

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

Version 2021						Introduction T	ype:	Post Launch Change		x Final Version			Date:	5/1/2	2023
			PRODUCT INFORMAT	TION						SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Jubilant Cadista Pharmaceuticals Inc.				Application: ANDA		a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/AN	ANDA/BLA (drug); PMA/510(k)(med device): 090839							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
Medical Device Class, if applicable:															
DUNS:	022490515							Other Temperature Range Requirement							
Proprietary Name (If Applicable) a		lame: Risperi	idone ODT		1	1150				(write in)					
Selling Unit NDC: UDI	59746-010-32		Unit of Use NDC: CVX Code:			UPC: MVX Code:	3-59746-0	10-32-4	No	les					
						intx oode.									
Description:	Risperidone Oral	I Disintegrating Tablets	0.5mg 30ct							his product to be shipped				No No	
Active Ingredient(s): Risperidone															
URL for Additional Product Inform	nation-	www.cadista.com	n/products/full-product	lict						nperature excursion qu me:	estions:	Customer Se	nvice		
Address:	207 Kiley Drive	www.cauista.com		-1150		Address 2:				mber:		(800) 313-46			
City:					MD	Zip: 21	1801	Group E-mail: customer.service@cadista.com							
Key Contact:						customer.servi	ice@cadis	ta.com	· · · · · · · · · · · · · · · · · · ·						
Phone Number:	(800) 313-4623				Fax:	N/A			c. Special regulations for product in any states? No						
Product Therapeutic Classificatio	n:	Antipsychotic							Sp	ecial returns requirement	s for this product?			No	
		IONAL PRODUCT INF				PRODUCT	DESCRIPTI	ON INFORMATION	d Store product /	unit of colo) unright?				No	
The product is 2	ADDIT	IONAL I KODUCI INI		Direct-Ship C	Inly	TRODUCTL	JESCKIP II	ON-INFORMATION		unit of sale) upright?	la) from L'				
The product is? a legend device?		No	Is the Product Is the Product	Neither	riiy		20	count	e. Shelf life:	otect product (unit of sa	le) from light?			No 24	Months
if yes, enter class #			Orphan Drug Status			Size:	30 0	Louin		ial shelf life at launch (	if different).			24	Months
a product kit?		No	orphan Drug otatuo			0	0.5	mg			an annon onny.				montho
if yes, list NDCs of			FDA Approval Status			Strength:					ORDER INFORM	IATION			
component parts						Dosage Forn	n: TAE	BLET, ODT							
reverse numbered? co-licensed?		No No	Allergens Present			-			Un	it of Sale Bottle		What is the 1 carton of 3		unit?	
latex-free?		Yes	Allergens Fresent				Ro	und, Flat		X Box/Carton			g. 1 Box of 1	) Vials)	
preservative-free?		No				Product Sha	pe:	and, r lat		Ampule		(11110 111, 01	g. 1 Dox of 1	, viaio,	
correctional institution block?		Yes				Product Cold	Yell	low		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Froduct Cold				Tube					
Cannabinoid?		No	Country of Origin	IN		Product Impr	rint: C /	01		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u hospital scanning?	unit dose for		Is this product covered u	nder the						Vial Liquid Multi Vial Powder Sql		If Yes, how 48	Each	сп раскаде т	ype?
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		No					Vial Power Multi		-	Inner/Carton	/Pack	
			3	,						Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS											
				_	A	uthorized Generic		zed Generic, other lds are not applicable	-		ARMACY ORDER				
I. Orange Book Rating: AB						Section her	ius are not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:							
II. Generic Equivalent to What Brand?: Risperdal®								1 carton of 30 tablets X Each (Write-in, e.g. 1 Vial) Gram							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION															
Does supplier meet DSCSA definition of manufacturer? Yes GLN: 8902805000006 ITEM AND PACKING INFORMATION															
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:	0359746				Weight Lbs.		ons (US msm	,		Saleable #
Other exemption - Write in: Is product repackaged?			No		If yoo	riginal product a	hacad 📃		Item/Each:		Depth	Width	Height	(Cube)	Pieces
Is product repackaged?	e avclusiva distrib	utor?	No	-	direct from n	riginal product purc	cnased		Item/Each:	0.05	1.9	1.9	4	14.44	1
Has FDA granted waiver/exceptio			No	-		rce manufacturer fo	r repackag	ed product	Box/Carton/Bund	le/				0.00	
If yes, attach documentation from	m FDA.								Inner Pack:					0.00	
									Case:	5	22.05	18.11	10.63	4244.83	48
		GTI	N AND HIBCC PRODUCT IN	FORMATION					Pallet:						
Saleable Unit of Measure		Saleable Quantity	HIBCC		GT	IN-14	Ur	nit of Use GTIN-14	Fallet.					0.00	
X Item/Each		1				359746010324	1				1				
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESALER USE ONLY:			
X Case		48			403	359746010322									
Pallet							-		Regular Cost	<b>o</b> ) ( <b>b</b> )	<b>.</b>	Vendor #:			
	-				-		-		Invoice Cost (WA	u) (\$)	\$49.84	Whsl. Code Fineline Co			
	-				-				As of date:						
							1					1			
							_					<u> </u>			
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza										
*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature:															

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

Version 2021 Fo	or Designated Drop Ship Only Products, Please Use Page 3
MAT	FERIAL 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? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? 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?	No     SDS Hazard Classification       No     Organic     Corrosive       No     Inorganic     Oxidizer       No     Steroid/Androgen     Contact Hazard       No     Does the product have an Aerosol class? If yes, identify NFPA Storage Level:     No       No     NFPA Storage Level:     Image: Contact Hazard
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 the product a NIOSH hazardous drug?     No       If yes, indicate which:     If yes, indicate which:         Hazardous Waste Identification         Image: No         EPA Hazardous Waste Code:         Waste Characteristics
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? 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	No       REMS or REGISTRY RESTRICTIONS         Is there a REMS on this product?       Is there a REMS on this product?         If Yes, is it managed with a pharmacy registry?       No         Website URL:       No         No       Med Guide Required         Limited Distribution Requirement       No         Comments / Details: (For example, iPledge program?)       No         REMS:       Phone:         Supplier Manages REMS registry exclusively:       Phone:         Wholesale distributor support:       Provider Name:         Site Enrollment Number assigned       DEA #:
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	by Supplier:     NPI #:       Comments
Is the Product Controlled Substance? No Controlled Substance Code Controlled by State(s)? ARCOS Reportable? No If yes, indicate which: Is it a scheduled listed chemical product?: CLASS OF TRADE RESTRICTION: No CLASS OF TRADE RESTRICTION:	No     RETURN INSTRUCTIONS       No     Contact tel. # if product received damaged:       Is product returnable for credit:     URL/Link to returns policy:
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:	Yes Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments? SCELLANEOUS NOTES and/or Image of Product Barcode:



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

Version 2021 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:	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:       Image: Comparison of the co
Class of Trade Restriction:	PO Receipt Cut off time:
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:	Saturday Overnight receipt available:       PO Receipt Cut off time:         Order receipt method:       Phone:         Fax:       EDI:         Overnight Fees apply:       Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?