

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

Version 2021						Introduction T	Гуре:	Post Launch Change		x Final \	/ersion			Date:	7/12/	2021	
			PRODUCT INFORMAT	TION						SPE	CIAL HAND	LING AND STOR	AGE REQUI	REMENTS*			
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.									
			e):	20:	2280	7.65.104.1		7.11.071	u. remperatur	Temperature Ra				and 25 C (68	° – 77° F)		
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 202280 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)  Medical Device Class, if applicable:																	
DUNS:	022490515									Other Temperat	ure Range R	equirement					
Proprietary Name (If Applicable) a	and Established N	ame: Escitale	opram Tablets							(write in)	•						
Selling Unit NDC:	59746-280-01		Unit of Use NDC:			UPC:	3-5974	46-280-01-7		Notes							
UDI			CVX Code:			MVX Code:											
Description:	Escitalopram 10n	ng 100ct Tablet								Is this product to	be shipped	to customers on ic	ce?		No		
Is this product to be shipped to customers on dry ice?																	
Active Ingredient(s): Escitalopram																	
										b. Contact for temperature excursion questions:							
URL for Additional Product Inform								Name:				Customer Service					
Address:	207 Kiley Drive					Address 2:  MD Zip: 21801			Number:				(800) 313-4623 customer.service@cadista.com				
City:	Salisbury				State:	MD			Group E-mail:				customer.	service@ca	<u>idista.com</u>		
Key Contact:	Jackie Emershaw (410) 912-3722				Email: Fax:	Jackie.Emersha		<u>ibi.com</u>	- Cussial sam		d !				Nie		
Phone Number:		Antidonometr			l ax.	(215) - 443 - 9646			c. Special regulations for product in any states?				No No				
Product Therapeutic Classification:         Antidepressants           Special returns requirements for this product?         No																	
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION									d Store produ	uct (unit of sale)	upriaht?				No		
	— ADDIII	ONALT RODUCT INF		Diseas Ohi: 1	Salu .	TRODUCTE	JE30KI	I HOW IN ORWATION	a. Store produ								
The product is?			Is the Product	Direct-Ship C Neither	Jnly			400	- 01-14-14-	Protect produc	t (unit of sal	e) from light?			No		
a legend device? if yes, enter class #		No	Is the Product	Neither		Size:		100 count	e. Shelf life:	Initial shalf life	at launah (if	difforent).			24	Months Months	
a product kit?		No	Orphan Drug Status					10mg		Initial shelf life	at iauricii (ii	umerent).				WOITIIS	
if yes, list NDCs of	of FDA Approval Status				Strength:						ORDER INFORM	IATION					
component parts			татт фризии опши					TABLETS									
reverse numbered?		No				Dosage Form	n:			Unit of Sale			What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present							X Bottle			1 bottle of 1	00 tablets			
latex-free?		Yes				Product Sha	ne.	Oval, Biconvex, Scored		Box/C			(Write-in, e	g. 1 Box of 1	0 Vials)		
preservative-free?		No					.po.			Ampul	е						
correctional institution block?		Yes				Product Cold	or:	White		Glass			Minimum o	rder quantity	?	Yes	
opioid?		No	Ott-O-tt-	IN				D : 0 : / 0		Tube							
Cannabinoid?		No	Country of Origin	IIN		Product Imp	rint:	B:3 / C			quid Sgl quid Multi		If Voc. how	many of whi	ch package	tuno?	
If Unit Dose, is item bar coded to the hospital scanning?	unit dose for		Is this product covered u	nder the									48	Each	cii package	typer	
If Unit Dose, indicate NDC here:				No	$\neg$			Vial Powder Sql Vial Power Multi				Inner/Carton/Pack					
iii ciiii 2000, iiialoato 1120 11010.											Write In			Case	,, don		
			FOR GENERIC DRUG PRO	DDUCTS		*											
									7								
	Authorized Generic *If Authorized Generic, other							horized Generic, other	PHARMACY ORDER / BILL UNIT								
. Orange Book Rating:			section fields are not applicable			Rec. sell unit to customer?				Rx billing unit to pharmacy:							
II. Generic Equivalent to What Brand?: Lexapro										1 bottle of 100 tablets				X Each			
-									(Write-in, e.g.	1 Vial)				Gram			
		DRUG SUPPLY	CHAIN SECURITY ACT (	DSCSA) INFOR	RMATION									Milliliter			
				_													
Does supplier meet DSCSA defin		rer?	Yes No	_	GLN:	8902805000006					ITEM	AND PACKING IN	NFORMATIO	<b>V</b>			
Is product exempt from DSCSA?			NO														
If yes, select exemption:					GCP:	0359746				Wei	ight Lbs.		ons (US msn		Volume	Saleable #	
Other exemption - Write in:			N.									Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?	o ovolucios dist-"	utor?	No No	-		riginal product irect from mfr?			Item/Each:		0.1	1.9	1.9	4	14.44	1	
Is product sold by manufacturer's Has FDA granted waiver/exception			No	_	-		or ronoc	kagad product	Box/Carton/B	undlo/							
If yes, attach documentation fro		Toductr	140		Frovide Soul	ce manufacturer fo	л герас	kageu product	Inner Pack:	undie/					0.00		
yoo, amaon accamonancii iro									Case:					_			
		GTIN	AND HIBCC PRODUCT IN	IFORMATION							5.85	14.88	11.13	5	828.07	48	
									Pallet:						0.00		
Saleable Unit of Measure	5	Saleable Quantity	HIBCC			N-14		Unit of Use GTIN-14							0.00		
X Item/Each		1			003	59746280017											
Box/Carton/Bundle/Inner Pack							COST INFORMATION				WHOLESALER USE ONLY:						
X Case		48			403	59746280015			Banul C:				Van d #				
Pallet					-		-		Regular Cost	1M(A C) (C)		<b>640.00</b>	Vendor #:	ш.			
									Invoice Cost (	**AC) (\$)		\$12.00	Whsl. Code Fineline Co				
									As of date:								
													<u> </u>				
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	rd letter, PACKAGE	INSER	T, LABEL AND PHOTO OF P	PRODUCT PACK	AGING and BARO	CODE.						
*Please provide any additional inf		•				C 2 f	. Daai	nated Dron Shin Only		Signature:							



