



Standard Pharmaceutical Product Information (Rx Product Only)

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

ADDITIONAL PRODUCT INFORMATION

Is the Product...
 a legend device?
 reverse numbered?
 co-licensed?
 Is the Product...
 Direct-Ship Only
 Is the Product...
 Unit of Use
 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
 Yes 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?:

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
 (Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:
 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?
 Is product sold by manufacturer's exclusive distributor?
 Has FDA granted waiver/exception/exemption for product?
 If Yes, was original product purchased direct from mfr?
 If yes, attach documentation from FDA.

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.072	NA	3	1.74	#VALUE!	90 Tablets per Bottle
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	#VALUE!	NA
Case:	2.5	11.5	4.2	7.2	347.76	24 Bottles per Case
Pallet:	240	48	48	40	92160	78 Cases per Pallet
UPC:	Case:	350228352901				
	Carton:					

GTIN PRODUCT INFORMATION

Serialized? If not, when? Items aggregated?	Yes <input type="text"/>	Level	Saleable Unit	Quantity	GTIN-14
	<input checked="" type="checkbox"/>	Item	<input checked="" type="checkbox"/>	1	00350228352901
	<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack			
	<input checked="" type="checkbox"/>	Case	<input checked="" type="checkbox"/>	24	20350228352905
		Pallet			

COST INFORMATION

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

WHOLESALE USE ONLY:
 Vendor #:
 Whsl. Code #:
 Finline Code:

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):
a. Cytotoxic? No
b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No
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.)
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?
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? Yes
Controlled by State(s)? No
ARCOS Reportable? No
Schedule No. (inc. N for non-narcotic) V N
Controlled Substance Code 2782
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 No
Restricted to retail pharmacy only: Yes
Restricted to hospital, clinics, and physician offices only: Yes
Restricted from US territories? (explain in comments) No
Comments: Not Applicable

SDS Hazard Classification

[X] Organic
Inorganic
Steroid/Androgen
Corrosive
Oxidizer
Contact Hazard
Aerosol Class; Identify NFPA Storage Level:
Is the product a NIOSH hazardous drug? No
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:
Supplier Manages REMS registry exclusively:
Wholesale distributor support:
Provider Name:
Site Enrollment Number assigned by Supplier:
Phone:
DEA #:
PCPDP #:
NPI #:

Comments
Registry:
Registry Program Contact Name:
Phone:
Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 1877-671-6307
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:

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%;"> <tr> <td style="width: 60%;">a. EDI</td> <td style="width: 10%;"><input type="checkbox"/></td> <td style="width: 10%;"></td> <td style="width: 20%;"></td> </tr> <tr> <td>b. Autofax</td> <td><input type="checkbox"/></td> <td>Fax Number:</td> <td><input type="text"/></td> </tr> <tr> <td>c. Fax</td> <td><input type="checkbox"/></td> <td>Fax Number:</td> <td><input type="text"/></td> </tr> <tr> <td>d. Phone only</td> <td><input type="checkbox"/></td> <td>Phone No.:</td> <td><input type="text"/></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td><input type="checkbox"/></td> <td>Site Address:</td> <td><input type="text"/></td> </tr> </table> <p>Minimum Order Quantity: <input style="width: 80%;" type="text"/></p> <p>Supplier's Customer Service Number: <input style="width: 90%;" type="text"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%;"> <tr> <td style="width: 20%;">Name:</td> <td><input style="width: 80%;" type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input style="width: 80%;" type="text"/></td> </tr> </table>	a. EDI	<input type="checkbox"/>			b. Autofax	<input type="checkbox"/>	Fax Number:	<input type="text"/>	c. Fax	<input type="checkbox"/>	Fax Number:	<input type="text"/>	d. Phone only	<input type="checkbox"/>	Phone No.:	<input type="text"/>	e. Supplier Web Site only	<input type="checkbox"/>	Site Address:	<input type="text"/>	Name:	<input style="width: 80%;" type="text"/>	Phone:	<input style="width: 80%;" type="text"/>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input style="width: 60%;" type="text"/></p> <p>Shipping lead time of PO: <input style="width: 50%;" type="text"/> Hours <input style="width: 50%;" 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>
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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: 50%;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 50%;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 50%;" type="text"/></p> <p>Comments: <input style="width: 90%; height: 40px;" type="text"/></p>	<p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input style="width: 60%;" type="text"/></p> <p>Days of week overnight is available:</p> <table style="width: 100%;"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input style="width: 60%;" type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input style="width: 60%;" type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%;"> <tr> <td style="width: 10%;">Phone:</td> <td style="width: 40%;"><input style="width: 90%;" type="text"/></td> <td style="width: 10%;">Phone #:</td> <td style="width: 40%;"><input style="width: 90%;" type="text"/></td> </tr> <tr> <td>Fax:</td> <td><input style="width: 90%;" type="text"/></td> <td>Fax #:</td> <td><input style="width: 90%;" type="text"/></td> </tr> <tr> <td>EDI:</td> <td><input style="width: 90%;" type="text"/></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>	<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday	Phone:	<input style="width: 90%;" type="text"/>	Phone #:	<input style="width: 90%;" type="text"/>	Fax:	<input style="width: 90%;" type="text"/>	Fax #:	<input style="width: 90%;" type="text"/>	EDI:	<input style="width: 90%;" type="text"/>				
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Other Data Information Required to Process PO:	ADDITIONAL INFORMATION																								
<p>Patient Procedure Date: <input style="width: 50%;" type="text"/></p> <p>Physician Name: <input style="width: 80%;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 80%;" type="text"/></p> <p>Physician State License #: <input style="width: 80%;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 80%;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 80%;" 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>																								
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