



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

Version 2021

Introduction Type: New Item☒ Final Version

Date: 09/22/2026

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): A219460				Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)			
Medical Device Class, if applicable:				Other Temperature Range Requirement (write in)			
DUNS: 118582565				Notes			
Proprietary Name (If Applicable) and Established Name: Propranolol Extended Release Capsule USP, 160mg				Is this product to be shipped to customers on ice? No			
Selling Unit NDC: 82619-135-01 Unit of Use NDC: 82619-135-01 UPC: 382619135015				Is this product to be shipped to customers on dry ice? No			
UDI: NA CVX Code: MXV Code: NA				b. Contact for temperature excursion questions:			
Description: Light blue opaque body and Dark blue opaque cap, size "1" hard gelatin capsule imprinted with "305" on cap and "160" on body in black ink, filled with white to off white spherical pellets.				Name: SUJIT SAKPAL			
Active Ingredient(s): Propranolol Hydrochloride				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: Anti Hypertensive				c. Special regulations for product in any states?			
				Special returns requirements for this product? No			
				d. Store product (unit of sale) upright?			
				Protect product (unit of sale) from light? No			
				e. Shelf life:			
				Initial shelf life at launch (if different): 24 Months			
				24 Months			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?		Is the Product...		Size:		Strength:	
a legend device? No		Direct-Ship Only		19.3mm		160mg	
if yes, enter class #		Is the Product...		Dosage Form:		Product Shape:	
a product kit? No		Orphan Drug Status		Capsules		Capsule shape	
if yes, list NDCs of component parts		FDA Approval Status		Product Color:		Product Imprint:	
reverse numbered? No				Light blue and Dark blue (opaque)		""305" on cap and "160" on body in black ink	
co-licensed? No		Allergens Present					
latex-free? Yes							
preservative-free? Yes							
correctional institution block? No							
opioid? No							
Cannabinoid? No							
If Unit Dose, is item bar coded to unit dose for hospital scanning? No							
If Unit Dose, indicate NDC here:							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating:				☐ Authorized Generic *If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: Inderal LA							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? Yes				GLN: 850045940003			
Is product exempt from DSCSA?				GCP: 850045940			
If yes, select exemption:				If yes, was original product purchased direct from mfr?			
Other exemption - Write in:				Provide source manufacturer for repackaged product			
Is product repackaged? No							
Is product sold by manufacturer's exclusive distributor? No							
Has FDA granted waiver/exception/exemption for product? No							
If yes, attach documentation from FDA.							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14		
☒ Item/Each		1		00382619135015	00382619135015		
☒ Box/ Carton/ Bundle/ Inner Pack		60		20382619135019			
☒ Case		3840					
☒ Pallet							
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost				Vendor #:			
Invoice Cost (WAC) (\$)				Whsl. Code #:			
As of date:				Fineline Code:			
*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			
Is this product (check all that apply):			
a. Cytotoxic?	☐ No		
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?			
Is the product a CA Prop 65 carcinogen?	☐ No		
Is the product a Pregabalin Capsules 75 mg	☐ No		
Does the product label bear a CA Prop 65 warning?	☐ No		
c. Contact Hazard?	☐ No		
d. Does this Pregabalin 75mg capsules are "Size 4" White body and orange cap, hard-gel (If yes, attach SDS with special instructions.)	☐ No		
e. Does the product contain DEHP?	☐ 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			
c. DOT Hazard Class			
d. Packing Group			
e. Inhalation Hazard?	☐ No		
Is this product regulated for shipment by IATA?			
(if yes, answer a-e below and provide SDS)			
a. UN/Identification Number			
b. Proper Shipping Name			
c. DOT Hazard Class			
d. Packing Group			
e. Inhalation Hazard?	☐ No		
Is the product restricted for air shipment? If so, indicate restriction:			
☐ Passenger			
☐ Cargo			
☐ Passenger & Cargo			
Is this a reportable quantity?			
RQ Threshold:	☐ No		
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)			
☐ Special Permit; DOT-SP			
☐ Special Provision (listed in Column 7 of 49 CFR 172.101);			
SP#			
ADD'L STORAGE INFORMATION			
Is the Product...			
Controlled Substance?	☐ No	Controlled Substance Code	
Controlled by State(s)?	☐ No	Listed Chemical (List I or II)	☐ No
ARCOS Reportable?	☐ No	If yes, indicate which:	
Schedule No.		Is it a scheduled listed chemical product?:	☐ No
CLASS OF TRADE RESTRICTION:			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		☐ Yes	
Restricted to retail pharmacy only:			
Restricted to hospital, clinics, and physician offices only:			
Restricted from US territories? (explain in comments)			
Comments:			
MISCELLANEOUS NOTES and/or Image of Product Barcode:			

