



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

Version 2020 Introduction Type:  New Item  Final Version Date:

## PRODUCT INFORMATION SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

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:  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:

**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?**   
**e. Shelf life:**  Months  
 Protect product (unit of sale) from light?   
 Initial shelf life at launch (if different):  Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? <input type="text" value="No"/>	Is the Product... <input type="text" value="Neither"/>	Direct-Ship Only <input type="text" value="Neither"/>	Size: <input type="text" value="10 x 2 mL Single Dose Disposable Prefilled"/> Strength: <input type="text" value="2 mg per 2 mL (1 mg/mL)"/> Dosage Form: <input type="text" value="Liquid"/>
if yes, enter class # <input type="text"/>	Is the Product... <input type="text"/>	Orphan Drug Status <input type="text"/>	
if yes, list NDCs of component parts <input type="text"/>	FDA Approval Status <input type="text"/>	Allergens Present <input type="text"/>	Product Shape: <input type="text" value="PFS"/> Product Color: <input type="text"/> Product Imprint: <input type="text"/>
reverse numbered? <input type="text" value="No"/>	Country of Origin <input type="text" value="India"/>	Is this product covered under the Trade Agreements Act (TAA)? <input type="text"/>	
co-licensed? <input type="text" value="No"/>			
latex-free? <input type="text" value="Yes"/>			
preservative-free? <input type="text" value="Yes"/>			
correctional institution block? <input type="text" value="No"/>			
opioid? <input type="text" value="No"/>			
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"/>			

**ORDER INFORMATION**

Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	<input type="text" value="1 Carton of 10 Pre-Filled Syringes"/>
<input checked="" type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	
<input type="checkbox"/> Vial Power Multi	
<input type="checkbox"/> Other: Write In	

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?	Rx billing unit to pharmacy:
<input type="text" value="10 Pre-Filled Syringes"/>	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input checked="" type="checkbox"/> 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/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:	0.704	6.3	4.13	8.07	209.97333	1 pack of 10
Case:	9.4	18.701	14.37	10.24	2751.8297	8 packs
Pallet:	315.058	48	40	56.18	107865.6	30 Cases

## GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00355150345106	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input type="checkbox"/> Case	8		50355150345101	
<input type="checkbox"/> Pallet	30		70355150345105	

## COST INFORMATION WHOLESALE USE ONLY:

Regular Cost   
 Invoice Cost (WAC) (\$)   
 As of date:   
 Vendor #:   
 Whsl. Code #:   
 Finline Code:

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.



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

Version 2020

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?  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?  No  
(If yes, attach SDS with special instructions.)
  - e. Does the product contain DEHP?  No
- Is this product regulated for shipment by DOT?  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 this product regulated for shipment by 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?

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 Substance Code
- Controlled by State(s)?  No      Listed Chemical (List I or II)  No
- ARCOS Reportable?  No      If yes, indicate which:
- Schedule No.       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
  - Inorganic
  - Steroid/Androgen
  - Corrosive
  - Oxidizer
  - 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:       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   
Limited Distribution Requirement   
Comments / Details: (For example, iPledge program?)

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

Comments

**Registry:**   
Registry Program Contact Name:       Phone:   
Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  888-238-7880

Is product returnable for credit:  Yes

URL/Link to returns policy:  <http://auromedics.com/policies/return-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:

