



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

Version 2024		Introduction Type: <input type="text" value="New Item"/>		<input type="text" value="Final Version"/>		Date: <input type="text" value="8/28/2025"/>																																																																																							
PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																																																																							
<div>Company Name: <input type="text" value="Novadoz Pharmaceuticals LLC"/> Application: <input type="text" value="ANDA"/> Application Number for NDA/ANDA/BLA; PMA/510(k): <input type="text" value="214817"/> NDA 505(b) Type: <input type="text"/> Medical Device Class, if applicable: <input type="text"/> DUNS: <input type="text" value="081109687"/> Proprietary Name (If Applicable) and Established Name: <input type="text" value="Rufinamide Oral Suspension 40 mg/mL"/> Selling Unit NDC: <input type="text" value="72205-038-77"/> Unit of Use NDC: <input type="text"/> UPC: <input type="text" value="372205038776"/> UDI <input type="text"/> CVX Code: <input type="text"/> MVX Code: <input type="text"/> Description: <input type="text"/> Active Ingredient(s): <input type="text" value="Rufinamide USP"/> URL for Additional Product Information: <input type="text"/> Address: <input type="text" value="20 Duke Road"/> City: <input type="text" value="Piscataway"/> State: <input type="text" value="NJ"/> Address 2: <input type="text"/> Key Contact: <input type="text"/> Zip: <input type="text" value="08854"/> Phone Number: <input type="text" value="908-360-1500"/> Email: <input type="text" value="sales@novadozpharma.com"/> Product Therapeutic Classification: <input type="text"/> Fax: <input type="text"/></div>						<div>a. Temperature – Indicate the USP temperature range for this product. Temperature Range <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/> Other Temperature Range Requirement (write in) <input type="text"/> Notes <input type="text"/> Is this product to be shipped to customers on ice? <input type="text" value="No"/> Is this product to be shipped to customers on dry ice? <input type="text" value="No"/> b. Contact for temperature excursion questions: Name: <input type="text"/> Number: <input type="text"/> Group E-mail: <input type="text"/> c. Special regulations for product in any states? Special returns requirements for this product? <input type="text" value="No"/> d. Store product (unit of sale) upright? <input type="text"/> Protect product (unit of sale) from light? <input type="text"/> e. Shelf life: Initial shelf life at launch (if different): <input type="text" value="24"/> Months</div>																																																																																							
ADDITIONAL PRODUCT INFORMATION			PRODUCT DESCRIPTION INFORMATION																																																																																										
<div>The product is? a legend device? <input type="text" value="No"/> if yes, enter class # <input type="text"/> a product kit? <input type="text" value="No"/> if yes, list NDCs of component parts reverse numbered? <input type="text"/> co-licensed? <input type="text" value="No"/> latex-free? <input type="text" value="Yes"/> preservative-free? <input type="text" value="No"/> correctional institution block? <input type="text" value="No"/> opioid? <input type="text" value="No"/> Cannabinoid? <input type="text" value="No"/> If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/> If Unit Dose, indicate NDC here: <input type="text" value="72205-038-77"/></div>			<div>Is the Product... <input type="text"/> Is the Product... <input type="text"/> Orphan Drug Status <input type="text"/> FDA Approval Status <input type="text"/> Allergens Present <input type="text" value="No"/> Country of Origin <input type="text" value="USA"/> Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="Yes"/></div>			<div>Size: <input type="text" value="460 mL"/> Strength: <input type="text" value="40 mg/mL"/> Dosage Form: <input type="text" value="Oral Suspension"/> Product Shape: <input type="text" value="Oral Suspension"/> Product Color: <input type="text" value="White to off white"/> Product Imprint: <input type="text" value="NA"/></div>																																																																																							
FOR GENERIC DRUG PRODUCTS						ORDER INFORMATION																																																																																							
