees apply: Other fees apply: Other Data Information 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 # 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?