



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

Version 2021 Introduction Type: New Item Final Version Date:

PRODUCT INFORMATION	
Company Name:	<input type="text" value="Novadoz Pharmaceuticals LLC"/>
Application:	<input type="text" value="ANDA"/>
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	<input type="text" value="217521"/>
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="Phenylephrine Hydrochloride Injection, USP 10 mg/mL"/>
Selling Unit NDC:	<input type="text" value="72205-264-25"/>
Unit of Use NDC:	<input type="text"/>
UDI	<input type="text"/>
CVX Code:	<input type="text"/>
UPC:	<input type="text" value="372205264250"/>
MX Code:	<input type="text"/>
Description:	<input type="text" value="Clear colorless solution, free from visible particulate matter"/>
Active Ingredient(s):	<input type="text" value="Phenylephrine Hydrochloride"/>
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" value="Suite A"/>
Zip:	<input type="text" value="08854"/>
Key Contact:	<input type="text"/>
Phone Number:	<input type="text" value="908-360-1500"/>
Email:	<input type="text" value="sales@novadozpharma.com"/>
Fax:	<input type="text" value="732-902-2113"/>
Product Therapeutic Classification:	<input type="text" value="Alpha-1 Adrenergic receptor agonist"/>

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	<input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>
Temperature Range	<input type="text"/>
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:	<input type="text" value="T Ch Hanumantha Rao"/>
Name:	<input type="text"/>
Number:	<input type="text" value="040-3044 9212/9362"/>
Group E-mail:	<input type="text" value="chrao.t@msnllabs.com"/>
c. Special regulations for product in any states?	<input type="text" value="No"/>
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	<input type="text" value="Yes"/>
Protect product (unit of sale) from light?	<input type="text" value="Yes"/>
e. Shelf life:	<input type="text" value="24"/>
Initial shelf life at launch (if different):	<input type="text"/>
	Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?	<input type="text"/>	Is the Product...	<input type="text" value="Direct-Ship Only"/>
a legend device?	<input type="text"/>	Is the Product...	<input type="text" value="Neither"/>
if yes, enter class #	<input type="text"/>	Orphan Drug Status	<input type="text"/>
a product kit?	<input type="text"/>	FDA Approval Status	<input type="text"/>
if yes, list NDCs of component parts	<input type="text"/>	Allergens Present	<input type="text"/>
reverse numbered?	<input type="text"/>	Country of Origin	<input type="text"/>
co-licensed?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>
latex-free?	<input type="text" value="Yes"/>	Size:	<input type="text" value="1mL"/>
preservative-free?	<input type="text" value="Yes"/>	Strength:	<input type="text" value="10mg/mL"/>
correctional institution block?	<input type="text"/>	Dosage Form:	<input type="text" value="Solution"/>
opioid?	<input type="text" value="No"/>	Product Shape:	<input type="text" value="N/A"/>
Cannabinoid?	<input type="text" value="No"/>	Product Color:	<input type="text" value="Clear colorless solution"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>	Product Imprint:	<input type="text" value="N/A"/>
If Unit Dose, indicate NDC here:	<input type="text" value="72205-264-25"/>		

ORDER INFORMATION	
Unit of Sale	<input type="text" value="Bottle"/>
What is the NDC selling unit?	<input type="text" value="1 carton of 25 vials"/>
<input checked="" type="checkbox"/> Box/Carton	<input type="text" value="(Write-in, e.g. 1 Box of 10 Vials)"/>
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="text" value="Yes"/>
<input type="checkbox"/> Tube	
<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="2"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="text"/>
<input type="checkbox"/> Other: Write In	Inner/ Carton/ Pack
	Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AP2"/>
II. Generic Equivalent to What Brand?:	<input type="text"/>
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	<input type="text" value="1 vial"/>
Rx billing unit to pharmacy:	<input type="text"/>
<input type="checkbox"/> Each	
<input type="checkbox"/> Gram	
<input type="checkbox"/> 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"/>
Other exemption - Write in:	<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?	<input type="text" value="No"/>
If yes, attach documentation from FDA.	<input type="text"/>
GLN:	<input type="text" value="8904159670843"/>
GCP:	<input type="text" value="89041596"/>
If yes, was original product purchased direct from mfr?	<input type="text"/>
Provide source manufacturer for repackaged product	<input type="text"/>

Item/Each:	Weight Lbs.		Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
			Depth	Width	Height		
Item/Each:	0.445		3.54	3.54	2.16	27.06	1
Box/Carton/Bundle/Inner Pack:	1.22		7.48	3.74	2.36	66.02	2
Case:	15.66		12.4	9.05	11.02	1,236.66	24
Pallet:	791.44		47.24	39.37	38.97	72,477.91	1,152

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	<input type="text" value="1 Carton Pack"/>	<input type="text"/>	<input type="text" value="00372205264250"/>	<input type="text" value="00372205264250"/>
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="text" value="2 Cartons in Outer pack"/>	<input type="text"/>	<input type="text" value="20372205264254"/>	<input type="text"/>
<input checked="" type="checkbox"/> Case	<input type="text" value="24 Cartons in case"/>	<input type="text"/>	<input type="text" value="30372205264251"/>	<input type="text"/>
<input checked="" type="checkbox"/> Pallet	<input type="text" value="1,152 Cartons in pallet"/>	<input type="text"/>	<input type="text" value="50372205264255"/>	<input type="text"/>

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	<input type="text" value="\$30.00"/>	Whsl. Code #:	<input type="text"/>
As of date:	<input type="text" value="5/29/2024"/>	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)

- 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)

- 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 No
- Cargo No
- Passenger & Cargo No

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 Yes Controlled Substance Code
- Controlled by State(s)? No Yes Listed Chemical (List I or II) No Yes
- ARCOS Reportable? No Yes If yes, indicate which:
- Schedule No. Is it a scheduled listed chemical product?: No Yes

CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes No
- Restricted to retail pharmacy only: No Yes
- Restricted to hospital, clinics, and physician offices only: No Yes
- Restricted from US territories? (explain in comments) No Yes

Comments:

SDS Hazard Classification

- Organic Corrosive
- Inorganic Oxidizer
- Steroid/Androgen Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No

Is the product a NIOSH hazardous drug? If yes, indicate which: No

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No Yes
If Yes, is it managed with a pharmacy registry? No Yes
Website URL:

Med Guide Required No Yes
Limited Distribution Requirement No Yes
Comments / Details: (For example, iPledge program?)

REMS: No Yes
REMS Program Manager Name: Phone:
Supplier Manages REMS registry exclusively: No Yes
Wholesale distributor support: No Yes
Provider Name: DEA #:
Site Enrollment Number assigned by Supplier: NCPDP#:
NPI #:

Comments

Registry: No Yes
Registry Program Contact Name: Phone:
Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:
Is product returnable for credit: No Yes
URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states? No Yes
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"> a. EDI <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> 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="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> <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"/></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:	
<p><input type="text"/></p>	
	ADDITIONAL INFORMATION
	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>