



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Final VersionDate:

PRODUCT INFORMATION	
Company Name:	Jubilant Cadista Pharmaceuticals Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	212902
DUNS:	022490515
Proprietary Name (If Applicable) and Established Name:	Hydroxychloroquine Sulfate 200mg Tablets
Selling Unit NDC:	59746-0780-05
Individual Unit NDC:	
UPC:	003-59746-780-05-0
CVX Code:	
MVX Code:	
Description:	Hydroxychloroquine Sulfate 200mg 500ct Tablets
Active Ingredient(s):	Hydroxychloroquine Sulfate
URL for Additional Product Information:	www.cadista.com
Address:	207 Kiley Drive
City:	Salisbury
Key Contact:	Jackie Emershaw
Phone Number:	(410) 912 - 3722
Product Therapeutic Classification:	Antiviral, Lupus treatment

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)	
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 Support
Number:	(800) 313 - 4623
Group E-mail:	
c. Special regulations for product in any states?	No
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):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	<input type="text" value="Yes"/>
reverse numbered?	<input type="text" value="No"/>
co-licensed?	<input type="text" value="No"/>
Is the Product... Direct-Ship Only	<input type="text" value="Direct-Ship Only"/>
Is the Product...	<input type="text" value=""/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text" value=""/>
If Unit Dose NDC, indicate NDC here:	<input type="text" value=""/>
Country of Origin	<input type="text" value=""/>
Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	500ct
Strength:	200mg
Dosage Form:	TAB
Product Shape:	film coated tablet
Product Color:	White to Off-White
Product Imprint:	A19' in black ink

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Case of 15 Bottles
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<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 Powder Multi	
<input type="checkbox"/> Other: Write In	
	Minimum order quantity? <input type="text" value="Yes"/>
	If Yes, how many of which package type?
	<input type="text" value="15"/> Each
	<input type="text" value=""/>
	<input type="text" value=""/>
	<input type="text" value=""/>

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

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value=""/>	<input type="text" value=""/>
(Write-in, e.g. 1 Vial)	Each
	Gram
	Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
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:	<input type="text" value=""/>
Other exemption - Write in:	<input type="text" value=""/>
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"/>
GLN:	<input type="text" value="8902805000006"/>
If Yes, was original product purchased direct from mfr?	<input type="text" value=""/>
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.48	2.62	4.75	2.62	32.61	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	8.69	12.36	7.56	11.54	1077.95	15
Pallet:					0	
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION												
Serialized?	If not, when?	Items aggregated?	Level	Saleable Unit	Quantity	GTIN-14	2D			Linear		
							X			X		
<input checked="" type="checkbox"/>	<input type="text" value=""/>	<input type="text" value=""/>	Item		1	00359746780050	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>		
			Box/Carton/Bundle/Inner Pack									
			Case		15	40359746780058	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>		
			Pallet									

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$258.88	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

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? No
 (If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT or IATA? No
 (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

SDS Hazard Classification	
<input type="checkbox"/> Organic <input type="checkbox"/> Inorganic <input type="checkbox"/> Steroid/Androgen <input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 50%;" type="text"/>	<input type="checkbox"/> Corrosive <input type="checkbox"/> Oxidizer <input type="checkbox"/> Contact Hazard Is the product a NIOSH hazardous drug? No If yes, indicate which: <input style="width: 100%;" type="text"/>

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#

Hazardous Waste Identification	
EPA Hazardous Waste Code:	<input style="width: 100%;" type="text"/>

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? <input style="width: 50%;" type="text"/> Website URL: <input style="width: 100%;" type="text"/> Comments / Details: (For example, iPledge program?) <input style="width: 100%; height: 20px;" type="text"/>	
REMS: No REMS Program Manager Name: <input style="width: 50%;" type="text"/> Phone: <input style="width: 20%;" type="text"/> Supplier Manages REMS registry exclusively: <input style="width: 50%;" type="text"/> Wholesale distributor support: Provider Name: <input style="width: 50%;" type="text"/> Site Enrollment Number assigned by Supplier: <input style="width: 50%;" type="text"/>	DEA #: <input style="width: 50%;" type="text"/> PCPDP #: <input style="width: 50%;" type="text"/> NPI #: <input style="width: 50%;" type="text"/>
Comments <input style="width: 100%; height: 20px;" type="text"/>	
Registry: Registry Program Contact Name: <input style="width: 50%;" type="text"/> Phone: <input style="width: 20%;" type="text"/> Comments <input style="width: 100%; height: 20px;" type="text"/>	

ADD'L STORAGE INFORMATION	
Is the Product... Controlled Substance? No Controlled by State(s)? No ARCOS Reportable? No Schedule No. (inc. N for non-narcotic) <input style="width: 100%;" type="text"/> Controlled Substance Code <input style="width: 100%;" type="text"/> Listed Chemical (List I or II) <input style="width: 100%;" type="text"/> If yes, indicate which: <input style="width: 100%;" type="text"/> Is it a scheduled listed chemical product?: <input style="width: 100%;" type="text"/>	

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?

CLASS OF TRADE RESTRICTION:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	
Restricted to retail pharmacy only: No	
Restricted to hospital, clinics, and physician offices only: No	
Restricted from US territories? (explain in comments) No	
Comments: <input style="width: 100%; height: 40px;" type="text"/>	

MISCELLANEOUS NOTES and/or Image of Product Barcode:	
<input style="width: 100%; height: 100%;" type="text"/>	



Standard Pharmaceutical Product Information (Page 3)

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"/> Yes</p> <p>b. Autofax <input type="checkbox"/> Yes Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Yes Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></p> <p>Minimum Order Quantity: <input type="text" value="15"/></p> <p>Supplier's Customer Service Number: <input type="text" value="(410) 912 - 3722"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <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>
Class of Trade Restriction:	Saturday Overnight receipt available:
<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>	<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"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></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>