



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

Version 2024

Introduction Type: ☐ Final Version

Date: 08/04/2026

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; PMA/510(k): 20269 NDA 505(b) Type:				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: Nitrofurantoin Capsules USP 100 mg (Monohydrate/Macrocystals)				Is this product to be shipped to customers on ice? ☐ No			
Selling Unit NDC: 82619-147-01 Unit of Use NDC: 82619-147-01 UPC: 382619147018				Is this product to be shipped to customers on dry ice? ☐ No			
UDI:				b. Contact for temperature excursion questions:			
Description: Yellow opaque body, blue opaque cap, size '1' hard gelatin capsule imprinted with '189' on cap and '100' on body in white ink, filled with yellow powder and a yellow capsule shaped tablet				Name: SUJIT SAKPAL			
Active Ingredient(s): Nitrofurantoin Hydrous USP, Nitrofurantoin Anhydrous USP				Number: 551-303-9330			
URL for Additional Product Information:				Group E-mail: sujit@creekwoodpharma.com			
Address: 1130 US 46 W Address 2: Suite 21				c. Special regulations for product in any states?			
City: Parsippany State: NJ Zip: 07054				Special returns requirements for this product? ☐ No			
Key Contact: Paul Thomas				d. Store product (unit of sale) upright? ☐ No			
Phone Number: 1-732-344-022 Fax:				Protect product (unit of sale) from light? ☐ No			
Product Therapeutic Classification: Anti- Bacterial				e. Shelf life:			
				Initial shelf life at launch (if different): Months			
				Months			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?				Size: 9.8 mm x 4.5 mm			
a legend device? ☐ No				Size 1			
if yes, enter class #				Strength: 100 mg			
a product kit? ☐ No				Dosage Form: Capsule			
if yes, list NDCs of component parts				Product Shape: Capsule shaped			
reverse numbered? ☐ No				Product Color: Yellow			
co-licensed? ☐ No				Product Imprint: 189 on cap and 100 on body			
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:							
Is the Product... Direct-Ship Only ☐							
Is the Product... Unit of Use ☐							
Orphan Drug Status							
FDA Approval Status							
Allergens Present							
Not present							
Country of Origin INDIA							
Is this product covered under the Trade Agreements Act (TAA)? ☐ No							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: AB ☐ Authorized Generic ☐ *If Authorized Generic, other section fields are not applicable							
II. Generic Equivalent to What Brand?: MACROBID							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? ☐ Yes GLN: 850045940003							
Is product exempt from DSCSA? ☐							
If yes, select exemption:							
Other exemption - Write in:							
GCP: 850045940							
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 RFID tag(Y/N) Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14							
☒ Item/Each ☐ Box/Carton/Bundle/Inner Pack ☐ Case ☐ Pallet							
1 60 64							
00382619147018 20382619147012 382619147018							
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Invoice Cost (WAC) (\$)				Vendor #:			
As of date:				Whsl. Code #:			
				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:							



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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 CA Prop 65 reproductive toxicant?	☐ No		
Does the product label bear a CA Prop 65 warning?	☐ No		
c. Contact Hazard?	☐ No		
d. Does this product require special clean-up instructions?	☐ No		
(If yes, attach SDS with special instructions.)			
e. Does the product contain DEHP?	☐ No		
Is this product regulated for shipment by DOT?	☐ No		
(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?	☐ No		
(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:	☐ No		
☐ Passenger			
☐ Cargo			
☐ Passenger & Cargo			
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)			
☐ Special Permit; DOT-SP			
☐ Special Provision (listed in Column 7 of 49 CFR 172.101);			
SP#	AB		
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:			
SDS Hazard Classification			
☐ Organic		☐ Corrosive	
☐ Inorganic		☐ Oxidizer	
☐ Steroid/Androgen		☐ Contact Hazard	
Does the product have an Aerosol class? If yes, identify NFPA Storage Level:	☐ No		
NFPA Storage Level:			
Is the product a NIOSH hazardous drug?	☐ No		
If yes, indicate which:			
Hazardous Waste Identification			
EPA Hazardous Waste Code:		Waste Characteristics	
REMS or REGISTRY RESTRICTIONS			
Is there a REMS on this product?	☐ No		
If Yes, is it managed with a pharmacy registry?			
Website URL:			
Med Guide Required	☐ No		
Limited Distribution Requirement	☐ No		
Comments / Details: (For example, iPledge program?)			
REMS:	☐ No		
REMS Program Manager Name:		Phone:	
Supplier Manages REMS registry exclusively:			
Wholesale distributor support:			
Provider Name:		DEA #:	
Site Enrollment Number assigned by Supplier:		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?			
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 b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Direct customer solutions (R & S) Phone: 1-800-655-7556	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight and Priority Overnight PO Processing Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday 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: Overnight Fees apply: Other fees apply:
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: Patient Procedure Date: Physician Name: Physician/Clinic Phone #: Physician State License #: Physician/Clinic DEA #: Physician/Clinic Specialty:	Return Instructions 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?