<div>I. Orange Book Rating: <input type="text" value="AB"/> Authorized Generic <input type="text"/> *If Authorized Generic, other section fields are not applicable II. Generic Equivalent to What Brand?: <input type="text" value="BANZEL"/></div>						<div>Unit of Sale <table border="1"><tr><td><input checked="" type="checkbox"/></td><td>Box/ Carton</td></tr><tr><td><input type="checkbox"/></td><td>Ampule</td></tr><tr><td><input type="checkbox"/></td><td>Glass</td></tr><tr><td><input type="checkbox"/></td><td>Tube</td></tr><tr><td><input type="checkbox"/></td><td>Vial Liquid Sgl</td></tr><tr><td><input type="checkbox"/></td><td>Vial Liquid Multi</td></tr><tr><td><input type="checkbox"/></td><td>Vial Powder Sgl</td></tr><tr><td><input type="checkbox"/></td><td>Vial Powder Multi</td></tr><tr><td><input type="checkbox"/></td><td>Other: Write In</td></tr></table></div> <div>What is the NDC selling unit? <input type="text" value="1 carton of 1 bottle"/> (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="text" value="Yes"/> If Yes, how many of which package type? <table border="1"><tr><td><input type="text" value="12"/></td><td>Each</td></tr><tr><td><input type="text"/></td><td>Inner/ Carton/ Pack</td></tr><tr><td><input type="text"/></td><td>Case</td></tr></table></div>		<input checked="" type="checkbox"/>	Box/ Carton	<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	<input type="text" value="12"/>	Each	<input type="text"/>	Inner/ Carton/ Pack	<input type="text"/>	Case																																																														
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DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						PHARMACY ORDER / BILL UNIT																																																																																							
<div>Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/> GLN: <input type="text" value="0382374000016"/> Is product exempt from DSCSA? <input type="text" value="No"/> If yes, select exemption: Other exemption - Write in: <input type="text"/> Is product repackaged? <input type="text" value="No"/> GCP: <input type="text" value="0382374"/> Is product sold by manufacturer's exclusive distributor? <input type="text" value="No"/> Has FDA granted waiver/exception/exemption for product? <input type="text"/> If yes, attach documentation from FDA. <input type="text"/> If yes, was original product purchased direct from mfr? <input type="text"/> Provide source manufacturer for repackaged product <input type="text"/></div>						<div>Rec. sell unit to customer? <input type="text"/> (Write-in, e.g. 1 Vial) HCPCS J-Code: <input type="text"/> Rx billing unit to pharmacy: <table border="1"><tr><td><input checked="" type="checkbox"/></td><td>Each</td></tr><tr><td><input type="checkbox"/></td><td>Gram</td></tr><tr><td><input type="checkbox"/></td><td>Milliliter</td></tr></table></div>		<input checked="" type="checkbox"/>	Each	<input type="checkbox"/>	Gram	<input type="checkbox"/>	Milliliter																																																																																
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<div>Regular Cost <input type="text"/> Invoice Cost (WAC) (\$) <input type="text" value="\$100.00"/> As of date: <input type="text" value="8/28/2025"/></div>						<div>Vendor #: <input type="text"/> Whsl. Code #: <input type="text"/> Fineline Code: <input type="text"/></div>																																																																																							
<div>*Please provide any additional information on page 2. 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: <input type="text"/></div>																																																																																													



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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?

Yes

(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP?

No

Is this product regulated for shipment by DOT?

(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?

Is this product regulated for shipment by IATA?

(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?

Is the product restricted for air shipment? If so, indicate restriction:

☐ Passenger

☐ Cargo

☐ Passenger & Cargo

Is this a reportable quantity?

RQ Threshold:

Is this a marine pollutant?

Is this product shipped utilizing an authorized DOT exception or Special Permit?

(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)?

Listed Chemical (List I or II)

ARCOS Reportable?

If yes, indicate which:

Schedule No.

Is it a scheduled listed chemical product?:

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:

SDS Hazard Classification

☒ Y

Organic

☐ Inorganic

☐ Steroid/Androgen

☐ Corrosive

☐ Oxidizer

☐ Contact Hazard

Does the product have an Aerosol class? If yes, identify

NFPA Storage Level:

NFPA Storage Level:

Is the product a NIOSH hazardous drug?

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

Limited Distribution Requirement

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

NCPDP#:

by Supplier:

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:

Release DATE



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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>