



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION			
Company Name:	<input type="text" value="Citron Pharma LLC"/>	Application:	<input type="text" value="NDA"/>
Application Number for NDA/ANDA/BLA, Med Device:	<input type="text" value="071611"/>		
Rx Product/Proprietary Name:	<input type="text" value="Cyclobenzaprine Tablets 7.5mg"/>		
NDC:	<input type="text" value="57237-266-01"/>	UPC:	<input type="text" value="357237266014"/>
CVX Code:	<input type="text"/>	MXV Code:	<input type="text"/>
Description:	<input type="text" value="Flexmid relieves skeletal muscle spasm of local origin without interfering with muscle function. It is ineffective in muscle spasm due to central nervous system disease."/>		
Active ingredients:	<input type="text" value="CYCLOBENZAPRINE HYDROCHLORIDE"/>		
URL for Additional Product Information:	<input type="text"/>		
Address:	<input type="text" value="2 Tower Center Drive Suite 1101"/>	Address 2:	<input type="text"/>
City:	<input type="text" value="East Brunswick"/>	State:	<input type="text" value="NJ"/>
Key Contact:	<input type="text" value="Kaitlin Alexander"/>	Email:	<input type="text" value="kalexander@citronpharma.com"/>
Phone Number:	<input type="text" value="732-917-6056"/>	Fax:	<input type="text" value="732-227-1513"/>

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<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="text"/>
<input type="checkbox"/>	VII. No Requirement
<b>b. Contact for temperature excursion questions:</b>	
Name:	<input type="text" value="Vikram Ganesh"/>
Number:	<input type="text" value="732-917-6062"/>
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"/>
<b>c. Special regulations for product in certain states?</b>	
Special returns requirements for this product?	<input type="text" value="No"/>
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
<b>e. Shelf life:</b>	
<input type="text" value="24"/> Months	Initial shelf life at launch (if different): <input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text"/>
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"/> Yes <input type="text"/> No
DUNS:	<input type="text" value="78731527"/>
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="Yes"/>
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"/>
Is Item... Unit of Use	<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 checked="" type="checkbox"/> Bottle
	<input 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="1 Bottle of 100"/>
(Write-in, e.g. 1 Box of 10 Vials)	
Minimum order quantity?	<input type="text" value="No"/>
If Yes, how many of which package type?	
	<input type="text"/> 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:		
Item:	0.14	1.78	3.38	1.78	10.709192	1
Box/ Carton:	N/A	N/A	N/A	N/A	N/A	N/A
Case:	6.82	11.13	6.94	7.38	570.047436	48
Pallet:	681.6	48	48	40	92160	100
UPC:	Case:	<input type="text"/>				
	Carton:	<input type="text"/>				

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="100/7.5mg/Tablets"/>	<input type="text" value="100/7.5mg/Tablets"/>
(Write-in, e.g. 1 Vial)	Product Shape:
Rx billing unit to pharmacy:	<input type="text" value="ROUND"/>
<input checked="" type="checkbox"/> Each	Product Color:
<input type="checkbox"/> Gram	<input type="text" value="WHITE (off-white)"/>
<input type="checkbox"/> Milliliter	Product Imprint:
	<input type="text" value="WATSON;3330"/>

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

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: