



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

Version 2021

Introduction Type: New Item

Final Version

Date: 11/08/2022

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: 3-59746-791-01-8		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: 3-59746-791-01-8		Is this product to be shipped to customers on dry ice?		<input type="checkbox"/> No	
Selling Unit NDC: 59746-791-01		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 400mg 100ct Tablets				c. Special regulations for product in any states?		<input type="checkbox"/> No	
Active Ingredient(s): Carbamazepine				Special returns requirements for this product?		<input type="checkbox"/> No	
URL for Additional Product Information: www.cadista.com/products/full-product-list				d. Store product (unit of sale) upright?		<input type="checkbox"/> No	
Address: 207 Kiley Drive		Address 2:		Protect product (unit of sale) from light?		<input type="checkbox"/> No	
City: Salisbury		State: MD		e. Shelf life:		24 Months	
Key Contact: Katie Jones		Zip: 21801		Initial shelf life at launch (if different):		<input type="text"/>	
Phone Number: (215) 550-2824		Email: Katie.Jones@jubl.com					
Product Therapeutic Classification: Anticonvulsant		Fax: (215) 443-9646					
ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION		ORDER INFORMATION			
The product is? a legend device? <input type="checkbox"/> No	Is the Product... Direct-Ship Only <input type="checkbox"/>	Size: 100 count	Unit of Sale: <input checked="" type="checkbox"/> Bottle	What is the NDC selling unit? <input type="text" value="1 Case of 24 Bottles"/>			
if yes, enter class # a product kit? <input type="checkbox"/> No	Is the Product... Neither <input type="checkbox"/>	Strength: 400mg	<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)			
if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No	Orphan Drug Status: <input type="checkbox"/>	Dosage Form: TABLET	<input type="checkbox"/> Ampule	Minimum order quantity? <input type="checkbox"/> Yes			
co-licensed? <input type="checkbox"/> No	FDA Approval Status: <input type="text"/>	Product Shape: Round, Biconvex	<input type="checkbox"/> Glass	If Yes, how many of which package type?			
latex-free? <input type="checkbox"/> Yes	Allergens Present: <input type="text"/>	Product Color: Peach	<input type="checkbox"/> Tube	24 Each			
preservative-free? <input type="checkbox"/> No	Country of Origin: US	Product Imprint: CR 400'	<input type="checkbox"/> Vial Liquid Sgl	Inner/ Carton/ Pack			
correctional institution block? <input type="checkbox"/> Yes	Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No		<input type="checkbox"/> Vial Liquid Multi	Case			
opioid? <input type="checkbox"/> No			<input type="checkbox"/> Vial Powder Sgl				
Cannabinoid? <input type="checkbox"/> No			<input type="checkbox"/> Vial Power Multi				
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/>			<input type="checkbox"/> Other: Write In				
If Unit Dose, indicate NDC here: <input type="text"/>							
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: <input checked="" type="checkbox"/> Item/Each	Saleable Quantity: 1	HIBCC:	GTIN-14: 00359746791018	Unit of Use GTIN-14:			
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack							
<input checked="" type="checkbox"/> Case	24		40359746791016				
<input type="checkbox"/> Pallet							
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost		Invoice Cost (WAC) (\$): \$160.00		Vendor #:			
As of date:				Whsl. Code #:			
				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?

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?

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?

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?
 RQ Threshold:

Is this a marine pollutant?

Is this product shipped utilizing an authorized DOT exception or Special Permit?
 (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#

SDS Hazard Classification

Organic
 Inorganic
 Steroid/Androgen

Corrosive
 Oxidizer
 Contact Hazard

Does the product have an Aerosol class? If yes, identify

NFPA Storage Level:

NFPA Storage Level:

Is the product a NIOSH hazardous drug?
 If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?
 Website URL:

Med Guide Required

Limited Distribution Requirement

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

ADD'L STORAGE INFORMATION

Is the Product...

Controlled Substance? Controlled Substance Code

Controlled by State(s)? Listed Chemical (List I or II)

ARCOS Reportable? If yes, indicate which:

Schedule No. Is it a scheduled listed chemical product?:

CLASS OF TRADE RESTRICTION:

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:

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:



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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
Purchase orders may be accepted by: 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"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/> Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <input type="text"/>	Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	Overnight receipt available: <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>