Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Item | [ ] Final Version | Date: 6/27/2019

PRODUCT INFORMATION

Company Name: TAGI Pharma, Inc. | Application: ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): A207057
DUNS:
Proprietary Name (If Applicable) and Established Name: Gabapentin Tablets, USP
Selling Unit NDC: 51224-021-50 | Individual Unit NDC: | UPC:
UDI: | CVX Code: | MVX Code:
Description: Gabapentin Tablets, USP 600mg 100 count
Active Ingredient(s): Gabapentin
URL for Additional Product Information: www.tagipharma.com
Address: 722 Progressive Lane | Address 2: Room 205
City: South Beloit | State: IL | Zip: 61080
Key Contact: Melissa Bradley | Email: mbradley@tagipharma.com
Phone Number: 815-624-7685 | Fax: 815-624-7687
Product Therapeutic Classification:

ADDITIONAL PRODUCT INFORMATION

Is the Product...
- a legend device? No
- reverse numbered? No
- co-licensed? No

Is the Product... Direct-Ship Only
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: 600mg
Dosage Form: Tablets
Product Shape: oval
Product Color: white
Product Imprint:

FOR GENERIC DRUG PRODUCTS

[ ] Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AB
II. Generic Equivalent to What Brand?:

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:
If Yes, was original product purchased direct from mfr?
If yes, attach documentation from FDA.

GTIN PRODUCT INFORMATION

	Level	Saleable Unit			Quantity	GTIN-14
Serialized? Yes						
If not, when?						
Items aggregated?						
x	Item		2D	x Linear		00351224021501
x	Box/Carton/Bundle/Inner Pack		2D	x Linear		30351224021502
x	Case		2D	x Linear		50351224021506
	Pallet		2D	Linear		
			2D	Linear		
			2D	Linear		
			2D	Linear		
			2D	Linear		

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? No
Special returns requirements for this product? No

d. Store product (unit of sale) upright? Yes
Protect product (unit of sale) from light? Yes

e. Shelf life: 24 Months
Initial shelf life at launch (if different): Months

ORDER INFORMATION

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

What is the NDC selling unit?
(Write-in, e.g. 1 Box of 10 Vials)
Minimum order quantity? Yes
If Yes, how many of which package type?
- 12 Each
- Inner/Carton/Pack
- Case

PHARMACY ORDER / BILL UNIT

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

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	0.3		4.55in	2.19in		1
Box/Carton/Bundle/ Inner Pack:	3.6					12
Case:	33.06	16.53	14.17	14.17		108
Pallet:						
UPC:	Case:					
	Carton:					

COST INFORMATION

Regular Cost:
Invoice Cost (WAC) ($): $15.60
Federal Excise Tax Per Unit of Sale:
As of date: 7/5/2019

WHOLESALER USE ONLY:

Vendor #:
Whsl. Code #:
Fineline Code:

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: Melissa Bradley

HDA

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?
  - 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#

SDS Hazard Classification

- ☐ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen
- ☐ Corrosive
- ☐ Oxidizer
- ☐ 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:

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:

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: No
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: 855-225-8244
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?
Georgia, Mississippi and North Carolina. Requests can be made via fax: 815-624-7687 or email: customercare@tagipharma.com

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

HDA

Standard Pharmaceutical Product Information (Page 3)

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

Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:

a. EDI	Yes		
b. Autofax	Yes	Fax Number:	815-624-7687
c. Fax	Yes	Fax Number:	815-624-7687
d. Phone only		Phone No.:	855-225-8244
e. Supplier Web Site only	No	Site Address:	

Minimum Order Quantity:

Supplier's Customer Service Number: 855-225-8244

Contracted 3PL company / contact #: Name:

Phone:

Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order: Yes

Drop Ship service fee billed with each order: No

Drop Ship miscellaneous fees billed: No

Comments:

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:

Other Data Information Required to Process PO:

Patient Procedure Date:

Physician Name:

Physician/Clinic Phone #

Physician State License #

Physician/Clinic DEA #:

Physician/Clinic Specialty:

Miscellaneous Notes:

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier

Cut off time: 12:00pm Central

Shipping lead time of PO: Hours Days

Ships same day for next day receipt: No

Ships for second day receipt: No

Ships regular ground for 3-10 days receipt: Yes

Overnight and Priority Overnight PO Processing

Overnight receipt available: Yes

PO Receipt cut off time: 12:00pm Central

Days of week overnight is available:

- [x] Monday
- [x] Tuesday
- [x] Wednesday
- [x] Thursday
- [ ] Friday

Priority Overnight receipt available: Yes

PO Receipt Cut off time: 12:00pm

Saturday Overnight receipt available: No

PO Receipt Cut off time:

Order receipt method:

Phone:	Yes	Phone #:	855-225-8244
Fax:	Yes	Fax #:	815-624-7687
EDI:	Yes		

Overnight Fees apply: Yes

Other fees apply:

Return Instructions

Contact # if product is received damaged: 855-225-8244

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?

