

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

Version 2021						Introduction T	Type: New	/ Item		X Final Version			Date:	6/13	/2022
			PRODUCT I	NFORMATION						SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Jubilant Cadista Pharmaceuticals Inc.					Applicat	Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 215483 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)															
Medical Device Class, if applicable:															
DUNS:	022490515									Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ame: [	Doxepin HCI Capsules			1150	0 50740 700 04 4			(write in)					
Selling Unit NDC: UDI	59746-703-01		CVX C	Jse NDC:		UPC: MVX Code:	3-59746-703-01-1			Notes					
				bde:		WVX Code.			1						1
								Is this product to be shippe				No No			
Active Ingredient(s):		Doxepin Hydr	ochloride							Is this product to be shippe		ily ice?		INU	
b. Contact for temperature excursion questions:															
URL for Additional Product Inform	nation:	www.cadist	a.com/products/ful	-product-list						Name:		Customer S	ervice		
Address:	207 Kiley Drive				_	Address 2:				Number:		(800) 313-4			
City:	Salisbury					MD	Zip: 21801		Group E-mail: <u>customer.service@cadista.com</u>						
Key Contact:	Jackie Emershaw (410) 912-3722					Jackie.Emersha (215) - 443 - 9646			c. Special regulations for product in any states? No					1	
Phone Number: Product Therapeutic Classification		Antidepressants			(213) - 443 - 3040			c. Special regulations for product in any states? Special returns requirements for this product?				No			
Froduct merapeutic classification		Antidepressa	11.5							Special returns requirement	is for this product?			INU	
	ADDITI	ONAL PRODU	CT INFORMATION			PRODUCT	DESCRIPTION INFOR	RMATION	d. Store prod	uct (unit of sale) upright?				No	1
The product is?			Is the Produc	Direct-Ship	Only					Protect product (unit of sa	ale) from light?			No	1
a legend device?		No	Is the Produc				100 count		e. Shelf life:	i roteet product (unit of s	ic) nom ngnt.			24	Months
if yes, enter class #		110	Orphan Drug			Size:				Initial shelf life at launch (	if different):				Months
a product kit?		No				Strength:	75mg								4
if yes, list NDCs of			FDA Approva	Status		onongan					ORDER INFORM	IATION			
component parts reverse numbered?		No				Dosage Form	m: CAPSULE			Unit of Sale		What is the	NDC selling		
co-licensed?		No No	Allergens Pre	cont						X Bottle		1 Case of 2	-	unit?	
latex-free?		Yes	Allergens Fre	sem			Gelatin capsu	ule, size 2		Box/Carton			.g. 1 Box of 1	0 Vials)	
preservative-free?		No				Product Sha	ipe:			Ampule		( , .	5	,	
correctional institution block?		Yes				Product Cold	Green opaque	e		Glass		Minimum o	rder quantity	?	Yes
opioid?		No				i ioduci ook				Tube					
Cannabinoid?	with all a set of a set	No	Country of Ori	gin US		Product Imp	rint: C 703			Vial Liquid Sgl		K Vaa haw	many of whi	ah naakana	4
If Unit Dose, is item bar coded to u hospital scanning?	Init dose for		Is this product	covered under the						Vial Liquid Multi Vial Powder Sql		24	Each	ich package	type?
If Unit Dose, indicate NDC here:				ents Act (TAA)?	Yes					Vial Power Multi			Inner/Cartor	/Pack	
					<u> </u>					Other: Write In			Case		
			FOR GENERIC	RUG PRODUCTS		•									
									<b></b>			_			
					A	uthorized Generic	*If Authorized Generi			PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB	1					section fields are not	t applicable		to customer?	-		nit to pharm	acy:	
II. Generic Equivalent to What Bra	nd?:	Sinequan®								ottles of 100 tablets		X	Each		
			UPPLY CHAIN SECUR	TY ACT (DSCSA) INFO	RMATION				(Write-in, e.g.	1 Vial)			Gram Milliliter		
		DROGG							-						
Does supplier meet DSCSA definit	tion of manufactu	rer?	Yes		GLN:	0359746000004				ITEN	I AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:	0359746			1	Market Land	Dimensi	ons (US msr	nts.)	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			original product			Item/Each:	0.1	2	2	4	16.00	1
Is product sold by manufacturer's			No No			lirect from mfr?			D						
Has FDA granted waiver/exception If yes, attach documentation from		roduct?	INU		Provide sou	rce manufacturer to	or repackaged produc	Ct	Box/Carton/B Inner Pack:	sundie/				0.00	
n yes, attach documentation nor	in DA.								Case:		10.75				
			GTIN AND HIBCC PR	ODUCT INFORMATIO	N					4.64	10.75	7.25	4	311.75	24
									Pallet:					0.00	
Saleable Unit of Measure	S	Saleable Quantit	y HIBCC			IN-14	Unit of Use (	GTIN-14							
X Item/Each Box/Carton/Bundle/Inner Pack		1			003	359746703011				COST INFORMATION				ER USE ONL	<b>v</b> .
X Case		24			403	359746703019	-			COST IN ORMATION			WHOLEGAL		
Pallet		27							Regular Cost			Vendor #:			
			-						Invoice Cost	(WAC) (\$)	\$73.60	Whsl. Code	#:		
												Fineline Co	de:		
	-				_		-		As of date:						
<u> </u>			Attach conv of S		(DS) or pop bor		INSERT LAREL AND			AGING and BARCODE.		I			
*Please provide any additional inf	ormation on page	2	Allach copy of SA	CITUAIA SHEET (S	i non naza (פיטו		Designated Drop Sh		NODUCI PACK	Signature:					
i icase provide any additional init	ormation on page	<b>-</b> -				000 new p. 3 101	Designated biop Sil	np only.		oignature.					

