



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

Version 2024		Introduction Type: <input type="text"/>		<input type="checkbox"/> Final Version		Date: <input type="text" value="2/24/2025"/>																																			
PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																			
<div><div>Company Name: <input type="text" value="Jubilant Cadista Pharmaceuticals Inc."/></div><div>Application: <input type="text" value="ANDA"/></div><div>Application Number for NDA/ANDA/BLA; PMA/510(k): <input type="text" value="075317"/></div><div>NDA 505(b) Type: <input type="text" value="NOT APPLICABLE"/></div><div>Medical Device Class, if applicable: <input type="text"/></div><div>DUNS: <input type="text" value="118694141"/></div><div>Proprietary Name (If Applicable) and Established Name: <input type="text" value="Terazosin HCl Capsules"/></div><div>Selling Unit NDC: <input type="text" value="59746-386-10"/></div><div>Unit of Use NDC: <input type="text"/></div><div>UPC: <input type="text" value="3-59746-386-10-8"/></div><div>UDI: <input type="text"/></div><div>CVX Code: <input type="text"/></div><div>MVX Code: <input type="text"/></div><div>Description: <input type="text" value="Terazosin Hydrochloride 10mg 1000ct Capsules"/></div><div>Active Ingredient(s): <input type="text" value="Terazosin Hydrochloride"/></div><div>URL for Additional Product Information: <input type="text" value="www.cadista.com/products/full-product-list"/></div><div>Address: <input type="text" value="790 Township Line Road"/></div><div>City: <input type="text" value="Yardley"/></div><div>State: <input type="text" value="PA"/></div><div>Address 2: <input type="text" value="Suite 325"/></div><div>Zip: <input type="text" value="19067"/></div><div>Key Contact: <input type="text" value="Customer Service"/></div><div>Email: <input type="text" value="customer.service@cadista.com"/></div><div>Phone Number: <input type="text" value="(800) 313-4623"/></div><div>Fax: <input type="text" value="N/A"/></div><div>Product Therapeutic Classification: <input type="text" value="Benign Prostatic Hypertrophy"/></div></div> <td colspan="6"><div>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)"/> Other Temperature Range Requirement (write in) <input type="text"/> Notes <input type="text"/> Is this product to be shipped to customers on ice? <input type="text" value="No"/> Is this product to be shipped to customers on dry ice? <input type="text" value="No"/></div><div>b. Contact for temperature excursion questions: Name: <input type="text" value="Customer Service"/> Number: <input type="text" value="(800) 313-4623"/> Group E-mail: <input type="text" value="customer.service@cadista.com"/></div><div>c. Special regulations for product in any states? Special returns requirements for this product? <input type="text" value="No"/></div><div>d. Store product (unit of sale) upright? Protect product (unit of sale) from light? <input type="text" value="No"/></div><div>e. Shelf life: Initial shelf life at launch (if different): <input type="text" value="24"/> Months</div></td>						<div>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)"/> Other Temperature Range Requirement (write in) <input type="text"/> Notes <input type="text"/> Is this product to be shipped to customers on ice? <input type="text" value="No"/> Is this product to be shipped to customers on dry ice? <input type="text" value="No"/></div> <div>b. Contact for temperature excursion questions: Name: <input type="text" value="Customer Service"/> Number: <input type="text" value="(800) 313-4623"/> Group E-mail: <input type="text" value="customer.service@cadista.com"/></div> <div>c. Special regulations for product in any states? Special returns requirements for this product? <input type="text" value="No"/></div> <div>d. Store product (unit of sale) upright? Protect product (unit of sale) from light? <input type="text" value="No"/></div> <div>e. Shelf life: Initial shelf life at launch (if different): <input type="text" value="24"/> Months</div>																																			
ADDITIONAL PRODUCT INFORMATION						PRODUCT DESCRIPTION INFORMATION																																			
