

Version 2024

Introduction Type: New Item

x Final Version

Date:

12/11/2025

PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*					
Company Name: Camber Pharmaceuticals, Inc.			Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.					
Application Number for NDA/ANDA/BLA; PMA/510(k): 217761			NDA 505(b) Type: NOT APPLICABLE			Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)					
Medical Device Class, if applicable:						Other Temperature Range Requirement (write in)					
DUNS: 11-856-3719						Notes					
Proprietary Name (If Applicable) and Established Name: Spironolactone Tablets, USP 100 mg						Is this product to be shipped to customers on ice?					
Selling Unit NDC: 31722-096-01			Unit of Use NDC: CVX Code: MVX Code: 331722096010			Is this product to be shipped to customers on dry ice?					
Description: Spironolactone Tablets, USP 100 mg						No			No		
Active Ingredient(s): Spironolactone, USP						b. Contact for temperature excursion questions:					
URL for Additional Product Information: www.camberpharma.com						Name: Soma Raju					
Address: 800 Centennial Ave, Suite 1			Address 2: NJ Zip: 08854			Number: 732-529-0423					
City: Piscataway			Email: customerservice@camberpharma.com			Group E-mail: somaraju@heterousa.com					
Key Contact: Customer Service			Fax: 732-562-8788			c. Special regulations for product in any states?					
Phone Number: 1-866-827-3647			Product Therapeutic Classification: Aldosterone antagonist			Special returns requirements for this product?					
ADDITIONAL PRODUCT INFORMATION						PRODUCT DESCRIPTION INFORMATION					
The product is? a legend device? <input checked="" type="checkbox"/> No			Is the Product... Direct-Ship Only <input type="checkbox"/>			Size: 100 ct			d. Store product (unit of sale) upright?		
if yes, enter class # a product kit? <input type="checkbox"/> No			Is the Product... Neither <input type="checkbox"/>			Strength: 100 mg			Protect product (unit of sale) from light?		
if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No			Orphan Drug Status <input type="checkbox"/>			Dosage Form: Film-coated tablet					
co-licensed? <input type="checkbox"/> No			FDA Approval Status <input type="checkbox"/>			Product Shape: Round, scored on both edges					
latex-free? <input type="checkbox"/> Yes			Allergens Present: Dairy, Lactose, Casein, Corn, Wheat			Product Color: White to off white					
preservative-free? <input type="checkbox"/> Yes			Country of Origin: India			Product Imprint: Debossed with 'V1' on one side and '75' bisected plain other side					
correctional institution block? <input type="checkbox"/> No			Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No								
opioid? <input type="checkbox"/> No											
Cannabinoid? <input type="checkbox"/> No											
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/>						e. Shelf life: Initial shelf life at launch (if different):					
If Unit Dose, indicate NDC here: <input type="checkbox"/>						Months: Months					
FOR GENERIC DRUG PRODUCTS											
I. Orange Book Rating: AB						Authorized Generic <input type="checkbox"/> *If Authorized Generic, other section fields are not applicable					
II. Generic Equivalent to What Brand?: Aldactone											
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION											
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes						GLN: 0331722498975					
Is product exempt from DSCSA? <input type="checkbox"/> No											
If yes, select exemption: Other exemption - Write in: <input type="checkbox"/>						GCP: <input type="checkbox"/>					
Is product repackaged? <input type="checkbox"/> No						If yes, was original product purchased direct from mfr? <input type="checkbox"/>					
Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> Yes						Provide source manufacturer for repackaged product <input type="checkbox"/>					
Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> No											
If yes, attach documentation from FDA. <input type="checkbox"/>											
GTIN AND HIBCC PRODUCT INFORMATION											
Saleable Unit of Measure		RFID tag(Y/N)		Saleable Quantity		HIBCC		GTIN-14		Unit of Use GTIN-14	
<input checked="" type="checkbox"/> Item/Each		N		1		<input type="checkbox"/>		00331722096010		<input type="checkbox"/>	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack						<input type="checkbox"/>		20331722096014		<input type="checkbox"/>	
<input type="checkbox"/> Case		N		24		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
<input type="checkbox"/> Pallet						<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
COST INFORMATION						WHOLESALER USE ONLY:					
Regular Cost <input type="checkbox"/> Invoice Cost (WAC) (\$)						Vendor #: Whsl. Code #: <input type="checkbox"/>					
\$23.80											
As of date: 12/5/2025						Fineline Code: <input type="checkbox"/>					
*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: <input type="checkbox"/>											

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:

*Please provide any additional information on page 2.



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?
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
Is the product a CA Prop 65 carcinogen?
- c. Is the product a CA Prop 65 reproductive toxicant?
- d. Does the product label bear a CA Prop 65 warning?

No

No

No

No

No

No

No

c. Contact Hazard?

- d. Does this product require special clean-up instructions?
(If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP?

Is this product regulated for shipment by DOT?
(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?
(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
- Passager & Cargo

Is this a reportable quantity? No

RQ Threshold: No

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) 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: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen

- Corrosive
- Oxidizer
- 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?

Yes

If yes, indicate which: Group 2 items (non-antineoplastic that meets a hazard criterion)

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

Limited Distribution Requirement

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:

Phone:

DEA #:

NCPDP#:

NPI #:

Comments:

Registry:

Registry Program Contact Name:

Phone:

Comments:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 1-866-827-3647

Is product returnable for credit: Yes

URL/Link to returns policy:

contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states?

No

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