



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Final VersionDate:

PRODUCT INFORMATION	
Company Name:	TAGI Pharma, Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	A075477
Application:	ANDA
DUNS:	963322560
Proprietary Name (if Applicable) and Established Name:	
Selling Unit NDC:	51224-219-50
Individual Unit NDC:	
UDI	
CVX Code:	
UPC:	
MXV Code:	
Description:	Gabapentin Capsules, USP 400mg 100 Count
Active Ingredient(s):	Gabapentin
URL for Additional Product Information:	www.tagipharma.com
Address:	722 Progressive Lane
City:	South Beloit
Key Contact:	Pierce Dewey
Phone Number:	815-624-7685
Product Therapeutic Classification:	Anticonvulsants
State:	IL
Address 2:	Room 205
Zip:	61080
Email:	pdewey@tagipharma.com
Fax:	(815) 624-4628

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
b. Contact for temperature excursion questions:	
Name:	Mat Mathis
Number:	815-624-7685
Group E-mail:	druginfo@tagipharma.com
c. Special regulations for product in any states?	
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
e. Shelf life:	
Initial shelf life at launch (if different):	24 Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	No
reverse numbered?	No
co-licensed?	Yes
Is the Product... Direct And Drop-Ship	
Is the Product... Neither	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose NDC, indicate NDC here:	
Country of Origin	China
Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION	
Size:	100 Count
Strength:	400mg
Dosage Form:	Capsules
Product Shape:	Capsule
Product Color:	White, Orange
Product Imprint:	400mg;OE;B58

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Bottle
<input 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 Powder Multi	
<input type="checkbox"/> Other: Write In	
	Minimum order quantity? Yes
	If Yes, how many of which package type?
	12 Each
	Inner/Carton/Pack
	Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Neurontin
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
(Write-in, e.g. 1 Vial)	Each
	Gram
	Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
GLN:	GLN 035122400001
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/Carton/Bundle/Inner Pack:	0.23	2.19	3.69	2.19	17.697609	1
Case:	2.76	4.38	3.69	13.14	212.371308	12
Pallet:	41.4	23.23	14.17	14.17	4664.32615	180
UPC:					0	
Case:						
Carton:						

GTIN PRODUCT INFORMATION						
Serialized?	If not, when?	Items aggregated?	Level		Quantity	GTIN-14
			Saleable Unit	2D		
<input checked="" type="checkbox"/>			Item	<input checked="" type="checkbox"/>	1	00351224219502
<input checked="" type="checkbox"/>			Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>	12	30351224219503
<input checked="" type="checkbox"/>			Case	<input checked="" type="checkbox"/>	180	50351224219507
			Pallet			

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$10.15	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

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?

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 or 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? 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#

ADD'L STORAGE INFORMATION

Is the Product...

Controlled Substance? No

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic)

Controlled Substance Code

Listed Chemical (List I or II) No
If yes, indicate which:

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

<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> 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:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No
If Yes, is it managed with a pharmacy registry?
Website URL:

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

REMS:

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:
Provider Name:

Site Enrollment Number assigned by Supplier: DEA #:

PCPDP #:

NPI #:

Comments:

Registry:

Registry Program Contact Name: Phone:

Comments:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit? Yes

URL/Link to returns policy:

