



Introduction Type:

Final Version

Date: 12/19/2024

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
	No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
	No
e. Shelf life:	
Initial shelf life at launch (if different):	24
	Months
	Months

PRODUCT DESCRIPTION INFORMATION

Is the product is?		No	Is the Product... Is the Product... Orphan Drug Status	Direct-Ship Only Neither		Size:	100 count
a legend device?						Strength:	200mg
if yes, enter class #			FDA Approval Status			Dosage Form:	TABLET
a product kit?		No	Allergens Present			Product Shape:	Round, Biconvex
if yes, list NDCs of component parts						Product Color:	Peach
reverse numbered?		No	Country of Origin	India		Product Imprint:	'CR 200'
co-licensed?		No					
latex-free?		Yes					
preservative-free?		No					
correctional institution block?		Yes					
opioid?		No					
Cannabinoid?		No					
If Unit Dose, is item bar coded to unit dose for hospital scanning?			Is this product covered under the Trade Agreements Act (TAA)?	No			
If Unit Dose, indicate NDC here:							

ORDER INFORMATION

Unit of Sale		What is the NDC selling unit?
<input checked="" type="checkbox"/> X	Bottle	1 Bottle of 100 tablets
<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 Power 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="24"/>	Each
<input type="text" value=""/>	Inner/Cartron/Pack
<input type="text" value=""/>	Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?	Rx billing unit to pharmacy:
1 Bottle of 100 tablets	X Each
(Write-in, e.g. 1 Vial)	Gram
HCP's J-Code:	Milliliter

ITEM AND PACKING INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes	GLN:	0359746000004
Is product exempt from DSCSA?	No	GCP:	0359746
If yes, select exemption:		If yes, was original product purchased direct from mfr?	
Other exemption - Write in:		Provide source manufacturer for repackaged product	
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.			

	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable Pieces
		Depth	Width	Height		
Item/Each:	0.11	1.56	1.56	2.94	7.1609421	1
Box/Carton/Bundle/ Inner Pack:					0	
Case:	1.84	11.02	7.56	5.12	426.55334	24
Pallet:					0	

COST INFORMATION

[illegible]**WHOLESALE USE ONLY:**

Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$80.00	Whsl. Code #:	
As of date:		Fineline Code:	

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

See new p. 3 for Designated Drop Ship Only.

Signature:



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

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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?	<input type="checkbox"/>	No	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	<input type="checkbox"/>	No	
Is the product a CA Prop 65 carcinogen?	<input type="checkbox"/>	No	
Is the product a CA Prop 65 reproductive toxicant?	<input type="checkbox"/>	No	
Does the product label bear a CA Prop 65 warning?	<input type="checkbox"/>	No	
c. Contact Hazard?	<input type="checkbox"/>	No	
d. Does this product require special clean-up instructions?	<input type="checkbox"/>	No	
(If yes, attach SDS with special instructions.)			
e. Does the product contain DEHP?	<input type="checkbox"/>	No	
Is this product regulated for shipment by DOT?		<input type="checkbox"/> 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?	<input type="checkbox"/>	No	
Is this product regulated for shipment by IATA?		<input type="checkbox"/> 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?	<input type="checkbox"/>	No	
Is the product restricted for air shipment? If so, indicate restriction:		<input type="checkbox"/> No	
<input type="checkbox"/> Passenger			
<input type="checkbox"/> Cargo			
<input type="checkbox"/> Passenger & Cargo			
Is this a reportable quantity?	<input type="checkbox"/> No		
RQ Threshold:			
Is this a marine pollutant?	<input type="checkbox"/> No		
Is this product shipped utilizing an authorized DOT exception or Special Permit?			
<input type="checkbox"/> No	(if yes, identify method below)		
<input type="checkbox"/> Limited Quantity			
<input type="checkbox"/> Consumer Commodity, ORM-D			
<input type="checkbox"/> Small Quantity (49 CFR 173.4)			
<input type="checkbox"/> Special Permit; DOT-SP			
<input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);			
SP#			
ADD'L STORAGE INFORMATION			
Is the Product...			
Controlled Substance?	<input type="checkbox"/> No	Controlled Substance Code	
Controlled by State(s)?	<input type="checkbox"/> No	Listed Chemical (List I or II)	<input type="checkbox"/> No
ARCOS Reportable?	<input type="checkbox"/> No	If yes, indicate which:	
Schedule No.		Is it a scheduled listed chemical product?:	<input type="checkbox"/> No
CLASS OF TRADE RESTRICTION:			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		<input type="checkbox"/> Yes	
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:			
SDS Hazard Classification			
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive		
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer		
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard		
Does the product have an Aerosol class? If yes, identify		<input type="checkbox"/> No	
NFPA Storage Level:			
NFPA Storage Level:			
Is the product a NIOSH hazardous drug?		<input type="checkbox"/> 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?		<input type="checkbox"/> No	
If Yes, is it managed with a pharmacy registry?		<input type="checkbox"/>	
Website URL:			
Med Guide Required		<input type="checkbox"/> No	
Limited Distribution Requirement		<input type="checkbox"/> 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:		<input type="checkbox"/>	
URL/Link to returns policy:			
Special regulations or returns requirements for this product in certain states?		<input type="checkbox"/>	
If so, which states? Other requirements? Comments?			
MISCELLANEOUS NOTES and/or Image of Product Barcode:			

Release DATE



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

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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="text"/></p> <p>b. Autofax <input type="text"/></p> <p>c. Fax <input type="text"/></p> <p>d. Phone only <input type="text"/></p> <p>e. Supplier Web Site only <input type="text"/></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="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></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="text"/></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="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></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="text"/></p> <p>Other fees apply: <input type="text"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></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="text"/></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="text"/></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="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>