## **HDA** 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? 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.) e. Does the product contain DEHP? No (If yes, answer a-e below and provide SDS) a. UN/Identification Number	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:       No						
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated for shipment by 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 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 Pervision (listed in Column 7 of 49 CFR 172.101); SP#	Med Guide Required     No       Limited Distribution Requirement     No       Comments / Details: (For example, iPledge program?)     No       REMS:     Phone:       REMS Program Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     DEA #:       Provider Name:     DEA #:       Site Enrollment Number assigned     NCPDP#:       by Supplier:     NPI #:						
ADD'L STORAGE INFORMATION Is the Product Controlled Substance? No Controlled Substance Code	Comments RETURN INSTRUCTIONS						
Controlled by State(s)?       No       Listed Chemical (List I or II)       No         ARCOS Reportable?       No       If yes, indicate which:       If yes, indicate which:       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         Restricted to retail pharmacy only:       Restricted to hospital, clinics, and physician offices only:         Restricted from US territories? (explain in comments)       Comments:	URL/Link to returns policy:						
MISCELLA	NEOUS 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
Purchase orders may be accepted by:         a. EDI         b. Autofax         c. Fax         d. Phone only         e. Supplier Web Site only         Minimum Order Quantity:         Supplier's Customer Service Number:         Contracted 3PL company / contact #:         Name:         Phone:	Purchase order daily receipt cut off time by supplier         Cut off time:         Shipping lead time of PO:       Hours         Days         Ships same day for next day receipt:         Ships for second day receipt:         Ships regular ground for 3-10 days receipt:
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:         PO Receipt cut off time:         Days of week overnight is available:         Monday         Tuesday         Wednesday         Thursday         Friday
Class of Trade Restriction:	Priority Overnight receipt available: PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	Saturday Overnight receipt available:       PO Receipt Cut off time:         Order receipt method:       Phone:         Fax:       EDI:         Overnight Fees apply:       Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	Contact # if product is 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:	
	ADDITIONAL INFORMATION  Is product order for scheduled patient procedure? Is product order for restocking purposes?