



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

Version 2021

Introduction Type: New Item

Final Version

Date: 1/26/2023

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Jubilant Cadista Pharmaceuticals Inc.		Application: ANDA		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)"/>	
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): ANDA 216594				Other Temperature Range Requirement (write in):		<input type="text"/>	
Medical Device Class, if applicable:				Notes:		<input type="text"/>	
DUNS: 022490515		Unit of Use NDC: 3-59746-789-01-5		Is this product to be shipped to customers on ice?		<input type="checkbox"/> No	
Proprietary Name (If Applicable) and Established Name: Carbamazepine ER Tablets		UPC: 3-59746-789-01-5		Is this product to be shipped to customers on dry ice?		<input type="checkbox"/> No	
Selling Unit NDC: 59746-789-01		CVX Code:		b. Contact for temperature excursion questions:		Name: Customer Service	
UDI:		MVX Code:		Number: (800) 313-4623		Group E-mail: customer.service@cadista.com	
Description: Carbamazepine ER 100mg 100ct Tablets		State: MD		Address 2:		Zip: 21801	
Active Ingredient(s): Carbamazepine		Email: customer.service@cadista.com		c. Special regulations for product in any states?		<input type="checkbox"/> No	
URL for Additional Product Information: www.cadista.com/products/full-product-list		Fax: N/A		Special returns requirements for this product?		<input type="checkbox"/> No	
Address: 207 Kiley Drive				d. Store product (unit of sale) upright?		<input type="checkbox"/> No	
City: Salisbury				Protect product (unit of sale) from light?		<input type="checkbox"/> No	
Key Contact: Customer Service				e. Shelf life:		24 Months	
Phone Number: (800) 313-4623				Initial shelf life at launch (if different):		<input type="text"/> Months	
Product Therapeutic Classification: Anticonvulsant							
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is? a legend device? <input type="checkbox"/> No		Is the Product... Direct-Ship Only <input type="checkbox"/> No		Size: 100 count			
if yes, enter class # a product kit? <input type="checkbox"/> No		Is the Product... Neither <input type="checkbox"/> No		Strength: 100mg			
if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No		Orphan Drug Status: <input type="checkbox"/> No		Dosage Form: TABLET			
co-licensed? <input type="checkbox"/> No		FDA Approval Status: <input type="text"/>		Product Shape: Round, Biconvex			
latex-free? <input type="checkbox"/> Yes		Allergens Present: <input type="text"/>		Product Color: Peach			
preservative-free? <input type="checkbox"/> No		Country of Origin: US		Product Imprint: CR 100'			
correctional institution block? <input type="checkbox"/> Yes		Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No					
opioid? <input type="checkbox"/> No							
Cannabinoid? <input type="checkbox"/> No							
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/>							
If Unit Dose, indicate NDC here: <input type="text"/>							
ORDER INFORMATION							
Unit of Sale				What is the NDC selling unit?			
<input checked="" type="checkbox"/>	Bottle			1 Bottle of 100 tablets			
<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			24 Each			
<input type="checkbox"/>	Vial Powder Sgl			Inner/Carton/Pack			
<input type="checkbox"/>	Vial Power Multi			Case			
<input type="checkbox"/>	Other: Write In						
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: AB		<input type="checkbox"/> Authorized Generic		*If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: Tegretol XR®							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes		GLN: 0359746000004					
Is product exempt from DSCSA? <input type="checkbox"/> No		GCP: 0359746					
If yes, select exemption: Other exemption - Write in: <input type="text"/>		If yes, was original product purchased direct from mfr? <input type="checkbox"/>		Provide source manufacturer for repackaged product			
Is product repackaged? <input type="checkbox"/> No							
Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> No							
Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> No							
If yes, attach documentation from FDA.							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		Saleable Quantity		HIBCC		GTIN-14	
<input checked="" type="checkbox"/>	Item/Each	1				00359746789015	
<input type="checkbox"/>	Box/Carton/Bundle/Inner Pack						
<input checked="" type="checkbox"/>	Case	24				40359746789013	
<input type="checkbox"/>	Pallet						
Unit of Use GTIN-14							
PHARMACY ORDER / BILL UNIT							
Rec. sell unit to customer? 1 Bottle of 100 tablets				Rx billing unit to pharmacy:			
(Write-in, e.g. 1 Vial)				<input checked="" type="checkbox"/> Each			
				<input type="checkbox"/> Gram			
				<input type="checkbox"/> Milliliter			
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	
	Depth	Width	Height				
Item/Each:	0.06	1.50	1.50	2.34	5.27	1	
Box/Carton/Bundle/Inner Pack:					0.00		
Case:	1.39	10.16	6.85	3.50	243.81	24	
Pallet:					0.00		
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost				Vendor #:			
Invoice Cost (WAC) (\$)		\$45.00		Whsl. Code #:			
As of date:				Fineline Code:			

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

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



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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?
 - 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 No
- Restricted to retail pharmacy only:
- Restricted to hospital, clinics, and physician offices only:
- Restricted from US territories? (explain in comments)
- Comments:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

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?



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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> <ul style="list-style-type: none"> a. EDI <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> <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> <ul style="list-style-type: none"> <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday <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: <input type="checkbox"/></p> <p>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>