



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:  Final VersionDate: 

**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:  UPC:

UDI  CVX Code:  MVX Code:

Description:

Active Ingredient(s):

URL for Additional Product Information:

Address:  Address 2:

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 Requirement (write in)

Is this product to be shipped to customers on ice?

Is this product to be shipped to customers on dry ice?

b. Contact for temperature excursion questions:

Name:  Number:  Group E-mail:

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:  Months Initial shelf life at launch (if different):  Months

**ADDITIONAL PRODUCT INFORMATION**

Is the Product...  
 a legend device?   
 reverse numbered?   
 co-licensed?   
 Is the Product...   
 Is the Product...

If Unit Dose, is item bar coded to unit dose for hospital scanning?

If Unit Dose NDC, indicate NDC here:

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?

6	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?:

**PHARMACY ORDER / BILL UNIT**

Rec. sell unit to customer?  Rx billing unit to pharmacy:

(Write-in, e.g. 1 Vial)  Each  Gram  Milliliter

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

Does supplier meet DSCSA definition of manufacturer?  GLN:

Is product exempt from DSCSA?

If yes, select exemption:

Other exemption - Write in:

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

Is product sold by manufacturer's exclusive distributor?  If yes, attach documentation from FDA.

Has FDA granted waiver/exception/exemption for product?

**ITEM AND PACKING INFORMATION**

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/Carton/Bundle/Inner Pack:	1.29	3.39	6.77	3.39	77.801517	1
Case:	7.74	6.78	6.77	10.17	466.809102	6
Pallet:	46.44	21.26	15.55	11.02	3643.13486	36
UPC:					0	

**GTIN PRODUCT INFORMATION**

Serialized?	If not, when?	Items aggregated?	Level		Quantity	GTIN-14
			Saleable Unit	2D		
<input checked="" type="checkbox"/>	<input type="text" value="Yes"/>	<input type="text"/>	<input checked="" type="checkbox"/> Item	<input type="text" value="2D"/>	<input type="text" value="1"/>	00351224219601
<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="text" value="2D"/>	<input type="text" value="6"/>	30351224219602
<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/> Case	<input type="text" value="2D"/>	<input type="text" value="36"/>	50351224219606
			<input type="checkbox"/> Pallet	<input type="text" value="2D"/>		
			<input type="checkbox"/>	<input type="text" value="2D"/>		
			<input type="checkbox"/>	<input type="text" value="2D"/>		
			<input type="checkbox"/>	<input type="text" value="2D"/>		
			<input type="checkbox"/>	<input type="text" value="2D"/>		
			<input type="checkbox"/>	<input type="text" value="2D"/>		

**COST INFORMATION**

Regular Cost  Invoice Cost (WAC) (\$)  Federal Excise Tax Per Unit of Sale  As of date:

**WHOLESALE USE ONLY:**

Vendor #:  Whsl. Code #:  FineLine Code:

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? No  
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT or 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?  
 (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 by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic)

Controlled Substance Code

Listed Chemical (List I or II) No  
If yes, indicate which:

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

Organic  Corrosive

Inorganic  Oxidizer

Steroid/Androgen  Contact Hazard

Aerosol Class; Identify NFPA Storage Level:

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

### Hazardous Waste Identification

EPA Hazardous Waste Code:

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

**REMS:**

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:  
Provider Name:

Site Enrollment Number assigned by Supplier:  DEA #:

PCPDP #:

NPI #:

Comments

**Registry:**

Registry Program Contact Name:  Phone:

Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  855-225-8244

Is product returnable for credit? Yes

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states? Yes

If so, which states? Other requirements? Comments?  
 Georgia, Mississippi and North Carolina. Requests can be made via fax: (815) 624-0608 or email: [customerare@tagipharma.com](mailto:customerare@tagipharma.com)

