



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

Version 2021 Introduction Type: Final Version Date:

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
Company Name: <input type="text" value="Jubilant Cadista Pharmaceuticals Inc."/>	Application: <input type="text" value="ANDA"/>	a. Temperature – Indicate the USP temperature range for this product.	
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="201506"/>		Temperature Range <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>	
Medical Device Class, if applicable: <input type="text"/>		Other Temperature Range Requirement (write in) <input type="text"/>	
DUNS: <input type="text" value="022490515"/>		Notes <input type="text"/>	
Proprietary Name (If Applicable) and Established Name: <input type="text" value="Valacyclovir HCl Capsules"/>	Unit of Use NDC: <input type="text" value="3-59746-324-37"/>	Is this product to be shipped to customers on ice? <input type="text" value="No"/>	
Selling Unit NDC: <input type="text" value="59746-324-37"/>	UPC: <input type="text"/>	Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>	
UDI <input type="text"/>	CVX Code: <input type="text"/>		
MVX Code: <input type="text"/>	UPC: <input type="text" value="3-59746-324-37"/>		
Description: <input type="text" value="Valacyclovir Hydrochloride 500mg 250ct Capsules"/>		b. Contact for temperature excursion questions:	
Active Ingredient(s): <input type="text" value="Valacyclovir HCl"/>		Name: <input type="text" value="Customer Service"/>	
URL for Additional Product Information: <input type="text" value="www.cadista.com/products/full-product-list"/>		Number: <input type="text" value="(800) 313-4623"/>	
Address: <input type="text" value="207 Kiley Drive"/>	Address 2: <input type="text"/>	Group E-mail: <input type="text" value="customer.service@cadista.com"/>	
City: <input type="text" value="Salisbury"/>	State: <input type="text" value="MD"/>		
Key Contact: <input type="text" value="Jackie Emershaw"/>	Zip: <input type="text" value="21801"/>		
Phone Number: <input type="text" value="(410) 912-3722"/>	Email: <input type="text" value="Jackie.Emershaw@jubl.com"/>		
Product Therapeutic Classification: <input type="text" value="Antiviral"/>	Fax: <input type="text" value="(215) - 443 - 9646"/>		
		c. Special regulations for product in any states?	
		Special returns requirements for this product? <input type="text" value="No"/>	
		d. Store product (unit of sale) upright? <input type="text" value="No"/>	
		e. Shelf life:	
		Protect product (unit of sale) from light? <input type="text" value="No"/>	
		Initial shelf life at launch (if different): <input type="text" value="24"/> Months	

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is? a legend device? <input type="text" value="No"/>	Is the Product... Direct-Ship Only <input type="text"/>	Size: <input type="text" value="250 count"/>	
if yes, enter class # <input type="text"/>	Is the Product... Neither <input type="text"/>	Strength: <input type="text" value="500mg"/>	
a product kit? <input type="text" value="No"/>	Orphan Drug Status <input type="text"/>	Dosage Form: <input type="text" value="CAPSULE"/>	
if yes, list NDCs of component parts <input type="text"/>	FDA Approval Status <input type="text"/>	Product Shape: <input type="text" value="Capsule"/>	
reverse numbered? <input type="text" value="No"/>	Allergens Present <input type="text"/>	Product Color: <input type="text" value="Blue"/>	
co-licensed? <input type="text" value="No"/>	Country of Origin <input type="text" value="IN"/>	Product Imprint: <input type="text" value="C324 500"/>	
latex-free? <input type="text" value="Yes"/>	Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/>		
preservative-free? <input type="text" value="No"/>			
correctional institution block? <input type="text" value="Yes"/>			
opioid? <input type="text" value="No"/>			
Cannabinoid? <input type="text" value="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"/>			

ORDER INFORMATION	
Unit of Sale <input checked="" type="checkbox"/> Bottle	What is the NDC selling unit? <input type="text" value="1 bottles of 250 capsule"/>
<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="text" value="Yes"/>
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value="12"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="text"/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<input type="text"/> Case

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

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer? <input type="text" value="1 bottles of 250 capsule"/>	Rx billing unit to pharmacy:
(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="text" value="Yes"/>	GLN: <input type="text" value="8902805000006"/>
Is product exempt from DSCSA? <input type="text" value="No"/>	GCP: <input type="text" value="0359746"/>
If yes, select exemption: <input type="text"/>	
Other exemption - Write in: <input type="text"/>	
Is product repackaged? <input type="text" value="No"/>	If yes, was original product purchased direct from mfr? <input type="text"/>
Is product sold by manufacturer's exclusive distributor? <input type="text" value="No"/>	Provide source manufacturer for repackaged product <input type="text"/>
Has FDA granted waiver/exception/exemption for product? <input type="text" value="No"/>	
If yes, attach documentation from FDA. <input type="text"/>	

ITEM AND PACKING INFORMATION						
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.54	3	3	5.26	47.34	1
Box/Carton/Bundle/Inner Pack:					0.00	
Case:	8.47	12.75	9.75	8.47	1052.93	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	<input type="text" value="1"/>	<input type="text"/>	<input type="text" value="00359746324377"/>	<input type="text"/>
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input checked="" type="checkbox"/> Case	<input type="text" value="12"/>	<input type="text"/>	<input type="text" value="40359746324375"/>	<input type="text"/>
<input type="checkbox"/> Pallet	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	<input type="text" value="\$108.51"/>	Whsl. Code #:	<input type="text"/>
As of date:	<input type="text"/>	Fineline Code:	<input type="text"/>

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



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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:

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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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
	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>