



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

Version 2021

Introduction Type:

Final Version

Date:

### PRODUCT INFORMATION

Company Name:  Application:

Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):

DUNS:

Proprietary Name (If Applicable) and Established Name:

Selling Unit NDC:  Individual Unit NDC:

UDI  CVX Code:  UPC:

UVI  MVX Code:

Description:

Active Ingredient(s):

URL for Additional Product Information:

Address:   
  
City:  State:  Zip:   
Key Contact:  Email:   
Phone Number:  Fax:

Product Therapeutic Classification:

### SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

a. Temperature - Indicate the USP temperature range for this product.  
Temperature Range:   
Other Temperature Range Requirements (write in):   
Is this product to be shipped to customers on ice?   
Is this product to be shipped to customer on dry ice?

b. Contact for temperature excursion questions:  
Name:   
Number:   
Group Email:

c. Special regulations for product in any states?  
Special returns requirements for this product?

d. Store product (unit of sale) upright?  
Protect product (unit of sale) from light?

e. Shelf Life:  
Initial shelf life at launch (if different):  Months

### ADDITIONAL PRODUCT INFORMATION

The product is?  
a legend device?   
if yes, enter class #   
a product kit?   
if yes, list NDC's of component parts reverse numbered?   
co-licensed?   
latex-free?   
preservative-free?   
correctional institution block?   
opioid?   
Cannabinoid?   
If Unit Dose, is item bar coded to unit dose for hospital scanning?   
If Unit Dose NDC, indicate here:

Is the Product...   
Is the Product...   
Orphan Drug Status   
FDA Approval Status   
Allergens Present:   
Country of Origin   
Is this product covered under the Trade Agreements Act (TAA)

### PRODUCT DESCRIPTION INFORMATION

Size:   
Strength:   
Dosage Form:   
Product Shape:   
Product Color:   
Product Imprint:

### ORDER INFORMATION

Unit of Sale  Bottle  Box/Carton  Ampule  Glass  Tube  Vial Liquid Sgl  Vial Liquid Multi  Vial Powder Sgl  Vial Powder Multi  Other: Write In

What is the NDC selling unit?  
  
(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?

If Yes, how many of which package type?  
 Each  
 Inner/ Carton/Pack  
 Case

### FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating:   Authorized Generic \* If Authorized Generic, other section fields are not applicable

II. Generic equivalent to What Brand?:

### DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?   
Is product exempt from DSCSA?   
If yes, select exemption:   
Other exemption - Write in:

GLN:   
GCP:

Is product repackaged?   
If Yes, was original product purchased direct from mfg?

Is product sold by manufacturer's exclusive distributor?   
Has FDA granted waiver/exception/exemption for product?   
If Yes, attach documentation from FDA

### GTIN PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	GTIN-14
X Item	1		00303787295530	00303787295530
Box/Carton/Bundle/Inner Pack				
X Case	72		20303787295534	
Pallet				

### PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?   
Rx billing unit to pharmacy  Each  Gram  Milliliter

### ITEM AND PACKING INFORMATION

Item:	Dimensions (US msmts.)				Volume (Cube)	Saleable # Pieces:
	Weight Lbs.	Depth	Height	Width		
Box/Carton/Bundle / Inner Pack:	0.205	6.1	2.08	3.46	43.90048	1
Case:	17.536	19.09	14.56	13.18	3663.38627	72
Pallet:						

### COST INFORMATION

Regular Invoice Cost (WAC) (\$)   
As of date:

### WHOLESALE USE ONLY:

Vendor #:   
Whsl. Code #:   
Fineline Code:



# 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
- 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?
  - Does the product label bear a CA Prop 65 warning?
- c. Contact Hazard?
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP?

Is this product regulated for shipment by DOT or 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-S
- Special Provision (listed in Column 7 of 49 CFR 172.101);

SP#

### ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance?  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 hospitals, clinics, and physician offices only:
- Restricted from US territories? (explain in comments)
- 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:

NFPA Storage Level:

Is this product a NIOSH hazardous drug?   
If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code: N/A

Waste Characteristics:

### REMS or REGISTRY RESTRICTIONS

- Is there a REMS on this product?
- 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:
- Supplier Manages REMS registry exclusively
- Wholesale distributor support:
- Provider Name:
- Site Enrollment Number assigned by Supplier:
- Phone:
- DEA #:
- NCPDP#:
- 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:



# Standard Pharmaceutical Product Information (Page 3)

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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="checkbox"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone Only <input type="checkbox"/></p> <p>e. Supplier Web Site Only <input type="checkbox"/></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>
<p>Expedited Freight Charges or Other Designated Drop Ship Fees:</p> <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 and Priority Overnight PO Processing</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>Class of Trade Restriction:</p> <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 the comments) <input type="text"/></p> <p>Comments: <input type="text"/></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: <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="text"/></p> <p>Other fees apply: <input type="text"/></p>
<p>Other Data Information Required to Process PO:</p> <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>Return Instructions</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 return 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>
<p>Miscellaneous Notes: <input type="text"/></p>	<p>ADDITIONAL INFORMATION</p> <p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>