



Date: 09/22/2026

PRODUCT INFORMATION			
Company Name:		CREEKWOOD PHARMACEUTICALS LLC	Application:
Application Number for NDA/ANDA/BLA; PMA/510(k):		A220269	NDA 505(b) Type:
Medical Device Class, if applicable:			
DUNS:	118582565		
Proprietary Name (if Applicable) and Established Name:		Nitrofurantoin Capsules USP 100 mg (Monohydrate/Macrocrystals)	
Selling Unit NDC:	82619-147-02	Unit of Use NDC:	82619-147-02
UDI		UPC:	382619147025
		CVX Code:	
		MXV Code:	
Description:	Yellow opaque body, blue opaque cap, size "1" hard gelatin capsule imprinted with with "189" on cap and "100" on body in white ink, filled with yellow powder and a yellow capsule shaped tablet		
Active Ingredient(s):	Nitrofurantoin Hydrous USP, Nitrofurantoin Anhydrous USP		
URL for Additional Product Information:			
Address:	1130 US 46 W		Address 2:
City:	Parsippany	State:	Suite 21
Key Contact:	Paul Thomas	NJ	Zip:
Phone Number:	1-732-344-0222	Email:	07054
		Fax:	paul@creekwoodpharma.com
Product Therapeutic Classification:	Anti-Bacterial		

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?	No	Is the Product... Direct-Ship Only	
a legend device?		Is the Product... Unit of Use	
if yes, enter class #		Orphan Drug Status	
a product kit?	No		
if yes, list NDCs of component parts		FDA Approval Status	
reverse numbered?	No		
co-licensed?	No	Allergens Present	
latex-free?	Yes	Not present	
preservative-free?	Yes		
correctional institution block?	No	Country of Origin	INDIA
opioid?	No		
Cannabinoid?	No	If Unit Dose, is item bar coded to unit dose for hospital scanning?	No
If Unit Dose, indicate NDC here:		Trade Agreements Act (TAA)?	No

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	MAROBID

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exemption/exemption for product?	No
If yes, attach documentation from FDA.	

GTIN AND HIBCC PRODUCT INFORMATION			
Saleable Unit of Measure	RFID tag(Y/N)	HIBCC	GTIN-14
X Item/Each	1		00382619147025
X Box/Carton/Bundle/Inner Pack			
X Case	24		20382619147029
X Pallet	648		

SPECIAL HANDLING AND STORAGE REQUIREMENTS*					
a. Temperature – Indicate the USP temperature range for this product.					
Temperature Range		Controlled Room – between 20 and 25 C (68° – 77° F)			
Other Temperature Range Requirement (write in)					
Notes					
Is this product to be shipped to customers on ice?		No			
Is this product to be shipped to customers on dry ice?		No			
b. Contact for temperature excursion questions:					
Name:	SUJIT SAKPAL				
Number:	551-303-9330				
Group E-mail:	suit@creekwoodpharma.com				
c. Special regulations for product in any states?	No				
Special returns requirements for this product?	No				
d. Store product (unit of sale) upright?	No				
e. Shelf life:	Protect product (unit of sale) from light?				
	Initial shelf life at launch (if different):				
	Months				
	Months				

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
x Bottle	1 bottle of 500 Tablets
Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
Ampule	
Glass	Minimum order quantity? Yes
Tube	
Vial Liquid Sgl	
Vial Liquid Multi	If Yes, how many of which package type?
Vial Powder Sgl	24 Each
Vial Power Multi	Inner/Carton/Pack
Other: Write In	1 Case

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
1 bottle of 500 tablets	x Each
(Write-in, e.g. 1 Vial)	Gram
HCPCS J-Code:	Milliliter

ITEM AND PACKING INFORMATION					
	Weight Lbs.	Dimensions (US msmts.)		Volume (Cube)	Saleable # Pieces
	Depth	Width	Height		
Item/Each:	0.76	1.89	3.793	5.68	1
Box/Carton/Bundle/ Inner Pack:					
Case:	12.78	12.99	9.84	13.38	24
Pallet:	345.06	38.97	29.52	46.06	648

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:



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

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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?	☐	No	
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)
ARCOS Reportable?	☐	No	
Schedule No.	☐		Is it a scheduled listed chemical product?:
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		☐ No	
NFPA Storage Level:			
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: <table border="1"><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: 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: 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?										