



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 Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): A213230 Medical Device Class, if applicable: DUNS: 118582565 Proprietary Name (If Applicable) and Established Name: Selling Unit NDC: 82619-113-01 UDI: NA Description: Silodosin 4 mg Capsules . Size 3 hard gelatin capsules, with white opaque cap and body. The cap is imprinted in black ink with "479". The body is imprinted in black ink with "4". Active Ingredient(s): Silodosin URL for Additional Product Information: Address: 1130 US 46 W City: Parsippany Key Contact: Paul Thomas Phone Number: 1-732-344-022 Product Therapeutic Classification: Silodosin, an alpha-1 adrenergic receptor antagonist Application: ANDA Unit of Use NDC: 82619-113-01 UPC: 382619113013 CVX Code: MVX Code: NA Address 2: Suite 21 State: NJ Email: paul@creekwoodpharma.com Zip: 07054 Fax:				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: sujit@creekwoodpharma.com 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																																		
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION																																		
The product is? a legend device? No if yes, enter class # a product kit? No if yes, list NDCs of component parts reverse numbered? No co-licensed? No 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 Unit of Use Orphan Drug Status FDA Approval Status Allergens Present Country of Origin INDIA Is this product covered under the Trade Agreements Act (TAA)? No Size: Size 3 Capsule Strength: 4 mg Dosage Form: Capsule Product Shape: Capsule Product Color: White Opaque Product Imprint: 479 and 4																																		
FOR GENERIC DRUG PRODUCTS																																						
I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: Rapaflo ☐ Authorized Generic *If Authorized Generic, other section fields are not applicable																																						
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/exception/exemption for product? No If yes, attach documentation from FDA. GLN: 850045940003 GCP: 850045940 If yes, was original product purchased direct from mfr? Provide source manufacturer for repackaged product																																						
GTIN AND HIBCC PRODUCT INFORMATION																																						
<table border="1"><thead><tr><th>Saleable Unit of Measure</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>1</td><td></td><td>00382619113013</td><td>00382619113013</td></tr><tr><td>☒ Box/Carton/Bundle/Inner Pack</td><td>48</td><td></td><td>20382619113017</td><td></td></tr><tr><td>☒ Case</td><td>5760</td><td></td><td></td><td></td></tr><tr><td>☒ Pallet</td><td></td><td></td><td></td><td></td></tr></tbody></table>								Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14	☒ Item/Each	1		00382619113013	00382619113013	☒ Box/Carton/Bundle/Inner Pack	48		20382619113017		☒ Case	5760				☒ Pallet										
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ORDER INFORMATION																																						
Unit of Sale ☒ Bottle ☐ Box/Carton ☐ Ampule ☐ Glass ☐ Tube ☐ Vial Liquid Sgl ☐ Vial Liquid Multi ☐ Vial Powder Sgl ☐ Vial Powder Multi ☐ Other: Write In What is the NDC selling unit? 1 bottle of 30 Capsules (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? Yes If Yes, how many of which package type? Each Inner/Carton/Pack 1 Case																																						
PHARMACY ORDER / BILL UNIT																																						
Rec. sell unit to customer? 1 bottle of 30 capsules (Write-in, e.g. 1 Vial) Rx billing unit to pharmacy: ☒ Each ☐ Gram ☐ Milliliter																																						
ITEM AND PACKING INFORMATION																																						
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COST INFORMATION																																						
Regular Cost Invoice Cost (WAC) (\$) As of date: Vendor #: Whsl. Code #: Fineline Code:																																						
WHOLESALE USE ONLY:																																						

*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?	☐	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:			
☐ 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#			
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	If yes, indicate which:
Schedule No.	☐	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:			
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:	☐ 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:	
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:	☐ No
Registry Program Contact Name:	
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>Fax Number:</td><td> </td></tr><tr><td>b. Autofax</td><td>☐</td><td>Fax Number:</td><td> </td></tr><tr><td>c. Fax</td><td>☐</td><td>Phone No.:</td><td> </td></tr><tr><td>d. Phone only</td><td>☐</td><td>Site Address:</td><td> </td></tr><tr><td>e. Supplier Web Site only</td><td>☐</td><td></td><td></td></tr></table> Minimum Order Quantity: Units Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Direct customer solutions (R & S) Phone: 1-800-655-7556	a. EDI	☐	Fax Number:		b. Autofax	☐	Fax Number:		c. Fax	☐	Phone No.:		d. Phone only	☐	Site Address:		e. Supplier Web Site only	☐			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: ☐
a. EDI	☐	Fax Number:																			
b. Autofax	☐	Fax Number:																			
c. Fax	☐	Phone No.:																			
d. Phone only	☐	Site Address:																			
e. Supplier Web Site only	☐																				
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: Overnight Fees apply: ☐ Other fees apply: ☐	☐	Monday	☐	Tuesday	☐	Wednesday	☐	Thursday	☐	Friday										
☐	Monday																				
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☐	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? ☐																				