Version 2021

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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 SDS Hazard Classification b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Nο Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? No Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard No c. Contact Hazard? No Does the product have an Aerosol class? If yes, identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No Is the product a NIOSH hazardous drug? No (if yes, answer a-e below and provide SDS) If yes, indicate which: a. UN/Identification Number b. Proper Shipping Name **Hazardous Waste Identification** c. DOT Hazard Class d. Packing Group EPA Hazardous Waste Code: Waste Characteristics e. Inhalation Hazard? No Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) REMS or REGISTRY RESTRICTIONS a. UN/Identification Number Is there a REMS on this product? b. Proper Shipping Name c. DOT Hazard Class If Yes, is it managed with a pharmacy registry? d. Packing Group Website URL: e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: No Med Guide Required No Passenger Limited Distribution Requirement No Cargo Comments / Details: (For example, iPledge program?) Passenger & Cargo Is this a reportable quantity? REMS: RQ Threshold: REMS Program Manager Name: Phone Is this a marine pollutant? Nο Supplier Manages REMS registry exclusively: Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: (if yes, identify method below) Provider Name: DEA #: Site Enrollment Number assigned NCPDP# Limited Quantity Consumer Commodity, ORM-D NPI#: by Supplier: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry: Phone: Registry Program Contact Name: ADD'L STORAGE INFORMATION Comments Is the Product RETURN INSTRUCTIONS 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: Contact tel. # if product received damaged: Schedule No. Is it a scheduled listed chemical product?: No Is product returnable for credit: CLASS OF TRADE RESTRICTION: URL/Link to returns policy: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) If so, which states? Other requirements? Comments? Comments: MISCELLANEOUS 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:	Overnight receipt available:							
Drop Ship service fee billed with each order:  Drop Ship miscellaneous fees billed:  Comments:	PO Receipt cut off time:  Days of week overnight is available:  Monday  Tuesday  Wednesday  Thursday  Friday  Priority Overnight receipt available:							
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:  Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:							
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:  Miscellaneous Notes:	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?							
	ADDITIONAL INFORMATION							
	Is product order for scheduled patient procedure? Is product order for restocking purposes?							