



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

Version 2021

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: <input type="text" value="Jubilant Cadista Pharmaceuticals Inc."/>		Application: <input type="text" value="ANDA"/>		<b>a. Temperature – Indicate the USP temperature range for this product.</b>			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="090839"/>				Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>			
Medical Device Class, if applicable: <input type="text"/>				Other Temperature Range Requirement (write in): <input type="text"/>			
DUNS: <input type="text" value="022490515"/>				Notes: <input type="text"/>			
Proprietary Name (if Applicable) and Established Name: <input type="text" value="Risperidone ODT"/>		Unit of Use NDC: <input type="text"/>		Is this product to be shipped to customers on ice? <input type="text" value="No"/>			
Selling Unit NDC: <input type="text" value="59746-050-22"/>		UPC: <input type="text" value="3-59746-050-22-1"/>		Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>			
UDI: <input type="text"/>		CVX Code: <input type="text"/>		MVX Code: <input type="text"/>			
Description: <input type="text" value="Risperidone Oral Disintegrating Tablets 4mg 28ct"/>				<b>b. Contact for temperature excursion questions:</b>			
Active Ingredient(s): <input type="text" value="Risperidone"/>				Name: <input type="text" value="Customer Service"/>			
URL for Additional Product Information: <input type="text" value="www.cadista.com/products/full-product-list"/>				Number: <input type="text" value="(800) 313-4623"/>			
Address: <input type="text" value="207 Kiley Drive"/>		Address 2: <input type="text"/>		Group E-mail: <input type="text" value="customer.service@cadista.com"/>			
City: <input type="text" value="Salisbury"/>		State: <input type="text" value="MD"/>		Zip: <input type="text" value="21801"/>			
Key Contact: <input type="text" value="Jackie Emershaw"/>		Email: <input type="text" value="Jackie.Emershaw@jubl.com"/>					
Phone Number: <input type="text" value="(410) 912-3722"/>		Fax: <input type="text" value="(215) - 443 - 9646"/>					
Product Therapeutic Classification: <input type="text" value="Antipsychotic"/>				<b>c. Special regulations for product in any states?</b>			
				Special returns requirements for this product?		<input type="text" value="No"/>	
<b>ADDITIONAL PRODUCT INFORMATION</b>				<b>PRODUCT DESCRIPTION INFORMATION</b>			
The product is? a legend device? <input type="text" value="No"/>		Is the Product... Direct-Ship Only <input type="text"/>		Size: <input type="text" value="28 count"/>			
if yes, enter class # a product kit? <input type="text"/>		Is the Product... Neither <input type="text"/>		Strength: <input type="text" value="4mg"/>			
if yes, list NDCs of component parts reverse numbered? <input type="text"/>		Orphan Drug Status: <input type="text"/>		Dosage Form: <input type="text" value="TABLET, ODT"/>			
co-licensed? <input type="text"/>		FDA Approval Status: <input type="text"/>		Product Shape: <input type="text" value="Round, Flat"/>			
latex-free? <input type="text"/>		Allergens Present: <input type="text"/>		Product Color: <input type="text" value="Pink"/>			
preservative-free? <input type="text"/>		Country of Origin: <input type="text" value="IN"/>		Product Imprint: <input type="text" value="C / 05"/>			
correctional institution block? opioid? <input type="text"/>		Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/>					
Cannabinoid? <input type="text"/>							
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/>							
If Unit Dose, indicate NDC here: <input type="text"/>							
				<b>ORDER INFORMATION</b>			
				Unit of Sale: <input checked="" type="checkbox"/> Box/Carton		What is the NDC selling unit? <input type="text" value="1 carton of 28 tablets"/>	
				<input type="checkbox"/> Ampule		(Write-in, e.g. 1 Box of 10 Vials)	
				<input type="checkbox"/> Glass		Minimum order quantity? <input type="text" value="Yes"/>	
				<input type="checkbox"/> Tube			
				<input type="checkbox"/> Vial Liquid Sgl		If Yes, how many of which package type?	
				<input type="checkbox"/> Vial Liquid Multi		<input type="text" value="48"/> Each	
				<input type="checkbox"/> Vial Powder Sgl		<input type="text"/>	
				<input type="checkbox"/> Vial Power Multi		Inner/ Carton/ Pack	
				<input type="checkbox"/> Other: Write In		Case	
				<b>PHARMACY ORDER / BILL UNIT</b>			
I. Orange Book Rating: <input type="text" value="AB"/>		Authorized Generic <input type="checkbox"/>		*If Authorized Generic, other section fields are not applicable		Rec. sell unit to customer? <input type="text" value="1 carton of 28 tablets"/>	
II. Generic Equivalent to What Brand?: <input type="text" value="Risperdal"/>						Rx billing unit to pharmacy: <input checked="" type="checkbox"/> Each	
						<input type="checkbox"/> Gram	
						<input type="checkbox"/> Milliliter	
				<b>DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION</b>			
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/>		GLN: <input type="text" value="8902805000006"/>					
Is product exempt from DSCSA? <input type="text"/>		GCP: <input type="text" value="0359746"/>					
If yes, select exemption: <input type="text"/>							
Other exemption - Write in: <input type="text"/>							
Is product repackaged? <input type="text"/>		If yes, was original product purchased direct from mfr? <input type="text"/>					
Is product sold by manufacturer's exclusive distributor? <input type="text"/>		Provide source manufacturer for repackaged product: <input type="text"/>					
Has FDA granted waiver/exception/exemption for product? <input type="text"/>							
If yes, attach documentation from FDA. <input type="text"/>							
				<b>GTIN AND HIBCC PRODUCT INFORMATION</b>			
Saleable Unit of Measure: <input checked="" type="checkbox"/> Item/Each		Saleable Quantity: <input type="text" value="1"/>		HIBCC: <input type="text"/>		GTIN-14: <input type="text" value="00359746050221"/>	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack						<input type="text"/>	
<input checked="" type="checkbox"/> Case		<input type="text" value="48"/>				<input type="text" value="40359746050229"/>	
<input type="checkbox"/> Pallet						<input type="text"/>	
				<b>COST INFORMATION</b>		<b>WHOLESALE USE ONLY:</b>	
Regular Cost: <input type="text"/>		Invoice Cost (WAC) (\$): <input type="text" value="\$254.57"/>		Vendor #: <input type="text"/>		<input type="text"/>	
As of date: <input type="text"/>				Whsl. Code #: <input type="text"/>		<input type="text"/>	
				Fineline Code: <input type="text"/>		<input type="text"/>	
				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: <input type="text"/>	



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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?  
 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)

- 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  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:

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

### 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?



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