



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:  Post Launch Change Final Version

Date: 10/15/19

**PRODUCT INFORMATION**

Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA  
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 203253  
 DUNS: 022490515  
 Proprietary Name (If Applicable) and Established Name: Spironolactone Tablet  
 Selling Unit NDC: 59746-0218-01 Individual Unit NDC: \_\_\_\_\_ UPC: 3-59746-218-01-0  
 UDI \_\_\_\_\_ CVX Code: \_\_\_\_\_ MVX Code: \_\_\_\_\_  
 Description: Spironolactone 100mg Tablet 100 count  
 Active Ingredient(s): Spironolactone  
 URL for Additional Product Information: www.cadista.com  
 Address: 207 Kiley Drive Salisbury, MD 21801  
 Key Contact: Jackie Emershaw Email: Jackie.Emershaw@cadista.com  
 Phone Number: (410) 912-3722 Fax: (215) 443-9646  
 Product Therapeutic Classification: \_\_\_\_\_

**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°)  
 Other Temperature Range Requirement (write in): \_\_\_\_\_  
 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: Customer Support  
 Number: (800) 313-4623  
 Group E-mail: \_\_\_\_\_  
 c. Special regulations for product in any states?  No  
 Special returns requirements for this product?  No  
 d. Store product (unit of sale) upright?  No  
 Protect product (unit of sale) from light?  No  
 e. Shelf life:  24 Months  
 Initial shelf life at launch (if different):  24 Months

**ADDITIONAL PRODUCT INFORMATION**

Is the Product...  
 a legend device?  Yes  
 reverse numbered?  No  
 co-licensed?  No  
 Is the Product...  Direct-Ship Only  
 Is the Product... \_\_\_\_\_  
 If Unit Dose, is item bar coded to unit dose for hospital scanning?   
 If Unit Dose NDC, indicate NDC here: \_\_\_\_\_  
 Country of Origin: \_\_\_\_\_  
 Is this product covered under the Trade Agreements Act (TAA)?

**PRODUCT DESCRIPTION INFORMATION**

Size: 100ct  
 Strength: 100mg  
 Dosage Form: TAB  
 Product Shape: Tablet  
 Product Color: Brown  
 Product Imprint: TL 218

**ORDER INFORMATION**

Unit of Sale:  Bottle,  Box/Carton,  Ampule,  Glass,  Tube,  Vial Liquid Sgl,  Vial Liquid Multi,  Vial Powder Sgl,  Vial Power Multi,  Other: Write In  
 What is the NDC selling unit? 1 Case of 48 bottles (Write-in, e.g. 1 Box of 10 Vials)  
 Minimum order quantity?  Yes  
 If Yes, how many of which package type?  
 48 Each  
 Inner/Carton/Pack  
 Case

**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?: Aldactone

**PHARMACY ORDER / BILL UNIT**

Rec. sell unit to customer? \_\_\_\_\_ (Write-in, e.g. 1 Vial)  
 Rx billing unit to pharmacy:  Each,  Gram,  Milliliter

**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

Does supplier meet DSCSA definition of manufacturer?  Yes GLN: 8902805000006  
 Is product exempt from DSCSA? \_\_\_\_\_  
 If yes, select exemption: \_\_\_\_\_  
 Other exemption - Write in: \_\_\_\_\_  
 Is product repackaged? \_\_\_\_\_  
 Is product sold by manufacturer's exclusive distributor? \_\_\_\_\_  
 Has FDA granted waiver/exception/exemption for product? \_\_\_\_\_  
 If Yes, was original product purchased direct from mfr? \_\_\_\_\_  
 If yes, attach documentation from FDA.

**ITEM AND PACKING INFORMATION**

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.19	1.87	4.37	1.87	15.28	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	11.56	15.63	6.1	11.89	1133.63	48
Pallet:					0	
UPC:	Case:					
	Carton:					

**GTIN PRODUCT INFORMATION**

Serialized?	If not, when?	Items aggregated?	Level		Quantity	GTIN-14
			Saleable Unit	Unit		
<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	Item	1	00359746218010
			<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack	48	40359746218018
			<input checked="" type="checkbox"/>	Case		
			<input checked="" type="checkbox"/>	Pallet		
				2D		
				2D		
				2D		
				2D		
				2D		
				2D		

**COST INFORMATION**

Regular Cost \_\_\_\_\_ Invoice Cost (WAC) (\$) \$38.86 Federal Excise Tax Per Unit of Sale \_\_\_\_\_ As of date: \_\_\_\_\_  
 Vendor #: \_\_\_\_\_ Whsl. Code #: \_\_\_\_\_  
 Fineline Code: \_\_\_\_\_

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?  Yes  
 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 or 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?

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 by State(s)?  No

ARCOS Reportable?  No

Schedule No. (inc. N for non-narcotic)

Controlled Substance Code

Listed Chemical (List I or II)

If yes, indicate which:

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:  No

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

Restricted from US territories? (explain in comments)  No

Comments:

### SDS Hazard Classification

Organic  Corrosive  
 Inorganic  Oxidizer  
 Steroid/Androgen  Contact Hazard

Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug?  Yes  
 If yes, indicate which:  FDA Pregnancy Category C; Black Box warning for tumorigenicity in laboratory studies

### Hazardous Waste Identification

EPA Hazardous Waste Code:

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  
 If Yes, is it managed with a pharmacy registry?   
 Website URL:

Comments / Details: (For example, iPledge program?)

REMS:  No

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:  
 Provider Name:   
 Site Enrollment Number assigned by Supplier:

DEA #:   
 PCPDP #:   
 NPI #:

Comments:

Registry:

Registry Program Contact Name:  Phone:

Comments:

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  (410) 912-3722

Is product returnable for credit:

URL/Link to returns policy:  www.cadista.com

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:



# Standard Pharmaceutical Product Information (Page 3)

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 <input type="checkbox"/> Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <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: <input type="checkbox"/> Phone: <input type="text"/> Phone #: <input type="text"/> <input type="checkbox"/> Fax: <input type="text"/> Fax #: <input type="text"/> <input type="checkbox"/> 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"/>