<div>The product is? a legend device? <input type="text" value="No"/> if yes, enter class # <input type="text"/> a product kit? <input type="text" value="No"/> if yes, list NDCs of component parts reverse numbered? <input type="text"/> co-licensed? <input type="text" value="No"/> latex-free? <input type="text" value="Yes"/> 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"/></div>			<div>Is the Product... Is the Product... <input type="text"/> Orphan Drug Status <input type="text"/> FDA Approval Status <input type="text"/> Allergens Present <input type="text"/> Country of Origin <input type="text" value="US"/> Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="Yes"/></div>			<div>Direct-Ship Only <input type="text"/> Neither <input type="text"/> Size: <input type="text" value="1000 count"/> Strength: <input type="text" value="10mg"/> Dosage Form: <input type="text" value="CAPSULE"/> Product Shape: <input type="text" value="Capsule, Size 3"/> Product Color: <input type="text" value="Light Green"/> Product Imprint: <input type="text" value="TL 386"/></div>																																			
FOR GENERIC DRUG PRODUCTS																																									
<div>I. Orange Book Rating: <input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable</div> <div>II. Generic Equivalent to What Brand?: <input type="text" value="Hytrin@"/></div>																																									
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION																																									
<div>Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/> Is product exempt from DSCSA? <input type="text" value="No"/> If yes, select exemption: Other exemption - Write in: <input type="text"/> Is product repackaged? <input type="text" value="No"/> Is product sold by manufacturer's exclusive distributor? <input type="text" value="No"/> Has FDA granted waiver/exception/exemption for product? <input type="text" value="No"/> If yes, attach documentation from FDA. <input type="text"/></div>						<div>GLN: <input type="text" value="0359746000004"/> GCP: <input type="text" value="0359746"/> If yes, was original product purchased direct from mfr? <input type="text"/> Provide source manufacturer for repackaged product <input type="text"/></div>																																			
GTIN AND HIBCC PRODUCT INFORMATION																																									
<table border="1" style="width:100%; border-collapse: collapse;"><thead><tr><th>Saleable Unit of Measure</th><th>RFID tag(Y/N)</th><th>Saleable Quantity</th><th>HIBCC</th><th>GTIN-14</th><th>Unit of Use GTIN-14</th></tr></thead><tbody><tr><td><input checked="" type="checkbox"/> Item/Each</td><td>N</td><td>1</td><td></td><td>00359746386108</td><td></td></tr><tr><td><input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack</td><td>N</td><td>12</td><td></td><td>40359746386106</td><td></td></tr><tr><td><input type="checkbox"/> Case</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td><input type="checkbox"/> Pallet</td><td></td><td></td><td></td><td></td><td></td></tr></tbody></table>												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		00359746386108		<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	N	12		40359746386106		<input type="checkbox"/> Case						<input type="checkbox"/> Pallet					
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COST INFORMATION						WHOLESALE USE ONLY:																																			
<div>Regular Cost <input type="text"/> Invoice Cost (WAC) (\$) <input type="text" value="\$176.40"/> As of date: <input type="text" value="2/24/2025"/></div>						<div>Vendor #: <input type="text"/> Whsl. Code #: <input type="text"/> Fineline Code: <input type="text"/></div>																																			
<div>*Please provide any additional information on page 2.</div> <div>Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.</div> <div>See new p. 3 for Designated Drop Ship Only.</div> <div>Signature: <input type="text"/></div>																																									



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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 Controlled Substance Code
- Controlled by State(s)? ☐ No Listed Chemical (List I or II) ☐ No
- ARCOS Reportable? ☐ No If yes, indicate which:
- Schedule No. Is it a scheduled listed chemical product?: ☐ No

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices

☐ Yes

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 ☐ Corrosive
- ☐ Inorganic ☐ Oxidizer
- ☐ Steroid/Androgen ☐ 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:

Release DATE



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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> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <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> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <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: 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
<input type="text"/>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>