



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

Version 2021 Introduction Type:   Final Version Date:

PRODUCT INFORMATION			
Company Name:	CREEKWOOD PHARMACEUTICALS LLC	Application:	ANDA
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:	82619-114-01	Unit of Use NDC:	82619-114-01
UDI	NA	CVX Code:	
		UPC:	382619114010
		MX Code:	NA
Description:	Silodosin 8mg Capsules . Size 1 hard gelatin capsules, with white opaque cap and body. The cap is imprinted in black ink with "480". The body is imprinted in black ink with '8'.		
Active Ingredient(s):	Silodosin		
URL for Additional Product Information:			
Address:	1130 US 46 W	Address 2:	Suite 21
City:	Parsippany	State:	NJ
Key Contact:	Paul Thomas	Zip:	07054
Phone Number:	1-732-344-022	Email:	<a href="mailto:paul@creekwoodpharma.com">paul@creekwoodpharma.com</a>
Product Therapeutic Classification:	Silodosin, an alpha-1 adrenergic receptor antagonist		

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?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
b. Contact for temperature excursion questions:	
Name:	SUJIT SAKPAL
Number:	551-303-9330
Group E-mail:	<a href="mailto:sujit@creekwoodpharma.com">sujit@creekwoodpharma.com</a>
c. Special regulations for product in any states?	<input type="text" value="No"/>
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	<input type="text" value="No"/>
Protect product (unit of sale) from light?	<input type="text" value="No"/>
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class #	<input type="text" value="No"/>	Is the Product... Direct-Ship Only	<input type="text" value="No"/>
a product kit? if yes, list NDCs of component parts reverse numbered?	<input type="text" value="No"/>	Is the Product... Unit of Use	<input type="text" value="No"/>
co-licensed?	<input type="text" value="No"/>	Orphan Drug Status	<input type="text" value="No"/>
latex-free?	<input type="text" value="No"/>	FDA Approval Status	<input type="text" value="No"/>
preservative-free?	<input type="text" value="Yes"/>	Allergens Present	<input type="text" value="No"/>
correctional institution block?	<input type="text" value="No"/>	Country of Origin	INDIA
opioid?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>
Cannabinoid?	<input type="text" value="No"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text" value="No"/>		
If Unit Dose, indicate NDC here:	<input type="text" value=""/>		
		Size:	Size 1 Capsule
		Strength:	8 mg
		Dosage Form:	Capsule
		Product Shape:	Capsule
		Product Color:	White Opaque
		Product Imprint:	480 and 8

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 bottle of 30 Capsules
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="text" value="Yes"/>
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value="1"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="text" value="1"/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<input type="text" value="1"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Rapaflo
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
1 bottle of 30 capsules	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="text" value="Yes"/>
Is product exempt from DSCSA?	<input type="text" value="No"/>
If yes, select exemption: Other exemption - Write in:	
Is product repackaged?	<input type="text" value="No"/>
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="No"/>
Has FDA granted waiver/exception/exemption for product?	<input type="text" value="No"/>
If yes, attach documentation from FDA.	
GLN:	850045940003
GCP:	850045940
If yes, was original product purchased direct from mfr?	<input type="text" value="No"/>
Provide source manufacturer for repackaged product	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.07	NA	1.57	2.95	7.27	1
Box/Carton/Bundle/ Inner Pack:						
Case:	4.69	12.99	10.03	4.13	538.09646	48
Pallet:	563.29	47.24	39.37	41.33	76867.138	120

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00382619114010	382619114010
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	48		20382619114014	
<input checked="" type="checkbox"/> Pallet	120			

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)		Whsl. Code #:	
As of date:		Fineline Code:	

