



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

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Version 2021 Introduction Type:  New Item  Final Version Date:

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: <input type="text" value="Novadoz Pharmaceuticals, LLC"/>		Application: <input type="text" value="ANDA"/>		a. Temperature – Indicate the USP temperature range for this product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="213879"/>				Temperature Range <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>			
Medical Device Class, if applicable: <input type="text"/>				Other Temperature Range Requirement (write in) <input type="text"/>			
DUNS: <input type="text" value="081109687"/>				Notes <input type="text"/>			
Proprietary Name (If Applicable) and Established Name: <input type="text" value="Dabigatran Etexilate Capsules 150 mg 60's"/>				Is this product to be shipped to customers on ice? <input type="text" value="No"/>			
Selling Unit NDC: <input type="text" value="72205-204-60"/>		Unit of Use NDC: <input type="text"/>		UPC: <input type="text" value="372205204607"/>		Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>	
UDI <input type="text"/>		CVX Code: <input type="text"/>		MVX Code: <input type="text"/>			
Description: <input type="text" value="White to light yellow colored blend compressing granular powder, pellets in size '0' Capsule having White Opaque cap imprinted 'MD' and White Opaque body imprinted '150' with black ink."/>				b. Contact for temperature excursion questions:			
Active Ingredient(s): <input type="text"/>				Name: <input type="text"/>			
URL for Additional Product Information: <input type="text"/>				Number: <input type="text"/>			
Address: <input type="text" value="20 Duke Road"/>		Address 2: <input type="text" value="Suite A"/>		Group E-mail: <input type="text"/>			
City: <input type="text" value="Piscataway"/>		State: <input type="text" value="NJ"/>					
Key Contact: <input type="text"/>		Email: <input type="text" value="sales@novadozpharma.com"/>					
Phone Number: <input type="text" value="908-360-1500"/>		Fax: <input type="text" value="732-902-2113"/>					
Product Therapeutic Classification: <input type="text"/>				c. Special regulations for product in any states?			
				Special returns requirements for this product? <input type="text"/>			
				d. Store product (unit of sale) upright? <input type="text"/>			
				Protect product (unit of sale) from light? <input type="text"/>			
				e. Shelf life: <input type="text"/>			
				Initial shelf life at launch (if different): <input type="text" value="36"/> Months			
				<input type="text" value="36"/> Months			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is? a legend device? <input type="text" value="No"/>		Is the Product... Is the Product... <input type="text" value="Direct-Ship Only"/>		Size: <input type="text" value="60's"/>			
if yes, enter class # a product kit? <input type="text" value="No"/>		Orphan Drug Status <input type="text" value="Neither"/>		Strength: <input type="text" value="150 mg"/>			
if yes, list NDCs of component parts reverse numbered? <input type="text"/>		FDA Approval Status <input type="text"/>		Dosage Form: <input type="text" value="Capsules"/>			
co-licensed? latex-free? <input type="text" value="Yes"/>		Allergens Present <input type="text"/>		Product Shape: <input type="text" value="Capsule shaped"/>			
preservative-free? correctional institution block? opioid? Cannabinoid? <input type="text"/>		Country of Origin <input type="text"/>		Product Color: <input type="text" value="White to light Yellow"/>			
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/>		Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/>		Product Imprint: <input type="text" value="White Opaque Cap&lt;br/&gt;Imprinted 'MD' and White&lt;br/&gt;Opaque body imprinted&lt;br/&gt;'150' with black ink"/>			
If Unit Dose, indicate NDC here: <input type="text" value="72205-204-60"/>							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: <input type="text" value="AB"/>		<input type="checkbox"/> Authorized Generic		*If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: <input type="text" value="Pradaxa"/>							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/>		GLN: <input type="text" value="8904159670843"/>					
Is product exempt from DSCSA? <input type="text" value="No"/>		GCP: <input type="text" value="89041596"/>					
If yes, select exemption: Other exemption - Write in: <input type="text"/>		If yes, was original product purchased direct from mfr? <input type="text"/>		Provide source manufacturer for repackaged product <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? If yes, attach documentation from FDA. <input type="text"/>							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		Saleable Quantity		HIBCC		GTIN-14	
Yes Item/Each <input type="text" value="1"/>						Unit of Use GTIN-14 <input type="text" value="00372205204607"/>	
Yes Box/ Carton/ Bundle/ Inner Pack <input type="text" value="48"/>						<input type="text" value="30372205204608"/>	
Yes Case <input type="text" value="1440"/>						<input type="text" value="50372205204602"/>	
Yes Pallet <input type="text"/>							
ORDER INFORMATION				PHARMACY ORDER / BILL UNIT			
Unit of Sale		What is the NDC selling unit?		Rec. sell unit to customer? <input type="text" value="1 bottle of 60ct"/>			
<input checked="" type="checkbox"/> Bottle		<input type="text" value="72205-204-60"/>		Rx billing unit to pharmacy:			
<input type="checkbox"/> Box/ Carton		(Write-in, e.g. 1 Box of 10 Vials)		<input checked="" type="checkbox"/> Each			
<input type="checkbox"/> Ampule				<input type="checkbox"/> Gram			
<input type="checkbox"/> Glass				<input type="checkbox"/> Milliliter			
<input type="checkbox"/> Tube				Minimum order quantity? <input type="text" value="Yes"/>			
<input type="checkbox"/> Vial Liquid Sgl							
<input type="checkbox"/> Vial Liquid Multi				If Yes, how many of which package type?			
<input type="checkbox"/> Vial Powder Sgl				<input type="text" value="48"/> Each			
<input type="checkbox"/> Vial Powder Multi				<input type="text"/>			
<input type="checkbox"/> Other: Write In				<input type="text"/>			
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	
		Depth	Width	Height			
Item/Each:	0.249	2.28	2.28	4.72	24.54	1	
Box/ Carton/ Bundle/ Inner Pack:	NA	NA	NA	NA	NA	NA	
Case:	13.58	14.96	10.43	10.83	1689.84	48	
Pallet:	447.22	47.24	39.37	38.38	71380.61	1,440	
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost <input type="text"/>		Invoice Cost (WAC) (\$) <input type="text" value="\$150.00"/>		Vendor #: <input type="text"/>		Whsl. Code #: <input type="text"/>	
As of date: <input type="text" value="6/14/2024"/>				Fineline Code: <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:



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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)  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      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:  No

Restricted to hospital, clinics, and physician offices only:  No

Restricted from US territories? (explain in comments)  No

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 NFPA Storage Level:  No

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:**  No

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:**  No

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?  No

If so, which states? Other requirements? Comments?

### MISCELLANEOUS NOTES and/or Image of Product Barcode:



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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> <ul style="list-style-type: none"> <li>a. EDI <input type="checkbox"/></li> <li>b. Autofax <input type="checkbox"/></li> <li>c. Fax <input type="checkbox"/></li> <li>d. Phone only <input type="checkbox"/></li> <li>e. Supplier Web Site only <input type="checkbox"/></li> </ul> <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: <input type="text"/></p> <p>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>