Georgia, Mississippi and North Carolina. Requests can be made via fax: 815-624-7687 or emai

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?

Is product order for restocking purposes?

SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/ UNDERTAKING

Material Name: Gabapentin Tablets 600mg/800mg

Trade Name: Gabapentin Tablets 600mg/800mg

Chemical Family: Mixture

Intended Use: Pharmaceutical product used for antiepileptic

Manufacturer Information

Company name CSPC Ouyi Pharmaceutical Co., Ltd.

Address No.276 Zhongshan West Road Shijiazhuang 050051,China

Telephone + 86-311-87896575

Website www.ouyipharma.com

Emergency phone number +1-877-436-7220

2. HAZARDS IDENTIFICATION

Appearance: White, eliptical, film-coated tablets

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

Short Term: Dust may cause irritation (based on components) The active ingredient is not acutely toxic.

Known Clinical Effects: Adverse effects associated with therapeutic use include dizziness, tiredness, swelling, and nausea.

EU Indication of danger: Not classified

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Gabapentin	60142-96-3	262-076-3	Not Listed	73.0
Corn Starch	9005-25-8	232-679-6	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Poloxamer 407	9003-11-6	Not listed	Not Listed	*
Povidone	9003-39-8	Not listed	Not Listed	*

Purified water	7732-18-5	231-791-2	Not Listed	*
Candelilla wax	8006-44-8	232-347-0	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not listed	Not Listed	*

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing and shoes. Wash skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Not known

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Spills: Large Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store in a cool, dry place away from direct sunlight. Storage Temperature: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Refer to available public information for specific member state Occupational Exposure Limits.

Gabapentin

Pfizer OEL TWA-8 Hr:	1200µg/m^3

Corn Starch

ACGIH Threshold Limit Value (TWA)	10 mg/m^3 TWA
Australia TWA	10 mg/m^3
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
OSHA - Final PELS - TWAs:	15 mg/m^3 total 5 mg/m^3
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA)	2 mg/m^3 TWA
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	2.5 mg/m^3 containing no asbestos fibers
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELs - Table Z-3 Mineral D:	TWA-20 mppcf
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m^3 TWA
Australia TWA	10 mg/m^3
Belgium OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed

Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Analytical Method:	Analytical method available for gabapentin. Contact Pfizer Inc for further information.
Engineering Controls:	Engineering controls should be used as the primary means to control exposures.
Environmental Exposure Controls:	Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin:	Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection:	Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Film-coated tablets **Color:** White Molecular

Formula: Mixture **Molecular Weight:** Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

Conditions to Avoid: None known

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Gabapentin

Mouse Oral LD50 > 5000 mg/kg

Rat Oral LD50 > 5000 mg/kg

Rat IV LD50 > 2000 mg/kg

Mouse IV LD50 1000-2000 mg/kg

Rat Subcutaneous LD50 > 4000 mg/kg

Povidone

Rat Oral LD50 100 g/kg

Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m3

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Gabapentin

Eye Irritation Rabbit Non-irritating

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Gabapentin

52 Week(s) Rat Oral 250 mg/kg/day NOAEL Liver, Kidney

52 Week(s) Monkey Oral 250 mg/kg/day NOAEL None identified

13 Week(s) Mouse Oral 1000 mg/kg/day NOAEL No effects at maximum dose

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Gabapentin

Reproductive & Fertility Rat Oral 500 mg/kg/day NOAEL Negative

Embryo / Fetal Development Mouse Oral 3000 mg/kg/day NOAEL No effects at maximum dose

Embryo / Fetal Development Rat Oral 300 mg/kg/day NOAEL Developmental toxicity, Not Teratogenic

Embryo / Fetal Development Rabbit Oral 1500 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity

Peri-/Postnatal Development Rat Oral 500 mg/kg/day NOAEL Negative

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Gabapentin

Bacterial Mutagenicity (Ames) Salmonella , E. coli Negative

In Vitro Chromosome Aberration Hamster Lung Cells Negative

In Vivo Unscheduled DNA Synthesis Rat Hepatocyte Negative

In Vivo Chromosome Aberration Hamster Bone Marrow Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Gabapentin

2 Year(s) Mouse Oral, in feed 2000 mg/kg/day NOEL Not carcinogenic

2 Year(s) Male Rat Oral, in feed 1000 mg/kg/day NOEL Malignant tumors, Pancreas

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Povidone IARC: Group 3

Talc (non-asbestiform) IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:

None required This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Gabapentin	
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	262-076-3
Corn Starch	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6
Poloxamer 407	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

Talc (non-asbestiform)	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	238-877-9
Povidone	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Purified water	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2
Candelilla wax	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	232-347-0
Hydroxypropyl cellulose	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Magnesium stearate	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	209-150-3

16. OTHER INFORMATION

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Issue Date: 09/2017

Prepared by: CSPC Ouyi Pharmaceutical Co., Ltd.

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