



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Pre-Approval Supplement Post Launch Change Final VersionDate:

PRODUCT INFORMATION	
Company Name:	Jubilant Cadista Pharmaceuticals Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	A202280
DUNS:	022490515
Proprietary Name (If Applicable) and Established Name:	Escitalopram Tablets
Selling Unit NDC:	59746-0281-01
Individual Unit NDC:	
UPC:	3-59746-281-01-4
CVX Code:	
MXV Code:	
Description:	Escitalopram 20mg Tablets 100ct
Active Ingredient(s):	Escitalopram Oxalate
URL for Additional Product Information:	www.cadista.com
Address:	207 Kiley Drive Salisbury Key Contact: Jackie Emershaw Phone Number: (410) 912-3722
State:	MD
Zip:	21801
Email:	Jackie.Emershaw@cadista.com
Fax:	(215) 443-9646
Product Therapeutic Classification:	

SPECIAL HANDLING AND STORAGE REQUIREMENTS	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77°)
Other Temperature Range Requirement (write in)	
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 Support
Number:	(800) 313-4623
Group E-mail:	
c. Special regulations for product in any states?	
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="text"/> Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	<input type="checkbox"/> Yes
reverse numbered?	<input type="checkbox"/> No
co-licensed?	<input type="checkbox"/> No
Is the Product... Direct-Ship Only?	<input type="checkbox"/>
Is the Product... <input type="checkbox"/>	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>
If Unit Dose NDC, indicate NDC here:	<input type="text"/>
Country of Origin	<input type="text"/>
Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	100ct
Strength:	20mg
Dosage Form:	TAB
Product Shape:	Round
Product Color:	White
Product Imprint:	debossed B4 C

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 case of 48 bottles
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="checkbox"/> 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"/> Each
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> Inner/ Carton/Pack
<input type="checkbox"/> Vial Power Multi	<input type="text"/> Case
<input type="checkbox"/> Other: Write In	

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB <input type="checkbox"/> Authorized Generic <input type="checkbox"/> If Authorized Generic, other section fields are not applicable
II. Generic Equivalent to What Brand?:	Lexapro®

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text"/> (Write-in, e.g. 1 Vial)	<input type="text"/> Each
	<input type="text"/> Gram
	<input type="text"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Is product exempt from DSCSA?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
GLN:	8902805000006
If Yes, was original product purchased direct from mfr?	<input type="checkbox"/>
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.1	1.69	3.19	1.69	9.110959	1
Box/Carton/Bundle/Inner Pack:						
Case:	7.95	14.88	5	11.13	828.072	48
Pallet:					0	
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit		Quantity	GTIN-14	
		Item	Unit			
<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>	2D	1	00359746281014	
<input type="checkbox"/>	Case	<input checked="" type="checkbox"/>	2D	48	40359746281012	
<input type="checkbox"/>	Pallet	<input type="checkbox"/>	2D			
<input type="checkbox"/>		<input type="checkbox"/>	2D			
<input type="checkbox"/>		<input type="checkbox"/>	2D			
<input type="checkbox"/>		<input type="checkbox"/>	2D			
<input type="checkbox"/>		<input type="checkbox"/>	2D			
<input type="checkbox"/>		<input type="checkbox"/>	2D			
<input type="checkbox"/>		<input type="checkbox"/>	2D			

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$15.00	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			