



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

Version 2021

Introduction Type:  New Item

Final Version

Date: 6/17/2024

## PRODUCT INFORMATION

Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA  
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): ANDA 202280  
 Medical Device Class, if applicable:  
 DUNS: 022490515  
 Proprietary Name (If Applicable) and Established Name: Escitalopram Tablets  
 Selling Unit NDC: 59746-280-10 Unit of Use NDC: UPC: 3-59746-280-10-9  
 UDI: CVX Code: MVX Code:  
 Description: Escitalopram 10mg 1000ct Tablets  
 Active Ingredient(s): Escitalopram  
 URL for Additional Product Information: [www.cadista.com/products/full-product-list](http://www.cadista.com/products/full-product-list)  
 Address: 790 Township Line Road Address 2: Suite 325  
 City: Yardley State: PA Zip: 19067  
 Key Contact: Customer Service Email: [customer.service@cadista.com](mailto:customer.service@cadista.com)  
 Phone Number: (800) 313-4623 Fax: N/A  
 Product Therapeutic Classification: Anti-depressant

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

a. Temperature – Indicate the USP temperature range for this product.  
 Temperature Range:   
 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  
 b. Contact for temperature excursion questions:  
 Name: Customer Service  
 Number: (800) 313-4623  
 Group E-mail: [customer.service@cadista.com](mailto:customer.service@cadista.com)  
 c. Special regulations for product in any states?  
 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:  
 Initial shelf life at launch (if different):  Months

## ADDITIONAL PRODUCT 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?  No  
 co-licensed?  No  
 latex-free?  Yes  
 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... Orphan Drug Status   
 FDA Approval Status:   
 Allergens Present:   
 Country of Origin: US   
 Is this product covered under the Trade Agreements Act (TAA)?  Yes

## PRODUCT DESCRIPTION INFORMATION

Size: 1000 count  
 Strength: 10mg  
 Dosage Form: TABLET  
 Product Shape: Oval, Biconvex, scored  
 Product Color: White  
 Product Imprint: "B" / "3" on one side "C" on the back

## ORDER INFORMATION

Unit of Sale:  Bottle  
 Box/Carton  
 Ampule  
 Glass  
 Tube  
 Vial Liquid Sgl  
 Vial Liquid Multi  
 Vial Powder Sgl  
 Vial Power Multi  
 Other: Write In  
 What is the NDC selling unit?  
  
 (Write-in, e.g. 1 Box of 10 Vials)  
 Minimum order quantity?  Yes  
 If Yes, how many of which package type?  
 Each  
 Inner/Carton/Pack  
 Case

## FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating:   
 II. Generic Equivalent to What Brand?:   
 Authorized Generic \*If Authorized Generic, other section fields are not applicable

## PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?   
 (Write-in, e.g. 1 Vial)  
 Rx billing unit to pharmacy:  
 Each  
 Gram  
 Milliliter

## 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:

## ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:	0.47	2.60	2.60	4.20	28.39	1
Case:	6.60	11.00	8.50	6.50	607.75	12
Pallet:					0.00	

## GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00359746280109	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	12		40359746280107	
<input type="checkbox"/> Pallet				

## COST INFORMATION

Regular Cost:   
 Invoice Cost (WAC) (\$):   
 As of date:   
 Vendor #:   
 Whsl. Code #:   
 Finline Code:

\*Please provide any additional information on page 2.

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

See new p. 3 for Designated Drop Ship Only.

Signature:



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

Version 2021

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  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 NFPA Storage Level:  No  
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:

