



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

Version 2024 Introduction Type: Post Launch Change Final Version Date: 6/17/2026

PRODUCT INFORMATION

Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA
 Application Number for NDA/ANDA/BLA; PMA/510(k): 90802 NDA 505(b) Type: NOT APPLICABLE
 Medical Device Class, if applicable:
 DUNS: 118694141
 Proprietary Name (If Applicable) and Established Name: Tacrolimus Capsules
 Selling Unit NDC: 59746-0798-01 Unit of Use NDC: UPC: 3-59746798017
 UDI CVX Code: MVX Code:
 Description: Tacrolimus 0.5mg 100ct Capsules
 Active Ingredient(s): Tacrolimus 0.5mg
 URL for Additional Product Information: www.cadista.com/products/full-product-list
 Address: 790 Township Line Road Address 2: Suite 325
 City: Yardley State: PA Zip: 19067
 Key Contact: Customer Service Email: customer.service@cadista.com
 Phone Number: (800) 313-4623 Fax: N/A
 Product Therapeutic Classification: Immunosuppressant

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° F)
 Other Temperature Range Requirement (write in):
 Notes:
 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 Service
 Number: (800) 313-4623
 Group E-mail: customer.service@cadista.com

c. Special regulations for product in any states?
 Special returns requirements for this product? No

d. Store product (unit of sale) upright? No
 Protect product (unit of sale) from light? No

e. Shelf life:
 Initial shelf life at launch (if different): 24 Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is? a legend device? if yes, enter class #	<input type="checkbox"/> No	Is the Product... Is the Product... Orphan Drug Status	<input type="checkbox"/> Direct-Ship Only <input type="checkbox"/> Neither
a product kit? if yes, list NDCs of component parts reverse numbered?	<input type="checkbox"/> No	FDA Approval Status	Size: 100 count
co-licensed?	<input type="checkbox"/> No	Allergens Present	Strength: 0.5mg
latex-free?	<input type="checkbox"/> Yes	Country of Origin	Dosage Form: CAPSULE
preservative-free?	<input type="checkbox"/> No	India	Product Shape: Body size "5" hard gelatin capsules
correctional institution block? opioid?	<input type="checkbox"/> Yes	Is this product covered under the Trade Agreements Act (TAA)?	Product Color: Light yellow
Cannabinoid?	<input type="checkbox"/> No	<input type="checkbox"/> Yes	Product Imprint: "PBT" on cap and "0.5" on body- desing in red ink
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 capsules
<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	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> 48 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: AB Authorized Generic *If Authorized Generic, other section fields are not applicable
 II. Generic Equivalent to What Brand?: Prograf®

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? 1 Bottle of 100 capsules
 (Write-in, e.g. 1 Vial)
 HCPCS J-Code:

Rx billing unit to pharmacy:
 Each
 Gram
 Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes No
 Is product exempt from DSCSA? Yes No
 If yes, select exemption:
 Other exemption - Write in:
 Is product repackaged? No
 Is product sold by manufacturer's exclusive distributor? No
 Has FDA granted waiver/exception/exemption for product? No
 If yes, attach documentation from FDA.

GLN: 0359746000004
 GCP: 0359746
 If yes, was original product purchased direct from mfr?
 Provide source manufacturer for repackaged product

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:	0.12	1.57	1.57	3.85	9.49	1
Case:	7.54	10.24	7.09	10.24	743.44	48
Pallet:					0	

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	N	1		00359746798017	
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	N	48		50359746798012	
<input type="checkbox"/> Case					
<input type="checkbox"/> Pallet					

COST INFORMATION

Regular Cost
 Invoice Cost (WAC) (\$) \$186.00
 As of date: 6/17/2026

WHOLESALE USE ONLY:
 Vendor #:
 Whsl. Code #:
 Fineline Code:



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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 NFPA Storage Level: No Yes

Is the product a NIOSH hazardous drug? If yes, indicate which: No Yes

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No Yes
If Yes, is it managed with a pharmacy registry? No Yes
Website URL:

Med Guide Required No Yes
Limited Distribution Requirement No Yes
Comments / Details: (For example, iPledge program?)

REMS:
REMS Program Manager Name: Phone:
Supplier Manages REMS registry exclusively: No Yes
Wholesale distributor support: No Yes
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: No Yes
URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states? No Yes
If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

