



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

Version 2021

Introduction Type: New Item Final Version

Date: 08-14-2024

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: CREEKWOOD PHARMACEUTICALS LLC Application: ANDA				a. Temperature – Indicate the USP temperature range for this product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 204989				Temperature Range <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>			
Medical Device Class, if applicable:				Other Temperature Range Requirement (write in) <input type="text"/>			
DUNS: 118582565				Notes <input type="text"/>			
Proprietary Name (if Applicable) and Established Name: Gabapentin capsules, USP 300 mg, 1000's per Bottle				Is this product to be shipped to customers on ice? <input type="checkbox"/> No			
Selling Unit NDC: 82619-143-03 Unit of Use NDC: 82619-143-03 UPC: N382619143034				Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No			
UDI: NA CVX Code: <input type="text"/> MXV Code: NA				b. Contact for temperature excursion questions:			
Description: White to off white powder filled in size "1" hard gelatin capsules with opaque Yellow colored cap and opaque Yellow colored body imprinted "SG" on cap and "180" on body with black ink				Name: SUJIT SAKPAL			
Active Ingredient(s): Gabapentin				Number: 551-303-9330			
URL for Additional Product Information:				Group E-mail: sujit@creekwoodpharma.com			
Address: 1130 US 46 W				Address 2: Suite 21			
City: Parsippany				State: NJ Zip: 07054			
Key Contact: Paul Thomas				Email: paul@creekwoodpharma.com			
Phone Number: 1-732-344-022				Fax:			
Product Therapeutic Classification: Anticonvulsant				c. Special regulations for product in any states?			
				Special returns requirements for this product? <input type="checkbox"/> No			
				d. Store product (unit of sale) upright?			
				Protect product (unit of sale) from light? <input type="checkbox"/> No			
				e. Shelf life: Initial shelf life at launch (if different): <input type="text"/> 36 Months			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?				Size: 19mm -Size '1'			
a legend device? <input type="checkbox"/> No				Strength: 300 mg			
if yes, enter class #				Dosage Form: capsule			
a product kit? <input type="checkbox"/> No				Product Shape: CAPSULE			
if yes, list NDCs of component parts				Product Color: Yellow color cap/Yellow color body			
reverse numbered? <input type="checkbox"/> No				Product Imprint: SG on Cap and 180 on Body			
co-licensed? <input type="checkbox"/> No							
latex-free? <input type="checkbox"/> Yes							
preservative-free? <input type="checkbox"/> Yes							
correctional institution block? <input type="checkbox"/> No							
opioid? <input type="checkbox"/> No							
Cannabinoid? <input type="checkbox"/> No							
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> No							
If Unit Dose, indicate NDC here: <input type="text"/>							
Is the Product... Direct-Ship Only <input type="checkbox"/>							
Is the Product... Unit of Use <input type="text"/>							
Orphan Drug Status <input type="checkbox"/>							
FDA Approval Status <input type="text"/>							
Allergens Present <input type="text"/>							
Country of Origin INDIA							
Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable							
II. Generic Equivalent to What Brand?: Neurontin (gabapentin) Capsules							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes GLN: 850045940003							
Is product exempt from DSCSA? <input type="checkbox"/>							
If yes, select exemption: <input type="text"/>							
Other exemption - Write in: <input type="text"/>							
Is product repackaged? <input type="checkbox"/> No GCP: 850045940							
Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> No							
Has FDA granted waiver/exemption/exemption for product? <input type="checkbox"/> No							
If yes, attach documentation from FDA. <input type="text"/>							
Provide source manufacturer for repackaged product <input type="text"/>							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure							
<input checked="" type="checkbox"/> Item/Each	Saleable Quantity		HIBCC		GTIN-14		Unit of Use GTIN-14
<input type="checkbox"/> Box/ Carton/Bundle/Inner Pack	1000				00382619143034		382619143034
<input checked="" type="checkbox"/> Case	12				20382619143038		
<input checked="" type="checkbox"/> Pallet							
PHARMACY ORDER / BILL UNIT							
Rec. sell unit to customer? <input type="checkbox"/> Bottle <input checked="" type="checkbox"/> Rx billing unit to pharmacy:							
<input type="text"/> (Write-in, e.g. 1 Vial)							
<input type="checkbox"/> Each							
<input type="checkbox"/> Gram							
<input type="checkbox"/> Milliliter							
ITEM AND PACKING INFORMATION							
Weight Lbs.							
Dimensions (US msmts.)							
Volume (Cube)							
Saleable # Pieces							
Item/Each:	2.75	NA	7.9	4.275	#VALUE!	1000 Caps per Bottle	
Box/ Carton/Bundle/ Inner Pack:						NA	
Case:	16	17.1	8.8	13	1956.24	12 Bottles per case	
Pallet:	720	48	54	40	103680	40 cases per Pallet	
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost				Vendor #: <input type="text"/>			
Invoice Cost (WAC) (\$)				Whsl. Code #: <input type="text"/>			
As of date: <input type="text"/>				Fineline Code: <input type="text"/>			

