



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

Version 2024

Introduction Type: ☐ 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; 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 CVX Code: MXV Code:				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 Hydrate 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: 1-732-344-0222 Fax:				Protect product (unit of sale) from light? No																																																			
Product Therapeutic Classification: Anti- Bacterial				e. Shelf life: 24 Months																																																			
Initial shelf life at launch (if different): 24 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:																																																							
Is product repackaged? No GCP: 850045940																																																							
Is product sold by manufacturer's exclusive distributor? No If yes, was original product purchased direct from mfr?																																																							
Has FDA granted waiver/exception/exemption for product? No Provide source manufacturer for repackaged product																																																							
If yes, attach documentation from FDA.																																																							
GTIN AND HIBCC PRODUCT INFORMATION																																																							
<table border="1"><thead><tr><th>Saleable Unit of Measure</th><th>RFID tag(Y/N)</th><th>Saleable Quantity</th><th>HIBCC</th><th>GTIN-14</th><th>Unit of Use GTIN-14</th></tr></thead><tbody><tr><td>☒ Item/Each</td><td></td><td>1</td><td></td><td>00382619147018</td><td>00382619147018</td></tr><tr><td>☐ Box/ Carton/ Bundle/ Inner Pack</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>☒ Case</td><td></td><td>60</td><td></td><td>20382619147012</td><td></td></tr><tr><td>☒ Pallet</td><td></td><td>3840</td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></tbody></table>								Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14	☒ Item/Each		1		00382619147018	00382619147018	☐ Box/ Carton/ Bundle/ Inner Pack						☒ Case		60		20382619147012		☒ Pallet		3840																					
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COST INFORMATION				WHOLESALE USE ONLY:																																																			
Regular Cost				Vendor #:																																																			
Invoice Cost (WAC) (\$)				Whsl. Code #:																																																			
As of date:				Fineline Code:																																																			
Signature:																																																							

*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: ☐ 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		SDS Hazard Classification <table><tr><td>☐ Organic</td><td>☐ Corrosive</td></tr><tr><td>☐ Inorganic</td><td>☐ Oxidizer</td></tr><tr><td>☐ Steroid/Androgen</td><td>☐ Contact Hazard</td></tr></table> Does the product have an Aerosol class? If yes, identify No NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug? No If yes, indicate which:		☐ Organic	☐ Corrosive	☐ Inorganic	☐ Oxidizer	☐ Steroid/Androgen	☐ Contact Hazard										
☐ Organic	☐ Corrosive																		
☐ Inorganic	☐ Oxidizer																		
☐ Steroid/Androgen	☐ Contact Hazard																		
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: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: DEA #: NCPDP#: NPI #: Comments IT IS NOT A REMS PRODUCT Registry: Registry Program Contact Name: Comments IT IS NOT A REMS PRODUCT																			
ADD'L STORAGE INFORMATION Is the Product... <table><tr><td>Controlled Substance?</td><td> No </td><td>Controlled Substance Code</td><td> </td></tr><tr><td>Controlled by State(s)?</td><td> No </td><td>Listed Chemical (List I or II)</td><td> No </td></tr><tr><td>ARCOS Reportable?</td><td> No </td><td>If yes, indicate which:</td><td> </td></tr><tr><td>Schedule No.</td><td> </td><td>Is it a scheduled listed chemical product?:</td><td> No </td></tr></table>				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
Controlled Substance?	No	Controlled Substance Code																	
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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:																			
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:																			

Release DATE



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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?