



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"/> Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="090839"/> Medical Device Class, if applicable: <input type="text"/> DUNS: <input type="text" value="022490515"/> Proprietary Name (if Applicable) and Established Name: <input type="text" value="Risperidone ODT"/> Unit of Use NDC: <input type="text"/> Selling Unit NDC: <input type="text" value="59746-030-22"/> UPC: <input type="text" value="3-59746-030-22-3"/> UDI <input type="text"/> CVX Code: <input type="text"/> MVX Code: <input type="text"/> Description: <input type="text" value="Risperidone Oral Disintegrating Tablets 2mg 28ct"/> Active Ingredient(s): <input type="text" value="Risperidone"/> URL for Additional Product Information: <input type="text" value="www.cadista.com/products/full-product-list"/> Address: <input type="text" value="207 Kiley Drive"/> State: <input type="text" value="MD"/> Address 2: <input type="text"/> City: <input type="text" value="Salisbury"/> 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"/>				a. Temperature – Indicate the USP temperature range for this product. Temperature Range <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/> Other Temperature Range Requirement (write in) <input type="text"/> Notes <input type="text"/> 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: <input type="text" value="Customer Service"/> Number: <input type="text" value="(800) 313-4623"/> Group E-mail: <input type="text" value="customer.service@cadista.com"/> 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"/> e. Shelf life: <input type="text" value="24"/> Months Initial shelf life at launch (if different): <input type="text"/> Months																																							
ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION		ORDER INFORMATION																																							
The product is? <input type="text" value="No"/> a legend device? if yes, enter class # <input type="text"/> a product kit? <input type="text" value="No"/> if yes, list NDCs of component parts reverse numbered? <input type="text"/> co-licensed? <input type="text" value="No"/> latex-free? <input type="text" value="Yes"/> preservative-free? <input type="text" value="No"/> correctional institution block? <input type="text" value="Yes"/> opioid? <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"/> If Unit Dose, indicate NDC here: <input type="text"/>	Is the Product... <input type="text" value="Direct-Ship Only"/> Is the Product... <input type="text" value="Neither"/> Orphan Drug Status <input type="text"/> FDA Approval Status <input type="text"/> Allergens Present <input type="text"/> Country of Origin <input type="text" value="IN"/> Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/>	Size: <input type="text" value="28 count"/> Strength: <input type="text" value="2mg"/> Dosage Form: <input type="text" value="TABLET, ODT"/> Product Shape: <input type="text" value="Round, Flat"/> Product Color: <input type="text" value="Blue"/> Product Imprint: <input type="text" value="C / 03"/>	Unit of Sale <input type="checkbox"/> Bottle <input checked="" type="checkbox"/> Box/Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Power Multi <input type="checkbox"/> Other: Write In <input type="text"/>		What is the NDC selling unit? <input type="text" value="1 carton of 28 tablets"/> (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="text" value="Yes"/> If Yes, how many of which package type? <input type="text" value="48"/> Each <input type="text"/> Inner/Carton/Pack <input type="text"/> Case																																						
FOR GENERIC DRUG PRODUCTS																																											
I. Orange Book Rating: <input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable II. Generic Equivalent to What Brand?: <input type="text" value="Risperdal"/>																																											
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: <input type="text"/> Other exemption - Write in: <input type="text"/> 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. <input type="text"/>																																											
GLN: <input type="text" value="8902805000006"/> GCP: <input type="text" value="0359746"/> If yes, was original product purchased direct from mfr? <input type="text"/> Provide source manufacturer for repackaged product <input type="text"/>																																											
GTIN AND HIBCC PRODUCT INFORMATION																																											
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>Saleable Unit of Measure</th> <th>Saleable Quantity</th> <th>HIBCC</th> <th>GTIN-14</th> <th>Unit of Use GTIN-14</th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/> Item/Each</td> <td><input type="text" value="1"/></td> <td><input type="text"/></td> <td><input type="text" value="00359746030223"/></td> <td><input type="text"/></td> </tr> <tr> <td><input type="checkbox"/> Box/Carton/Bundle/Inner Pack</td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> <tr> <td><input checked="" type="checkbox"/> Case</td> <td><input type="text" value="48"/></td> <td><input type="text"/></td> <td><input type="text" value="40359746030221"/></td> <td><input type="text"/></td> </tr> <tr> <td><input type="checkbox"/> Pallet</td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> </tbody> </table>						Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14	<input checked="" type="checkbox"/> Item/Each	<input type="text" value="1"/>	<input type="text"/>	<input type="text" value="00359746030223"/>	<input type="text"/>	<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/> Case	<input type="text" value="48"/>	<input type="text"/>	<input type="text" value="40359746030221"/>	<input type="text"/>	<input type="checkbox"/> Pallet	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>													
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COST INFORMATION			WHOLESALE USE ONLY:																																								
Regular Cost <input type="text"/> Invoice Cost (WAC) (\$) <input type="text" value="\$93.52"/> As of date: <input type="text"/>			Vendor #: <input type="text"/> Whsl. Code #: <input type="text"/> Fineline Code: <input type="text"/>																																								

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.



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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 Yes Controlled Substance Code
- Controlled by State(s)? No Yes Listed Chemical (List I or II) No Yes
- ARCOS Reportable? No Yes If yes, indicate which:
- Schedule No. Is it a scheduled listed chemical product? No Yes

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
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- 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:



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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>Purchase order daily receipt cut off time by supplier</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>Overnight receipt available: <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>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <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>