*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship Only.

Signature:

Paul Thomas

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/> No Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions? <input type="checkbox"/> No (If yes, attach SDS with special instructions.)</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger <input type="checkbox"/> Cargo <input type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? <input type="checkbox"/> No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity <input type="checkbox"/> Consumer Commodity, ORM-D <input type="checkbox"/> Small Quantity (49 CFR 173.4) <input type="checkbox"/> Special Permit; DOT-SP <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input type="text"/></p>	<div style="background-color: #002060; color: white; padding: 2px; text-align: center; font-weight: bold;">SDS Hazard Classification</div> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input type="checkbox"/> Organic</td> <td style="width: 50%; border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p>Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="checkbox"/> No</p> <p>NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? <input type="checkbox"/> No If yes, indicate which: <input type="text"/></p>	<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive	<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer	<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive						
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer						
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard						
Hazardous Waste Identification							
EPA Hazardous Waste Code: <input type="text"/> Waste Characteristics: <input type="text"/>							
REMS or REGISTRY RESTRICTIONS							
<p>Is there a REMS on this product? <input type="checkbox"/> No</p> <p>If Yes, is it managed with a pharmacy registry? <input type="text"/></p> <p>Website URL: <input type="text"/></p> <p>Med Guide Required <input type="checkbox"/> No</p> <p>Limited Distribution Requirement <input type="checkbox"/> No</p> <p>Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p>REMS:</p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="checkbox"/> No</p> <p>Wholesale distributor support: <input type="text"/></p> <p>Provider Name: <input type="text"/> DEA #: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/> NCPDP#: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments <input type="text"/> IT IS NOT A REMS PRODUCT</p> <p>Registry: <input type="checkbox"/> No</p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments <input type="text"/> IT IS NOT A REMS PRODUCT</p>							
ADD'L STORAGE INFORMATION							
<p>Is the Product...</p> <p>Controlled Substance? <input type="checkbox"/> No Controlled Substance Code <input type="text"/></p> <p>Controlled by State(s)? <input type="checkbox"/> No Listed Chemical (List I or II) <input type="text"/> <input type="checkbox"/> No</p> <p>ARCOS Reportable? <input type="checkbox"/> No If yes, indicate which: <input type="text"/></p> <p>Schedule No. <input type="text"/> Is it a scheduled listed chemical product? <input type="checkbox"/> No</p>							
CLASS OF TRADE RESTRICTION:							
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>							
RETURN INSTRUCTIONS							
<p>Contact tel. # if product received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: https://creekwoodpharma.com/wp-content/uploads/2023/07/Return-Goods-Policy.pdf</p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>							
MISCELLANEOUS NOTES and/or Image of Product Barcode:							



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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 <input type="checkbox"/> Yes b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Units Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: Direct customer solutions (R & S) Phone: 1-800-655-7556 Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <input type="text"/>	Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	Overnight receipt available: <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: <input type="text"/> Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	
<input type="text"/>	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>