



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:	<input type="text" value="ANDA"/>
Application Number for NDA/ANDA/BLA, Med Device:	<input type="text" value="205520"/>
Rx Product/Proprietary Name:	<input type="text" value="ESMOLOL HYDROCHLORIDE INJECTION 100 mg10 mL (10 mg/mL)"/>
NDC:	<input type="text" value="55150-194-10"/>
UPC:	<input type="text" value="355150194100"/>
CVX Code:	<input type="text"/>
MX Code:	<input type="text"/>
Description:	<input type="text" value="ESMOLOL HYDROCHLORIDE INJECTION 100 mg10 mL (10 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"/>
State:	<input type="text" value="NJ"/>
Zip:	<input type="text" value="08810"/>
Key Contact:	<input type="text"/>
Email:	<input type="text"/>
Phone Number:	<input type="text" value="888-238-7880"/>
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="Yes"/>
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"/>
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 checked="" type="checkbox"/> Box/Carton
	<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 Powder Multi
	<input type="checkbox"/> Other: Write In <input type="text"/>
What is the NDC selling unit?	<input type="text" value="25 vials in one carton"/>
(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="200"/> Each
	<input type="text" value="8"/> Inner/ Carton/Pack
	<input type="text" value="1"/> Case

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Box/ Carton:	1.64 lbs	5.31 Inches	2.36 Inches	5.31 Inches		25 Vials
Case:	14.460 lbs	11.22 Inches	5.51 Inches	11.22 Inches		200 vials (25x8)
Pallet:	1074.16 lbs	48 Inches	44.21 Inches	40 Inches		72 Shippers
UPC:	Case:					
	Carton:	<input type="text" value="355150194100"/>				

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"/>	<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"/>
	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="\$110.00"/>	<input type="text"/>
As of date: <input type="text" value="2/12/2016"/>		

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? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

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

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

Is this product regulated for shipment by the DOT? 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?
_____ (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? _____

ADDITIONAL PRODUCT INFORMATION - Serialization					
Serialized?	Level	How?	RFID	GTIN-14	
<input type="checkbox"/>	Item	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	10355150194107	
If not, when? _____	Box/Carton	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	00355150221004	
Items aggregated to case? _____	Case	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	50355150221009	
	Pallet	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	70355150221003	

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

Passenger

Cargo

Passenger & Cargo

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry? No

Website URL: _____

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic Inorganic

Antineoplastic Steroid/Androgen

Corrosive Oxidizer

Aerosol Class; Identify NFPA Storage Level: _____

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

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: _____

Is product returnable for credit: No

URL/Link to returns policy: _____

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

If so, which states? Other requirements? Comments? _____

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 No

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) _____

Comments: _____

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here: _____

MISCELLANEOUS NOTES and/or Image of Product Barcode:
