

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																																																																																
Company Name: <b>AuroMedics Pharma LLC</b>		<input type="checkbox"/> NDA <input type="checkbox"/> ANDA <input type="checkbox"/> BLA <input type="checkbox"/> Med Device 7		<b>a. Temperature – Indicate the USP temperature range for this product.</b> <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="checkbox"/> VII. No Requirement																																																																																																
Application number for NDA/ ANDA/ BLA, Med Device: _____																																																																																																				
Rx Product / Proprietary Name: <b>Acyclovir Sodium Injection 500 mg/10 mL</b>		NDC: <b>55150-154-10</b>																																																																																																		
Description: <b>Acyclovir Sodium Injection 500 mg/10 mL (10x10 mL SDV)</b>		UPC: _____																																																																																																		
Active ingredients: _____		CVX Code: _____																																																																																																		
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Phone Number: _____		Fax: _____																																																																																																		
FOR GENERIC DRUG PRODUCTS				<b>b. Contact for temperature excursion questions:</b> Name: _____ Number: _____  Is this product to be shipped to customers on ice? <input type="radio"/> Yes <input type="radio"/> No Is this product to be shipped to customers on dry ice? <input type="radio"/> Yes <input type="radio"/> No																																																																																																
I. Orange Book Rating: _____		II. Brand Name: _____																																																																																																		
III. Generic Equivalent for Brand: _____																																																																																																				
ADDITIONAL PRODUCT INFORMATION				<b>c. Special regulations for this product in certain states?</b> Special returns requirements for this product? <input type="radio"/> *Yes <input type="radio"/> No  <b>d. Store product (unit of sale) upright?</b> <input type="radio"/> Yes <input type="radio"/> No <b>Protect product (unit of sale) from light?</b> <input type="radio"/> Yes <input type="radio"/> No  <b>e. Shelf life:</b> _____ Months Initial shelf life at launch (if different): _____ Months																																																																																																
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<b>Hazardous Material / Cytotoxic Agent?</b> <input type="radio"/> *Yes <input type="radio"/> No <b>Is Item...</b> <input type="radio"/> Unit Dose <input type="radio"/> Unit of Use If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="radio"/> Yes <input type="radio"/> No <b>Is it reverse numbered?</b> <input type="radio"/> Yes <input type="radio"/> No				<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2" style="text-align: center; color: red;">Order Information</th> <th rowspan="2">Weight Lbs.</th> <th colspan="3" style="text-align: center; color: red;">Dimensions (US msmts.)</th> <th rowspan="2">Volume (Cube)</th> <th rowspan="2"># Pieces:</th> </tr> <tr> <th>Unit of Sale</th> <th>What is the NDC selling unit?</th> <th>Depth</th> <th>Height</th> <th>Width:</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/> Bottle</td> <td>1 Box of 10 Vials</td> <td></td> <td></td> <td></td> <td></td> <td>0</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Box / Carton</td> <td>(Write-in, e.g. 1 Box of 10 Vials)</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td><input type="checkbox"/> Ampule</td> <td>Minimum order quantity? <input type="radio"/> Yes <input type="radio"/> No</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td><input type="checkbox"/> Glass</td> <td>If Yes, how many of which package type?</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td><input type="checkbox"/> Tube</td> <td><input type="checkbox"/> Eac</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td><input checked="" type="checkbox"/> Vial Liquid Sgl</td> <td><input type="checkbox"/> Inner / Carton</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td><input type="checkbox"/> Vial Liquid Multil</td> <td><input type="checkbox"/> Case</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td><input type="checkbox"/> Vial Powder Sgl</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td><input type="checkbox"/> Vial Powder Multi</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td><input type="checkbox"/> Other: Write In</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>				Order Information		Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:	Unit of Sale	What is the NDC selling unit?	Depth	Height	Width:	<input type="checkbox"/> Bottle	1 Box of 10 Vials					0		<input type="checkbox"/> Box / Carton	(Write-in, e.g. 1 Box of 10 Vials)							<input type="checkbox"/> Ampule	Minimum order quantity? <input type="radio"/> Yes <input type="radio"/> No							<input type="checkbox"/> Glass	If Yes, how many of which package type?							<input type="checkbox"/> Tube	<input type="checkbox"/> Eac							<input checked="" type="checkbox"/> Vial Liquid Sgl	<input type="checkbox"/> Inner / Carton							<input type="checkbox"/> Vial Liquid Multil	<input type="checkbox"/> Case							<input type="checkbox"/> Vial Powder Sgl								<input type="checkbox"/> Vial Powder Multi								<input type="checkbox"/> Other: Write In							
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Attach copy of MATERIAL SAFETY DATA SHEET (MSDS) 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: \_\_\_\_\_

New Item  Promotion/Deal  Open Stock  Post Launch Change

Date: \_\_\_\_\_

**PRODUCT INFORMATION**

**SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

Company Name: **AuroMedics Pharma LLC**  NDA  ANDA  BLA  Med Device 7

Application number for NDA/ ANDA/ BLA, Med Device: \_\_\_\_\_

Rx Product / Proprietary Name: **Acyclovir Sodium Injection 1000 mg/20 mL**

NDC: **55150-155-20** UPC: \_\_\_\_\_

CVX Code: \_\_\_\_\_ MVX Code: \_\_\_\_\_

Description: **Acyclovir Sodium Injection 1000 mg/20 mL (10x20 mL SDV)**

Active ingredients: \_\_\_\_\_

URL for additional product information: \_\_\_\_\_

Address: **6 Wheeling Road** Address 2: \_\_\_\_\_

City: **Dayton, NJ 08810** State: \_\_\_\_\_ Zip: \_\_\_\_\_

Key Contact: \_\_\_\_\_ Email: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Fax: \_\_\_\_\_

a. Temperature – Indicate the USP temperature range for this product.

I. Freezer – between -25 and -10 C (-13° – 14° F)

II. Cold – between 2 and 8 C (36° – 46° F)

III. Cool – between 8 and 15 C (46° – 59° F)

IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)

V. Avoid Excessive Heat – above 40 C (>104° F)

VI. Other Temperature Range Requirement (write in) \_\_\_\_\_

VII. No Requirement

b. Contact for temperature excursion questions:

Name: \_\_\_\_\_ Number: \_\_\_\_\_

Is this product to be shipped to customers on ice?  Yes  No

Is this product to be shipped to customers on dry ice?  Yes  No

c. Special regulations for this product in certain states?  \*Yes  No

Special returns requirements for this product?  \*Yes  No

d. Store product (unit of sale) upright?  Yes  No

Protect product (unit of sale) from light?  Yes  No

e. Shelf life: \_\_\_\_\_ Months

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

**FOR GENERIC DRUG PRODUCTS**

I. Orange Book Rating: \_\_\_\_\_ II. Brand Name: \_\_\_\_\_

III. Generic Equivalent for Brand: \_\_\_\_\_

**ADDITIONAL PRODUCT INFORMATION**

Serialized?  Yes  No

Level	How?	GTIN-14
<input type="checkbox"/> Item	<input type="checkbox"/> 2D <input type="checkbox"/> Linear <input type="checkbox"/> RFID	_____
<input type="checkbox"/> Case	<input type="checkbox"/> 2D <input type="checkbox"/> Linear <input type="checkbox"/> RFID	<b>50355150155205</b>
<input type="checkbox"/> Pallet	<input type="checkbox"/> 2D <input type="checkbox"/> Linear <input type="checkbox"/> RFID	<b>70355150155209</b>

Is the Product...  Direct Ship Item  Direct and Drop Ship  Drop Ship only item (See new page 3.)

a Legend Device?  Yes  No

a State Control?  Yes  No

ARCOS reportable?  Yes  No

Co-Licensed?  Yes  No

Repackaged?  Yes  No

Controlled Substance?  Yes  No

Schedule No.? \_\_\_\_\_ (incl. N for non-narcotic)

Hazardous Material / Cytotoxic Agent?  \*Yes  No

Is Item...  Unit Dose  Unit of Use

If Unit Dose, is item bar coded to unit dose for hospital scanning?  Yes  No

Is it reverse numbered?  Yes  No

**ITEM AND PACKING INFORMATION**

**Order Information**

Unit of Sale:  Bottle  Box / Carton  Ampule  Glass  Tube  Vial Liquid Sgl  Vial Liquid Multil  Vial Powder Sgl  Vial Powder Multi  Other: Write In

What is the NDC selling unit? **1 Box of 10 Vials**

(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?  Yes  No

If Yes, how many of which package type?

Eac  Inner / Carton  Case

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
<b>Box/ Carton:</b>	<b>1.075</b>	<b>6.496</b>	<b>2.755</b>	<b>2.677</b>	<b>47.90888</b>	<b>10 vials</b>
<b>Case:</b>	<b>13.77</b>	<b>14.173</b>	<b>4.33</b>	<b>14.173</b>	<b>869.7841</b>	<b>100 vials</b> 2x5x10 vials
<b>Pallet:</b>	<b>698.54</b>	<b>47.2441</b>	<b>45.472</b>	<b>39.3701</b>	<b>84578.14</b>	<b>48 shippers</b>
<b>UPC:</b>	<b>Case:</b>					
<b>Carton:</b>	<b>Carton:</b>					

PHARMACY ORDER / BILL UNIT	Other Product Information	COST INFORMATION		
Rec. sell unit to customer? _____ (Write-in, e.g. 1 Vial)	Size/Strength/Form: _____	Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
Rx billing unit to pharmacy: <input type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Millilite	Product Shape: _____			
	Product Color: _____			
	Product Imprint: _____			

**WHOLESALE USE ONLY:**

Vendor #: \_\_\_\_\_

Whsl. Code #: \_\_\_\_\_

Fineline Code: \_\_\_\_\_

Attach copy of MATERIAL SAFETY DATA SHEET (MSDS) 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: \_\_\_\_\_