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

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> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">a. EDI</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> <td style="width: 10%; text-align: center;">Yes</td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> </tr> <tr> <td>b. Autofax</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">Yes</td> <td>Fax Number:</td> <td colspan="2" style="border: 1px solid black;">(815) 624-0608</td> </tr> <tr> <td>c. Fax</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">Yes</td> <td>Fax Number:</td> <td colspan="2" style="border: 1px solid black;">(815) 624-0608</td> </tr> <tr> <td>d. Phone only</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">No</td> <td>Phone No.:</td> <td colspan="2" style="border: 1px solid black;">855-225-8244</td> </tr> <tr> <td>e. Supplier Web Site only</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">No</td> <td>Site Address:</td> <td colspan="2" style="border: 1px solid black;"></td> </tr> </table> <p>Minimum Order Quantity: <input style="width: 100px;" type="text" value="6 Bottles"/></p> <p>Supplier's Customer Service Number: <input style="width: 100px;" type="text" value="855-225-8244"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td style="border: 1px solid black;"></td> </tr> <tr> <td>Phone:</td> <td style="border: 1px solid black;"></td> </tr> </table>	a. EDI	<input type="checkbox"/>	Yes				b. Autofax	<input type="checkbox"/>	Yes	Fax Number:	(815) 624-0608		c. Fax	<input type="checkbox"/>	Yes	Fax Number:	(815) 624-0608		d. Phone only	<input type="checkbox"/>	No	Phone No.:	855-225-8244		e. Supplier Web Site only	<input type="checkbox"/>	No	Site Address:			Name:		Phone:		<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input style="width: 100px;" type="text" value="12:00pm"/> <input style="width: 100px;" type="text" value="Central"/></p> <p>Shipping lead time of PO: <input style="width: 50px;" type="text"/> Hours <input style="width: 50px;" type="text"/> Days</p> <p>Ships same day for next day receipt: <input style="width: 100px;" type="text" value="No"/></p> <p>Ships for second day receipt: <input style="width: 100px;" type="text" value="No"/></p> <p>Ships regular ground for 3-10 days receipt: <input style="width: 100px;" type="text" value="Yes"/></p>	
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Name:																																				
Phone:																																				
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																																			
<p>Expedited freight fees billed with each order: <input style="width: 100px;" type="text" value="Yes"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 100px;" type="text" value="No"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 100px;" type="text" value="No"/></p> <p>Comments: <div style="border: 1px solid black; height: 40px; width: 100%;"></div></p>	<p><b>Overnight receipt available:</b> <input style="width: 100px;" type="text" value="Yes"/></p> <p>PO Receipt cut off time: <input style="width: 100px;" type="text" value="12:00pm"/> <input style="width: 100px;" type="text" value="Central"/></p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 20px; text-align: center;"><input checked="" type="checkbox"/></td><td>Monday</td></tr> <tr><td style="text-align: center;"><input checked="" type="checkbox"/></td><td>Tuesday</td></tr> <tr><td style="text-align: center;"><input checked="" type="checkbox"/></td><td>Wednesday</td></tr> <tr><td style="text-align: center;"><input checked="" type="checkbox"/></td><td>Thursday</td></tr> <tr><td style="text-align: center;"><input type="checkbox"/></td><td>Friday</td></tr> </table> <p><b>Priority Overnight receipt available:</b> <input style="width: 100px;" type="text" value="Yes"/></p> <p>PO Receipt Cut off time: <input style="width: 100px;" type="text" value="12:00pm"/></p> <p><b>Saturday Overnight receipt available:</b> <input style="width: 100px;" type="text" value="No"/></p> <p>PO Receipt Cut off time: <input style="width: 100px;" type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Phone:</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> <td style="width: 10%; text-align: center;">Yes</td> <td style="width: 10%;">Phone #:</td> <td style="width: 10%; border: 1px solid black;">855-225-8244</td> </tr> <tr> <td>Fax:</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">Yes</td> <td>Fax #:</td> <td style="border: 1px solid black;">(815) 624-0608</td> </tr> <tr> <td>EDI:</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">Yes</td> <td></td> <td></td> </tr> <tr> <td>Overnight Fees apply:</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">Yes</td> <td></td> <td></td> </tr> <tr> <td>Other fees apply:</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"></td> <td></td> <td></td> </tr> </table>	<input checked="" type="checkbox"/>	Monday	<input checked="" type="checkbox"/>	Tuesday	<input checked="" type="checkbox"/>	Wednesday	<input checked="" type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday	Phone:	<input type="checkbox"/>	Yes	Phone #:	855-225-8244	Fax:	<input type="checkbox"/>	Yes	Fax #:	(815) 624-0608	EDI:	<input type="checkbox"/>	Yes			Overnight Fees apply:	<input type="checkbox"/>	Yes			Other fees apply:	<input type="checkbox"/>			
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Other Data Information Required to Process PO:	ADDITIONAL INFORMATION																																			
<p>Patient Procedure Date: <input style="width: 100px;" type="text"/></p> <p>Physician Name: <input style="width: 100px;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 100px;" type="text"/></p> <p>Physician State License #: <input style="width: 100px;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 100px;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 100px;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input style="width: 100px;" type="text"/></p> <p>Is product order for restocking purposes? <input style="width: 100px;" type="text"/></p>																																			
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