



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

Version 2021 Introduction Type: New Item Final Version Date: 1/25/2023

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*				
Company Name: <input type="text"/> Jubilant Cadista Pharmaceuticals Inc. Application: <input type="text"/> ANDA Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text"/> 215483 Medical Device Class, if applicable: <input type="text"/> DUNS: <input type="text"/> 022490515 Proprietary Name (if Applicable) and Established Name: <input type="text"/> Doxepin HCl Capsules Selling Unit NDC: <input type="text"/> 59746-702-01 Unit of Use NDC: <input type="text"/> UPC: <input type="text"/> 3-59746-702-01-4 UDI <input type="text"/> CVX Code: <input type="text"/> MVX Code: <input type="text"/> Description: <input type="text"/> Doxepin HCl 50mg 100ct Capsule Active Ingredient(s): <input type="text"/> Doxepin Hydrochloride URL for Additional Product Information: <input type="text"/> www.cadista.com/products/full-product-list Address: <input type="text"/> 207 Kiley Drive Address 2: <input type="text"/> City: <input type="text"/> Salisbury State: <input type="text"/> MD Zip: <input type="text"/> 21801 Key Contact: <input type="text"/> Customer Service Email: <input type="text"/> customer.service@cadista.com Phone Number: <input type="text"/> (800) 313-4623 Fax: <input type="text"/> N/A Product Therapeutic Classification: <input type="text"/> Antidepressants		a. Temperature – Indicate the USP temperature range for this product. Temperature Range <input type="text"/> Controlled Room – between 20 and 25 C (68° – 77° F) Other Temperature Range Requirement <input type="text"/> (write in) Notes <input type="text"/> Is this product to be shipped to customers on ice? <input type="text"/> No Is this product to be shipped to customers on dry ice? <input type="text"/> No b. Contact for temperature excursion questions: Name: <input type="text"/> Customer Service Number: <input type="text"/> (800) 313-4623 Group E-mail: <input type="text"/> customer.service@cadista.com c. Special regulations for product in any states? <input type="text"/> No Special returns requirements for this product? <input type="text"/> No d. Store product (unit of sale) upright? <input type="text"/> No Protect product (unit of sale) from light? <input type="text"/> No e. Shelf life: <input type="text"/> 24 Months Initial shelf life at launch (if different): <input type="text"/> Months				
ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION				
The product is? a legend device? <input type="text"/> No if yes, enter class # <input type="text"/> a product kit? <input type="text"/> No if yes, list NDCs of component parts <input type="text"/> reverse numbered? <input type="text"/> No co-licensed? <input type="text"/> No latex-free? <input type="text"/> Yes preservative-free? <input type="text"/> No correctional institution block? <input type="text"/> Yes opioid? <input type="text"/> No Cannabinoid? <input type="text"/> No If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/> If Unit Dose, indicate NDC here: <input type="text"/>		Is the Product... <input type="text"/> Direct-Ship Only Is the Product... <input type="text"/> Neither Orphan Drug Status <input type="text"/> FDA Approval Status <input type="text"/> Allergens Present <input type="text"/> Country of Origin <input type="text"/> US Is this product covered under the Trade Agreements Act (TAA)? <input type="text"/> Yes				
		Size: <input type="text"/> 100 count Strength: <input type="text"/> 50mg Dosage Form: <input type="text"/> CAPSULE Product Shape: <input type="text"/> Gelatin capsule, size 3 Product Color: <input type="text"/> Yellow opaque Product Imprint: <input type="text"/> C 702				
FOR GENERIC DRUG PRODUCTS						
I. Orange Book Rating: <input type="text"/> AB <input type="checkbox"/> Authorized Generic <input type="checkbox"/> *If Authorized Generic, other section fields are not applicable II. Generic Equivalent to What Brand?: <input type="text"/> Sinequan®						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						
Does supplier meet DSCSA definition of manufacturer? <input type="text"/> Yes Is product exempt from DSCSA? <input type="text"/> No If yes, select exemption: Other exemption - Write in: <input type="text"/> Is product repackaged? <input type="text"/> No Is product sold by manufacturer's exclusive distributor? <input type="text"/> No Has FDA granted waiver/exception/exemption for product? <input type="text"/> No If yes, attach documentation from FDA.		GLN: <input type="text"/> 0359746000004 GCP: <input type="text"/> 0359746 If yes, was original product purchased direct from mfr? <input type="text"/> Provide source manufacturer for repackaged product <input type="text"/>				
GTIN AND HIBCC PRODUCT INFORMATION						
Saleable Unit of Measure <input checked="" type="checkbox"/> Item/Each <input type="checkbox"/> Box/Carton/Bundle/Inner Pack <input checked="" type="checkbox"/> Case <input type="checkbox"/> Pallet		Saleable Quantity <input type="text"/> 1 HIBCC <input type="text"/> GTIN-14 <input type="text"/> 00359746702014 <input type="text"/> 40359746702012 Unit of Use GTIN-14 <input type="text"/>				
COST INFORMATION		WHOLESALE USE ONLY:				
Regular Cost <input type="text"/> Invoice Cost (WAC) (\$) <input type="text"/> \$48.00 As of date: <input type="text"/>		Vendor #: <input type="text"/> Whsl. Code #: <input type="text"/> Fineline Code: <input type="text"/>				
ORDER INFORMATION						
Unit of Sale <input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box/Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Power Multi <input type="checkbox"/> Other: Write In <input type="text"/>		What is the NDC selling unit? <input type="text"/> 1 bottles of 100 tablets (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="text"/> Yes If Yes, how many of which package type? <input type="text"/> 24 Each <input type="text"/> Inner/Carton/Pack <input type="text"/> Case				
PHARMACY ORDER / BILL UNIT						
Rec. sell unit to customer? <input type="text"/> 1 bottles of 100 tablets (Write-in, e.g. 1 Vial)		Rx billing unit to pharmacy: <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:	0.1	1.8	1.8	3	9.72	1
Box/Carton/Bundle/Inner Pack:					0.00	
Case:	3.6	12.25	8.5	5	520.63	24
Pallet:					0.00	

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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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 No
- 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 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?

MISCELLANEOUS NOTES and/or Image of Product Barcode:



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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 <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"/>