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

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing																								
<p>Purchase orders may be accepted by:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">a. EDI</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/> Yes</td> <td style="width: 10%;"></td> <td style="width: 60%;"></td> </tr> <tr> <td>b. Autofax</td> <td style="text-align: center;"><input type="checkbox"/> Yes</td> <td>Fax Number:</td> <td><input type="text" value="(815) 624-0608"/></td> </tr> <tr> <td>c. Fax</td> <td style="text-align: center;"><input type="checkbox"/> Yes</td> <td>Fax Number:</td> <td><input type="text" value="(815) 624-0608"/></td> </tr> <tr> <td>d. Phone only</td> <td style="text-align: center;"><input type="checkbox"/></td> <td>Phone No.:</td> <td><input type="text" value="855-225-8244"/></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td style="text-align: center;"><input type="checkbox"/> No</td> <td>Site Address:</td> <td><input type="text"/></td> </tr> </table> <p>Minimum Order Quantity: <input type="text" value="12 Bottles"/></p> <p>Supplier's Customer Service Number: <input type="text" value="855-225-8244"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td><input type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input type="text"/></td> </tr> </table>	a. EDI	<input type="checkbox"/> Yes			b. Autofax	<input type="checkbox"/> Yes	Fax Number:	<input type="text" value="(815) 624-0608"/>	c. Fax	<input type="checkbox"/> Yes	Fax Number:	<input type="text" value="(815) 624-0608"/>	d. Phone only	<input type="checkbox"/>	Phone No.:	<input type="text" value="855-225-8244"/>	e. Supplier Web Site only	<input type="checkbox"/> No	Site Address:	<input type="text"/>	Name:	<input type="text"/>	Phone:	<input type="text"/>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text" value="12:00pm"/> Central</p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/> No</p> <p>Ships for second day receipt: <input type="checkbox"/> No</p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/> Yes</p>
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Name:	<input type="text"/>																								
Phone:	<input type="text"/>																								
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																								
<p>Expedited freight fees billed with each order: <input type="checkbox"/> Yes</p> <p>Drop Ship service fee billed with each order: <input type="checkbox"/> No</p> <p>Drop Ship miscellaneous fees billed: <input type="checkbox"/> No</p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	<p>Overnight receipt available: <input type="checkbox"/> Yes</p> <p>PO Receipt cut off time: <input type="text" value="12:00pm"/> Central</p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 20px; text-align: center;"><input checked="" type="checkbox"/></td><td>Monday</td></tr> <tr><td style="text-align: center;"><input checked="" type="checkbox"/></td><td>Tuesday</td></tr> <tr><td style="text-align: center;"><input checked="" type="checkbox"/></td><td>Wednesday</td></tr> <tr><td style="text-align: center;"><input checked="" type="checkbox"/></td><td>Thursday</td></tr> <tr><td style="text-align: center;"><input type="checkbox"/></td><td>Friday</td></tr> </table> <p>Priority Overnight receipt available: <input type="checkbox"/> Yes</p> <p>PO Receipt Cut off time: <input type="text" value="12:00pm"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/> No</p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Phone:</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/> Yes</td> <td style="width: 10%;">Phone #:</td> <td><input type="text" value="855-225-8244"/></td> </tr> <tr> <td>Fax:</td> <td style="text-align: center;"><input type="checkbox"/> Yes</td> <td>Fax #:</td> <td><input type="text" value="(815) 624-0608"/></td> </tr> <tr> <td>EDI:</td> <td style="text-align: center;"><input type="checkbox"/> Yes</td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input type="checkbox"/> Yes</p> <p>Other fees apply: <input type="checkbox"/></p>	<input checked="" type="checkbox"/>	Monday	<input checked="" type="checkbox"/>	Tuesday	<input checked="" type="checkbox"/>	Wednesday	<input checked="" type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday	Phone:	<input type="checkbox"/> Yes	Phone #:	<input type="text" value="855-225-8244"/>	Fax:	<input type="checkbox"/> Yes	Fax #:	<input type="text" value="(815) 624-0608"/>	EDI:	<input type="checkbox"/> Yes				
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EDI:	<input type="checkbox"/> Yes																								
Class of Trade Restriction:																									
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/> No</p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No</p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/> No</p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>																									
Other Data Information Required to Process PO:	Return Instructions																								
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Contact # if product is received damaged: <input type="text" value="855-225-8244"/></p> <p>Is product returnable for credit: <input type="checkbox"/> Yes</p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> Yes</p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 20px;" type="text" value="Georgia, Mississippi and North Carolina. Requests can be made via fax: (815) 624-0608 or email"/></p>																								
Miscellaneous Notes:	ADDITIONAL INFORMATION																								
<input style="width: 100%; height: 60px;" type="text"/>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>																								