



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

Version 2021

Introduction Type:

Final Version

Date:

| PRODUCT INFORMATION   |             |   |       | SPECIAL HANDLING AND STORAGE REQUIREMENTS*   |               |  |  |   |  |   |  |  |             |                        |  |  |               |                   |  |  |       |       |        |  |  |            |      |     |     |   |       |   |                               |  |  |  |  |      |  |       |       |      |       |      |        |    |         |  |  |  |  |      |  |
|---|-------------|---|-------|--|---------------|--|--|---|--|---|--|--|-------------|------------------------|--|--|---------------|-------------------|--|--|-------|-------|--------|--|--|------------|------|-----|-----|---|-------|---|-------------------------------|--|--|--|--|------|--|-------|-------|------|-------|------|--------|----|---------|--|--|--|--|------|--|
| <b>Company Name:</b> <input type="text" value="Jubilant Cadista Pharmaceuticals Inc."/> <b>Application:</b> <input type="text" value="ANDA"/><br><b>Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):</b> <input type="text" value="201170"/><br><b>Medical Device Class, if applicable:</b> <input type="text"/><br><b>DUNS:</b> <input type="text" value="022490515"/><br><b>Proprietary Name (If Applicable) and Established Name:</b> <input type="text" value="Losartan Potassium Tablets"/><br><b>Selling Unit NDC:</b> <input type="text" value="59746-334-30"/> <b>Unit of Use NDC:</b> <input type="text"/> <b>UPC:</b> <input type="text" value="3-59746-334-30-7"/><br><b>UDI</b> <input type="text"/> <b>CVX Code:</b> <input type="text"/> <b>MVX Code:</b> <input type="text"/><br><b>Description:</b> <input type="text" value="Losartan Potassium 50mg 30cct Tablet"/><br><b>Active Ingredient(s):</b> <input type="text" value="Losartan Potassium"/><br><b>URL for Additional Product Information:</b> <input type="text" value="www.cadista.com/products/full-product-list"/><br><b>Address:</b> <input type="text" value="207 Kiley Drive"/> <b>Address 2:</b> <input type="text"/><br><b>City:</b> <input type="text" value="Salisbury"/> <b>State:</b> <input type="text" value="MD"/> <b>Zip:</b> <input type="text" value="21801"/><br><b>Key Contact:</b> <input type="text" value="Jackie Emershaw"/> <b>Email:</b> <input type="text" value="Jackie.Emershaw@jubl.com"/><br><b>Phone Number:</b> <input type="text" value="(410) 912-3722"/> <b>Fax:</b> <input type="text" value="(215) - 443 - 9646"/><br><b>Product Therapeutic Classification:</b> <input type="text" value="Antihypertensive"/> |             |   |       | <b>a. Temperature – Indicate the USP temperature range for this product.</b><br><b>Temperature Range</b> <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/><br><b>Other Temperature Range Requirement (write in)</b> <input type="text"/><br><b>Notes</b> <input type="text"/><br><b>Is this product to be shipped to customers on ice?</b> <input type="text" value="No"/><br><b>Is this product to be shipped to customers on dry ice?</b> <input type="text" value="No"/><br><b>b. Contact for temperature excursion questions:</b><br><b>Name:</b> <input type="text" value="Customer Service"/><br><b>Number:</b> <input type="text" value="(800) 313-4623"/><br><b>Group E-mail:</b> <input type="text" value="customer.service@cadista.com"/><br><b>c. Special regulations for product in any states?</b> <input type="text" value="No"/><br><b>Special returns requirements for this product?</b> <input type="text" value="No"/><br><b>d. Store product (unit of sale) upright?</b> <input type="text" value="No"/><br><b>Protect product (unit of sale) from light?</b> <input type="text" value="No"/><br><b>e. Shelf life:</b> <input type="text" value="24"/> <b>Months</b><br><b>Initial shelf life at launch (if different):</b> <input type="text"/> <b>Months</b> |               |  |  |   |  |   |  |  |             |                        |  |  |               |                   |  |  |       |       |        |  |  |            |      |     |     |   |       |   |                               |  |  |  |  |      |  |       |       |      |       |      |        |    |         |  |  |  |  |      |  |
| ADDITIONAL PRODUCT INFORMATION  |             | PRODUCT DESCRIPTION INFORMATION   |       | ORDER INFORMATION  |               |  |  |   |  |   |  |  |             |                        |  |  |               |                   |  |  |       |       |        |  |  |            |      |     |     |   |       |   |                               |  |  |  |  |      |  |       |       |      |       |      |        |    |         |  |  |  |  |      |  |
| <b>The product is?</b><br><b>a legend device?</b> <input type="text" value="No"/><br><b>if yes, enter class #</b> <input type="text"/><br><b>a product kit?</b> <input type="text" value="No"/><br><b>if yes, list NDCs of component parts</b> <input type="text"/><br><b>reverse numbered?</b> <input type="text" value="No"/><br><b>co-licensed?</b> <input type="text" value="No"/><br><b>latex-free?</b> <input type="text" value="Yes"/><br><b>preservative-free?</b> <input type="text" value="No"/><br><b>correctional institution block?</b> <input type="text" value="Yes"/><br><b>opioid?</b> <input type="text" value="No"/><br><b>Cannabinoid?</b> <input type="text" value="No"/><br><b>If Unit Dose, is item bar coded to unit dose for hospital scanning?</b> <input type="text"/><br><b>If Unit Dose, indicate NDC here:</b> <input type="text"/>   |             | <b>Is the Product... Direct-Ship Only?</b> <input type="text" value="Neither"/><br><b>Is the Product... Orphan Drug Status?</b> <input type="text"/><br><b>FDA Approval Status</b> <input type="text"/><br><b>Allergens Present</b> <input type="text"/><br><b>Country of Origin</b> <input type="text" value="US"/><br><b>Is this product covered under the Trade Agreements Act (TAA)?</b> <input type="text" value="Yes"/> |       | <b>Size:</b> <input type="text" value="30 count"/><br><b>Strength:</b> <input type="text" value="50mg"/><br><b>Dosage Form:</b> <input type="text" value="TABLETS"/><br><b>Product Shape:</b> <input type="text" value="Oval, Scored"/><br><b>Product Color:</b> <input type="text" value="Green"/><br><b>Product Imprint:</b> <input type="text" value="C / 334"/>  |               | <b>Unit of Sale</b><br><input checked="" type="checkbox"/> Bottle<br><input type="checkbox"/> Box/Carton<br><input type="checkbox"/> Ampule<br><input type="checkbox"/> Glass<br><input type="checkbox"/> Tube<br><input type="checkbox"/> Vial Liquid Sgl<br><input type="checkbox"/> Vial Liquid Multi<br><input type="checkbox"/> Vial Powder Sgl<br><input type="checkbox"/> Vial Power Multi<br><input type="checkbox"/> Other: Write In <input type="text"/><br><b>What is the NDC selling unit?</b> <input type="text" value="1 bottle of 30 tablets"/><br><small>(Write-in, e.g. 1 Box of 10 Vials)</small><br><b>Minimum order quantity?</b> <input type="text" value="Yes"/> |  |   |  |   |  |  |             |                        |  |  |               |                   |  |  |       |       |        |  |  |            |      |     |     |   |       |   |                               |  |  |  |  |      |  |       |       |      |       |      |        |    |         |  |  |  |  |      |  |
| FOR GENERIC DRUG PRODUCTS   |             |   |       | PHARMACY ORDER / BILL UNIT   |               |  |  |   |  |   |  |  |             |                        |  |  |               |                   |  |  |       |       |        |  |  |            |      |     |     |   |       |   |                               |  |  |  |  |      |  |       |       |      |       |      |        |    |         |  |  |  |  |      |  |
| <b>I. Orange Book Rating:</b> <input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic <small>*If Authorized Generic, other section fields are not applicable</small><br><b>II. Generic Equivalent to What Brand?:</b> <input type="text" value="Cozzaar"/>  |             |   |       | <b>Rec. sell unit to customer?</b> <input type="text" value="1 bottle of 30 tablets"/><br><small>(Write-in, e.g. 1 Vial)</small><br><b>Rx billing unit to pharmacy:</b><br><input checked="" type="checkbox"/> Each<br><input type="checkbox"/> Gram<br><input type="checkbox"/> Milliliter  |               |  |  |   |  |   |  |  |             |                        |  |  |               |                   |  |  |       |       |        |  |  |            |      |     |     |   |       |   |                               |  |  |  |  |      |  |       |       |      |       |      |        |    |         |  |  |  |  |      |  |
| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION  |             |   |       | ITEM AND PACKING INFORMATION   |               |  |  |   |  |   |  |  |             |                        |  |  |               |                   |  |  |       |       |        |  |  |            |      |     |     |   |       |   |                               |  |  |  |  |      |  |       |       |      |       |      |        |    |         |  |  |  |  |      |  |
| <b>Does supplier meet DSCSA definition of manufacturer?</b> <input type="text" value="Yes"/><br><b>Is product exempt from DSCSA?</b> <input type="text" value="No"/><br><b>If yes, select exemption:</b> <input type="text"/><br><b>Other exemption - Write in:</b> <input type="text"/><br><b>Is product repackaged?</b> <input type="text" value="No"/><br><b>Is product sold by manufacturer's exclusive distributor?</b> <input type="text" value="No"/><br><b>Has FDA granted waiver/exception/exemption for product?</b> <input type="text" value="No"/><br><b>If yes, attach documentation from FDA.</b> <input type="text"/>  |             |   |       | <b>GLN:</b> <input type="text" value="0359746000004"/><br><b>GCP:</b> <input type="text" value="0359746"/>   |               | <b>If yes, was original product purchased direct from mfr?</b> <input type="text"/><br><b>Provide source manufacturer for repackaged product</b> <input type="text"/>  |  | <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th>Weight Lbs.</th> <th colspan="3">Dimensions (US msmts.)</th> <th>Volume (Cube)</th> <th>Saleable # Pieces</th> </tr> <tr> <th></th> <th></th> <th>Depth</th> <th>Width</th> <th>Height</th> <th></th> <th></th> </tr> </thead> <tbody> <tr> <td>Item/Each:</td> <td>0.09</td> <td>1.9</td> <td>1.9</td> <td>4</td> <td>14.44</td> <td>1</td> </tr> <tr> <td>Box/Carton/Bundle/Inner Pack:</td> <td></td> <td></td> <td></td> <td></td> <td>0.00</td> <td></td> </tr> <tr> <td>Case:</td> <td>15.11</td> <td>16.5</td> <td>12.25</td> <td>4.75</td> <td>960.09</td> <td>48</td> </tr> <tr> <td>Pallet:</td> <td></td> <td></td> <td></td> <td></td> <td>0.00</td> <td></td> </tr> </tbody> </table> |  |   |  |  | Weight Lbs. | Dimensions (US msmts.) |  |  | Volume (Cube) | Saleable # Pieces |  |  | Depth | Width | Height |  |  | Item/Each: | 0.09 | 1.9 | 1.9 | 4 | 14.44 | 1 | Box/Carton/Bundle/Inner Pack: |  |  |  |  | 0.00 |  | Case: | 15.11 | 16.5 | 12.25 | 4.75 | 960.09 | 48 | Pallet: |  |  |  |  | 0.00 |  |
|   | Weight Lbs. | Dimensions (US msmts.)  |       |  | Volume (Cube) | Saleable # Pieces  |  |   |  |   |  |  |             |                        |  |  |               |                   |  |  |       |       |        |  |  |            |      |     |     |   |       |   |                               |  |  |  |  |      |  |       |       |      |       |      |        |    |         |  |  |  |  |      |  |
|   |             | Depth   | Width | Height   |               |  |  |   |  |   |  |  |             |                        |  |  |               |                   |  |  |       |       |        |  |  |            |      |     |     |   |       |   |                               |  |  |  |  |      |  |       |       |      |       |      |        |    |         |  |  |  |  |      |  |
| Item/Each:  | 0.09        | 1.9   | 1.9   | 4  | 14.44         | 1  |  |   |  |   |  |  |             |                        |  |  |               |                   |  |  |       |       |        |  |  |            |      |     |     |   |       |   |                               |  |  |  |  |      |  |       |       |      |       |      |        |    |         |  |  |  |  |      |  |
| Box/Carton/Bundle/Inner Pack:   |             |   |       |  | 0.00          |  |  |   |  |   |  |  |             |                        |  |  |               |                   |  |  |       |       |        |  |  |            |      |     |     |   |       |   |                               |  |  |  |  |      |  |       |       |      |       |      |        |    |         |  |  |  |  |      |  |