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION	
<b>Is this product (check all that apply):</b>	
a. Cytotoxic?	<input type="checkbox"/> No
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	<input type="checkbox"/> No
Is the product a CA Prop 65 carcinogen?	<input type="checkbox"/> No
Is the product a CA Prop 65 reproductive toxicant?	<input type="checkbox"/> No
Does the product label bear a CA Prop 65 warning?	<input type="checkbox"/> No
c. Contact Hazard?	<input type="checkbox"/> No
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	<input type="checkbox"/> No
e. Does the product contain DEHP?	<input type="checkbox"/> No
<b>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)</b>	
a. UN/Identification Number	<input type="text"/>
b. Proper Shipping Name	<input type="text"/>
c. DOT Hazard Class	<input type="text"/>
d. Packing Group	<input type="text"/>
e. Inhalation Hazard?	<input type="checkbox"/> No
<b>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)</b>	
a. UN/Identification Number	<input type="text"/>
b. Proper Shipping Name	<input type="text"/>
c. DOT Hazard Class	<input type="text"/>
d. Packing Group	<input type="text"/>
e. Inhalation Hazard?	<input type="checkbox"/> No
<b>Is the product restricted for air shipment? If so, indicate restriction:</b>	
<input type="checkbox"/> Passenger	<input type="checkbox"/> No
<input type="checkbox"/> Cargo	
<input type="checkbox"/> Passenger & Cargo	
<b>Is this a reportable quantity? <input type="checkbox"/> No</b>	
RQ Threshold: <input type="text"/>	
<b>Is this a marine pollutant? <input type="checkbox"/> No</b>	
<b>Is this product shipped utilizing an authorized DOT exception or Special Permit?</b>	
<input type="checkbox"/> No (if yes, identify method below)	
<input type="checkbox"/> Limited Quantity	
<input type="checkbox"/> Consumer Commodity, ORM-D	
<input type="checkbox"/> Small Quantity (49 CFR 173.4)	
<input type="checkbox"/> Special Permit; DOT-SP	
<input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input type="text"/>	
ADD'L STORAGE INFORMATION	
<b>Is the Product...</b>	
Controlled Substance?	<input type="checkbox"/> No
Controlled by State(s)?	<input type="checkbox"/> No
ARCOS Reportable?	<input type="checkbox"/> No
Schedule No.	<input type="text"/>
Controlled Substance Code	<input type="text"/>
Listed Chemical (List I or II)	<input type="checkbox"/> No
If yes, indicate which:	<input type="text"/>
Is it a scheduled listed chemical product?:	<input type="checkbox"/> No
CLASS OF TRADE RESTRICTION:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	<input type="checkbox"/> Yes
Restricted to retail pharmacy only:	<input type="text"/>
Restricted to hospital, clinics, and physician offices only:	<input type="text"/>
Restricted from US territories? (explain in comments)	<input type="text"/>
Comments:	<input type="text"/>
SDS Hazard Classification	
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
Does the product have an Aerosol class? If yes, identify NFPA Storage Level:	<input type="checkbox"/> No
NFPA Storage Level:	<input type="text"/>
Is the product a NIOSH hazardous drug? If yes, indicate which:	<input type="checkbox"/> No
	<input type="text"/>
Hazardous Waste Identification	
EPA Hazardous Waste Code:	<input type="text"/>
Waste Characteristics	<input type="text"/>
REMS or REGISTRY RESTRICTIONS	
<b>Is there a REMS on this product?</b>	
If Yes, is it managed with a pharmacy registry?	<input type="checkbox"/> No
Website URL:	<input type="text"/>
<b>Med Guide Required</b>	
Limited Distribution Requirement	<input type="checkbox"/> No
Comments / Details: (For example, iPledge program?)	<input type="text"/>
<b>REMS:</b>	
REMS Program Manager Name:	<input type="text"/>
Supplier Manages REMS registry exclusively:	<input type="checkbox"/> No
Wholesale distributor support:	<input type="text"/>
Provider Name:	<input type="text"/>
Site Enrollment Number assigned by Supplier:	<input type="text"/>
DEA #:	<input type="text"/>
NCPDP#:	<input type="text"/>
NPI #:	<input type="text"/>
Comments	<input type="text" value="IT IS NOT A REMS PRODUCT"/>
<b>Registry:</b>	
Registry Program Contact Name:	<input type="checkbox"/> No
Comments	<input type="text" value="IT IS NOT A REMS PRODUCT"/>
Phone:	<input type="text"/>
RETURN INSTRUCTIONS	
<b>Contact tel. # if product received damaged:</b>	
Is product returnable for credit:	<input type="text"/>
URL/Link to returns policy:	<a href="https://creekwoodpharma.com/wp-content/uploads/2023/07/Return-Goods-Policy.pdf">https://creekwoodpharma.com/wp-content/uploads/2023/07/Return-Goods-Policy.pdf</a>
<b>Special regulations or returns requirements for this product in certain states?</b>	
If so, which states? Other requirements? Comments?	<input type="text"/>
MISCELLANEOUS NOTES and/or Image of Product Barcode:	
<input type="text"/>	



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

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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 <input type="checkbox"/> Yes b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text" value="140"/> Units Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: Name: <input type="text" value="Direct customer solutions (R &amp; S)"/> Phone: <input type="text" value="1-800-655-7556"/> Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <input type="text"/>	<b>Purchase order daily receipt cut off time by supplier</b> Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	<b>Overnight receipt available:</b> <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday <b>Priority Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> <b>Saturday Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>