



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

Final Version Date:

PRODUCT INFORMATION	
Company Name:	<input type="text" value="AuroMedics Pharma LLC"/>
Application Number for NDA/ANDA/BLA, Med Device:	<input type="text"/>
Rx Product/Proprietary Name:	<input type="text" value="SILDENAFIL INJECTION 10 mg/12.5 mL (0.8 mg/mL)"/>
NDC:	<input type="text" value="55150-166-13"/>
CVX Code:	<input type="text"/>
UPC:	<input type="text" value="355150166138"/>
MXV Code:	<input type="text"/>
Description:	<input type="text" value="SILDENAFIL INJECTION 10 mg/12.5 mL (0.8 mg/mL)"/>
Active ingredients:	<input type="text"/>
URL for Additional Product Information:	<input type="text"/>
Address:	<input type="text" value="6 Wheeling Road"/>
City:	<input type="text" value="Dayton"/>
Key Contact:	<input type="text"/>
Phone Number:	<input type="text" value="888-238-7880"/>
Address 2:	<input type="text"/>
State:	<input type="text" value="NJ"/>
Zip:	<input type="text" value="08810"/>
Email:	<input type="text"/>
Fax:	<input type="text" value="732-355-9449"/>

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
<input type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input checked="" type="checkbox"/>	IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input type="checkbox"/>	VI. Other Temperature Range Requirement (write in) <input type="text"/>
<input type="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
Name:	<input type="text"/>
Number:	<input type="text"/>
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
c. Special regulations for product in certain states?	
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
e. Shelf life:	
<input type="text" value="24"/> Months	<input type="text"/>
Initial shelf life at launch (if different):	<input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AP"/>
II. Brand Name:	<input type="text" value="Revatio"/>
III. Generic Equivalent for Brand:	<input type="text"/>

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="text" value="Yes"/>
DUNS:	<input type="text" value="968961354"/>
Is product exempt from DSCSA?	<input type="text" value="No"/>
If yes, select exemption:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	<input type="text" value="No"/>
If Yes, was original product purchased direct from mfr?	<input type="text"/>
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="No"/>
Are any waivers granted for product ID/barcode?	<input type="text" value="No"/>
If yes, attach documentation from FDA	<input type="text"/>

ADDITIONAL PRODUCT INFORMATION	
Is the Product... Direct Ship Item	<input type="text"/>
Legend Device?	<input type="text" value="No"/>
State Control?	<input type="text" value="No"/>
ARCOS reportable?	<input type="text" value="No"/>
Co-Licensed?	<input type="text" value="No"/>
Controlled Substance?	<input type="text" value="No"/>
Schedule No.?	<input type="text"/>
(incl. N for non-narcotic)	
Controlled Substance Code:	<input type="text"/>
Hazardous Material/Cytotoxic Agent?	<input type="text" value="No"/>
Is Item...	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>
Is it reverse numbered?	<input type="text"/>

ORDER INFORMATION	
Unit of Sale	<input type="checkbox"/> Bottle
	<input type="checkbox"/> Box/Carton
	<input type="checkbox"/> Ampule
	<input type="checkbox"/> Glass
	<input type="checkbox"/> Tube
<input checked="" type="checkbox"/>	Vial Liquid Sgl
	Vial Liquid Multi
	Vial Powder Sgl
	Vial Powder Multi
	Other: Write In <input type="text"/>
What is the NDC selling unit?	<input type="text" value="1 box of 1 vial"/>
(Write-in, e.g. 1 Box of 10 Vials)	
Minimum order quantity?	<input type="text" value="Yes"/>
If Yes, how many of which package type?	
<input type="text" value="24"/>	Each
<input type="text"/>	Inner/Carton/Pack
<input type="text"/>	Case

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Box/ Carton:	0.1094	1.574 Inches	2.755 Inches	2.0866 Inches		1 vial
Case:	20.661	18.7007 Inches	12.2047 Inches	10.433 Inches		144 vials (1x24x6)
Pallet:	694.192	48 Inches	57.20 Inches	40 Inches		32 Shippers
UPC:	Case:					
	Carton:	<input type="text" value="355150166138"/>				

WHOLESALE USE ONLY:	
Vendor #:	<input type="text"/>
Whsl. Code #:	<input type="text"/>
Fineline Code:	<input type="text"/>

PHARMACY ORDER / BILL UNIT	Other Product Information
Rec. sell unit to customer?	Size/Strength/Form:
<input type="text" value="1 Vial"/>	<input type="text"/>
(Write-in, e.g. 1 Vial)	
Rx billing unit to pharmacy:	Product Shape:
<input type="checkbox"/> Each	<input type="text"/>
<input type="checkbox"/> Gram	Product Color:
<input type="checkbox"/> Milliliter	<input type="text" value="colorless"/>
	Product Imprint:
	<input type="text"/>

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
<input type="text"/>	<input type="text" value="\$185.00"/>	<input type="text"/>
As of date: <input type="text" value="6/3/2015"/>		

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

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



Standard Pharmaceutical Product Information (Page 2)

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?

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

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?

Hazardous Waste Identification	
EPA Hazardous Waste Code:	<input type="text"/>

Is this product regulated for shipment by the DOT?

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#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization					
Serialized?	Level	How?	GTIN-14		
<input type="checkbox"/>	Item	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID	<input type="text"/>	
If not, when? <input type="text"/>	Box/Carton	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID	<input type="text"/>	
Items aggregated to case? <input type="checkbox"/>	Case	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID	<input type="text"/>	
	Pallet	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID	<input type="text"/>	

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? <input type="checkbox"/>	<input type="text"/>
If Yes, is it managed with a pharmacy registry? <input type="checkbox"/>	<input type="text"/>
Website URL: <input type="checkbox"/>	<input type="text"/>
Comments / Details: (For example, iPledge program?) <input type="text"/>	

ADD'L STORAGE INFORMATION	
Please check as appropriate for this product.	
<input type="checkbox"/> Organic	<input type="checkbox"/> Inorganic
<input type="checkbox"/> Antineoplastic	<input type="checkbox"/> Steroid/Androgen
<input type="checkbox"/> Corrosive	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input type="text"/>	

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged: <input type="checkbox"/>	<input type="text"/>
Is product returnable for credit: <input type="checkbox"/>	<input type="text"/>
URL/Link to returns policy: <input type="checkbox"/>	<input type="text"/>
Special regulations or returns requirements for this product in certain states? <input type="checkbox"/>	<input type="text"/>
If so, which states? Other requirements? Comments? <input type="checkbox"/>	<input type="text"/>

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (≥2.2%)

Other:

CLASS OF TRADE RESTRICTION:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/>	<input type="text"/>
Restricted to retail pharmacy only: <input type="checkbox"/>	<input type="text"/>
Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/>	<input type="text"/>
Restricted from US territories? (explain in comments) <input type="checkbox"/>	<input type="text"/>
Comments: <input type="text"/>	<input type="text"/>

ADDITIONAL INFORMATION	
If Unit Dose NDC, indicate NDC here: <input type="checkbox"/>	<input type="text"/>
MISCELLANEOUS NOTES and/or Image of Product Barcode:	
<input type="text"/>	

