



Date: 3/27/2025

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA Application Number for NDA/ANDA/BLA; PMA/510(k): 203253 NDA 505(b) Type: NOT APPLICABLE Medical Device Class, if applicable: DUNS: 118694141 Proprietary Name (If Applicable) and Established Name: Spironolactone Tablets Selling Unit NDC: 59746-217-06 Unit of Use NDC: UPC: 3-59746-217-06-8 UDI: CVX Code: MVX Code:				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			
Description: Spironolactone 50mg 100 Tablets Active Ingredient(s): Spironolactone URL for Additional Product Information: www.cadista.com/products/full-product-list Address: 790 Township Line Road City: Yardley Key Contact: Customer Service Phone Number: (800) 313-4623 Product Therapeutic Classification: Antihypertensive Address 2: Suite 325 State: PA Zip: 19067 Email: customer.service@cadista.com Fax: N/A				b. Contact for temperature excursion questions: Name: Customer Service Number: (800) 313-4623 Group E-mail: customer.service@cadista.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 Protect product (unit of sale) from light? No e. Shelf life: 24 Months Initial shelf life at launch (if different): 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? co-licensed? No latex-free? No preservative-free? No correctional institution block? Yes opioid? No Cannabinoid? No If Unit Dose, is item bar coded to unit dose for hospital scanning? If Unit Dose, indicate NDC here: Is the Product... Direct-Ship Only Is the Product... Neither Orphan Drug Status FDA Approval Status Allergens Present Country of Origin India Is this product covered under the Trade Agreements Act (TAA)? No				Size: 100 count Strength: 50mg Dosage Form: TABLETS Product Shape: Round, biconvex Product Color: Brown Product Imprint: TL 217			
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: Aldactone®							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? Yes Is product exempt from DSCSA? No 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: 0359746000004 GCP: 0359746 If yes, was original product purchased direct from mfr? Provide source manufacturer for repackaged product							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure RFID tag(Y/N) Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14							
X Item/Each N 1 00359746217068							
X Box/ Carton/ Bundle/ Inner Pack N 48 40359746217066							
Case							
Pallet							
0							
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.							
*Please provide any additional information on page 2.				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? (If yes, attach SDS with special instructions.)	☐	No	
e. Does the product contain DEHP?	☐	No	
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)		☐ No	
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)		☐ No	
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#			
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:		☐	
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:			
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			
Registry:			
Registry Program Contact Name:		Phone:	
Comments			
RETURN INSTRUCTIONS			
Contact tel. # if product 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 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 Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone: Fax Number: Fax Number: Phone No.: Site Address:	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:	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: ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday 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:
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?