SDS Hazard Classification	
☐ Organic	☐ Corrosive
☐ Inorganic	☐ Oxidizer
# ☐ Steroid/Androgen	☐ Contact Hazard
Does the product have an Aerosol class? If yes, identify NFPA Storage Level:	
NFPA Storage Level:	
Is the product a NIOSH hazardous drug?	
If yes, indicate which:	

Hazardous Waste Identification	
EPA Hazardous Waste Code:	Waste Characteristics

REMS or REGISTRY RESTRICTIONS	
4	
Is there a REMS on this product?	☐ No
75 mg	
Website URL:	
Med Guide Required	☐ No
Limited Distribution Requirement	☐ No
Comments / Details: (For example, iPledge program?)	
White body and Orange cap, printed with black ink	
REMS	☐ No
REMS Program Manager Name:	
Supplier Manages REMS registry exclusively:	
Wholesale distributor support:	
Provider Name:	
Site Enrollment Number assigned by Supplier:	
Phone:	
DEA #:	
NCPDP#:	
NPI #:	
Comments	IT IS NOT A REMS PRODUCT
Registry:	☐ No
Registry Program Contact Name:	
Phone:	
Comments	IT IS NOT A REMS PRODUCT

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged:	
Is product returnable for credit:	
URL/Link to returns policy:	https://creekwoodpharma.com/wp-content/uploads/2023/07/Return-Goods-Policy.pdf
Special regulations or returns requirements for this product in certain states?	
If so, which states? Other requirements? Comments:	



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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: <table border="0"><tr><td>a. EDI</td><td>☐</td><td>Yes</td></tr><tr><td>b. Autofax</td><td>☐</td><td></td></tr><tr><td>c. Fax</td><td>☐</td><td></td></tr><tr><td>d. Phone only</td><td>☐</td><td></td></tr><tr><td>e. Supplier Web Site on 82619-124-01</td><td>☐</td><td></td></tr></table> Minimum Order Quantity: Units Supplier's Customer Service Number: Contracted 3PL company / c Pregabalin 75n Name: Direct customer solutions (R & S) Phone: 1-800-655-7556	a. EDI	☐	Yes	b. Autofax	☐		c. Fax	☐		d. Phone only	☐		e. Supplier Web Site on 82619-124-01	☐		Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days 82619-124-01 3.826E+11 Ships for second day receipt: Ships regular ground for 3-10 days receipt:
a. EDI	☐	Yes														
b. Autofax	☐															
c. Fax	☐															
d. Phone only	☐															
e. Supplier Web Site on 82619-124-01	☐															
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: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: ☐ PO Receipt cut off time: Days of week overnight is available: <table border="0"><tr><td>☐</td><td>Monday</td></tr><tr><td>☐</td><td>Tuesday</td></tr><tr><td>☐</td><td>Wednesday</td></tr><tr><td>☐</td><td>Thursday</td></tr><tr><td>☐</td><td>Friday</td></tr></table> Priority Overnight receipt available: ☐ PO Receipt Cut off time: Saturday Overnight receipt available: ☐ PO Receipt Cut off time: Order receipt method: Phone: Phone #: Fax: Fax #: EDI: White body and Orange cap, printed with black Overnight Fees apply: Other fees apply:	☐	Monday	☐	Tuesday	☐	Wednesday	☐	Thursday	☐	Friday					
☐	Monday															
☐	Tuesday															
☐	Wednesday															
☐	Thursday															
☐	Friday															
Class of Trade Restriction:																
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) ☐ Comments:																
Other Data Information Required to Process PO:	Return Instructions															
Patient Procedure Date: Physician Name: Physician/Clinic Phone #: Physician State License #: 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? ☐															