| Case:   | 15.11       | 16.5  | 12.25 | 4.75   | 960.09        | 48   |  |   |  |   |  |  |             |                        |  |  |               |                   |  |  |       |       |        |  |  |            |      |     |     |   |       |   |                               |  |  |  |  |      |  |       |       |      |       |      |        |    |         |  |  |  |  |      |  |
| Pallet:   |             |   |       |  | 0.00          |  |  |   |  |   |  |  |             |                        |  |  |               |                   |  |  |       |       |        |  |  |            |      |     |     |   |       |   |                               |  |  |  |  |      |  |       |       |      |       |      |        |    |         |  |  |  |  |      |  |
| GTIN AND HIBCC PRODUCT INFORMATION  |             |   |       | COST INFORMATION   |               |  |  |   |  |   |  |  |             |                        |  |  |               |                   |  |  |       |       |        |  |  |            |      |     |     |   |       |   |                               |  |  |  |  |      |  |       |       |      |       |      |        |    |         |  |  |  |  |      |  |
| <b>Saleable Unit of Measure</b><br><input checked="" type="checkbox"/> Item/Each<br><input type="checkbox"/> Box/Carton/Bundle/Inner Pack<br><input checked="" type="checkbox"/> Case<br><input type="checkbox"/> Pallet  |             | <b>Saleable Quantity</b><br><input type="text" value="1"/><br><input type="text" value="48"/>   |       | <b>HIBCC</b><br><input type="text"/><br><input type="text"/><br><input type="text"/>   |               | <b>GTIN-14</b><br><input type="text" value="00359746334307"/><br><input type="text" value="40359746334305"/>   |  | <b>Unit of Use GTIN-14</b><br><input type="text"/>  |  | <b>Regular Cost</b> <input type="text"/><br><b>Invoice Cost (WAC) (\$)</b> <input type="text" value="\$5.69"/><br><b>As of date:</b> <input type="text"/> |  |  |             |                        |  |  |               |                   |  |  |       |       |        |  |  |            |      |     |     |   |       |   |                               |  |  |  |  |      |  |       |       |      |       |      |        |    |         |  |  |  |  |      |  |
|   |             |   |       | WHOLESALE USE ONLY:  |               |  |  |   |  |   |  |  |             |                        |  |  |               |                   |  |  |       |       |        |  |  |            |      |     |     |   |       |   |                               |  |  |  |  |      |  |       |       |      |       |      |        |    |         |  |  |  |  |      |  |
|   |             |   |       | <b>Vendor #:</b> <input type="text"/><br><b>Whsl. Code #:</b> <input type="text"/><br><b>Fineline Code:</b> <input type="text"/>   |               |  |  |   |  |   |  |  |             |                        |  |  |               |                   |  |  |       |       |        |  |  |            |      |     |     |   |       |   |                               |  |  |  |  |      |  |       |       |      |       |      |        |    |         |  |  |  |  |      |  |

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:



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

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)  No

- 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)  No

- 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:  No

- 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

### 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
- 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:



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

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  |
|---|--|
| <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><b>Purchase order daily receipt cut off time by supplier</b></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><b>Overnight receipt available:</b> <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><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <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   |
| <p><input type="text"/></p>   | <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>  |