



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

Version 2024 Introduction Type:   Final Version Date:

**PRODUCT INFORMATION**

Company Name:  Application:  Application Number for NDA/ANDA/BLA; PMA/510(k):  NDA 505(b) Type:  Medical Device Class, if applicable:

DUNS:  Proprietary Name (If Applicable) and Established Name:  Selling Unit NDC:  Unit of Use 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):   
Notes:   
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                                      |                                  | PRODUCT DESCRIPTION INFORMATION                               |   |
|---|----------------------------------|---|---|
| The product is?<br>a legend device?<br>if yes, enter class #        | <input type="text" value="No"/>  | Is the Product...<br>Is the Product...<br>Orphan Drug Status  | <input type="text" value="Neither"/>            |
| if yes, list NDCs of component parts reverse numbered?              | <input type="text" value="No"/>  | FDA Approval Status   | <input type="text"/>                            |
| co-licensed?  | <input type="text" value="No"/>  | Allergens Present   | <input type="text"/>                            |
| latex-free?   | <input type="text" value="Yes"/> | Country of Origin   | <input type="text" value="India"/>              |
| preservative-free?  | <input type="text" value="No"/>  | Is this product covered under the Trade Agreements Act (TAA)? | <input type="text" value="No"/>                 |
| correctional institution block? opioid?                             | <input type="text" value="Yes"/> |   |   |
| 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"/>             |   |   |
|   |                                  | Size:   | <input type="text" value="30 count"/>           |
|   |                                  | Strength:   | <input type="text" value="200mg"/>              |
|   |                                  | Dosage Form:  | <input type="text" value="Tablet"/>             |
|   |                                  | Product Shape:  | <input type="text" value="Oblong"/>             |
|   |                                  | Product Color:  | <input type="text" value="White to off white"/> |
|   |                                  | Product Imprint:  | <input type="text" value="CS1"/>                |

**ORDER INFORMATION**

| Unit of Sale                               | What is the NDC selling unit?                                   |
|--|---|
| <input checked="" type="checkbox"/> Bottle | <input type="text" value="1 Bottle of 30 tablets"/>             |
| <input 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="48"/> Each                            |
| <input type="checkbox"/> Vial Power Multi  | <input type="text"/> Inner/ Carton/ Pack                        |
| <input type="checkbox"/> Other: Write In   | <input type="text"/> 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)  
HCPCS J-Code:

Rx billing unit to pharmacy:  
 Each  
 Gram  
 Milliliter

**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:   
Is product repackaged?   
Is product sold by manufacturer's exclusive distributor?   
Has FDA granted waiver/exception/exemption for product?   
If yes, attach documentation from FDA.

GLN:   
GCP:   
If yes, was original product purchased direct from mfr?   
Provide source manufacturer for repackaged product

**ITEM AND PACKING INFORMATION**

| Item/Each:                       | Weight Lbs. | Dimensions (US msmts.) |       |        | Volume (Cube) | Saleable # Pieces |
|----------------------------------|-------------|------------------------|-------|--------|---------------|-------------------|
|                                  |             | Depth                  | Width | Height |               |                   |
| Box/ Carton/ Bundle/ Inner Pack: | 0.08        | 1.53                   | 1.53  | 2.80   | 6.55          | 1                 |
| Case:                            | 4.27        | 12.52                  | 9.45  | 4.13   | 488.64        | 48                |
| Pallet:                          |             |                        |       |        | 0             |                   |

**GTIN AND HIBCC PRODUCT INFORMATION**

| Saleable Unit of Measure  | RFID tag(Y/N) | Saleable Quantity | HIBCC | GTIN-14        | Unit of Use GTIN-14 |
|---|---------------|-------------------|-------|----------------|---------------------|
| <input checked="" type="checkbox"/> Item/Each                       | N             | 1                 |       | 00359746717308 |                     |
| <input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack | N             | 48                |       | 40359746717306 |                     |
| <input type="checkbox"/> Case                                       |               |                   |       |                |                     |
| <input type="checkbox"/> Pallet                                     |               |                   |       |                |                     |

**COST INFORMATION**

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

**WHOLESALE USE ONLY:**  
Vendor #:   
Whsl. Code #:   
Fineline Code:



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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

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

### SDS Hazard Classification

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

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

NFPA Storage Level:

Is the product a NIOSH hazardous drug?  No

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  No

Limited Distribution Requirement  No

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 by Supplier:  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:

