Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Post Launch Change | [x] Final Version | Date: 1/2/2020

PRODUCT INFORMATION

Company Name:	TAGI Pharma, Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	A208249
DUNS:	963322560
Proprietary Name (If Applicable) and Established Name:	Azithromycin Tablets, USP
Selling Unit NDC:	51224-122-30
Individual Unit NDC:	
UPC:	
UDI	
CVX Code:	
MVX Code:	
Description:	Azithromycin Tablet, USP 500mg 30 Count Bottle
Active Ingredient(s):	Azithromycin Dihydrate
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:	Pierce Dewey
Email:	pdewey@tagipharma.com
Phone Number:	(815)624-7685
Fax:	(815)624-4628
Product Therapeutic Classification:	Antibiotic

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:	30
Strength:	500mg
Dosage Form:	tablets
Product Shape:	oval
Product Color:	red
Product Imprint:	OE;500

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?:	ZITHROMAX

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes
GLN:	
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
If Yes, was original product purchased direct from mfr?	
Has FDA granted waiver/exception/exemption for product?	No
If yes, attach documentation from FDA.	

GTIN PRODUCT INFORMATION

Serialized? | If not, when? | Items aggregated?

	Level	Saleable Unit			Quantity	GTIN-14
[x]	Item		2D	[x] Linear	1	00351224122307
[x]	Box/Carton/Bundle/Inner Pack		2D	[x] Linear	12	30351224122308
[x]	Case		2D	[x] Linear	240	50351224122302
	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?	No
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 Sgl
	Vial Power Multi
	Other: Write In

What is the NDC selling unit? 30 count Bottle (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:	0.14	1.5	3.5	1.5	7.875	1
Box/Carton/Bundle/ Inner Pack:	1.68	10.23	3.5	3.34	119.5887	12
Case:	33.6	22.05	18.11	9.25	3693.76088	240
Pallet:					0	
UPC:	Case:					
	Carton:					

COST INFORMATION

Regular Cost	
Invoice Cost (WAC) ($)	$143.25
Federal Excise Tax Per Unit of Sale	
As of date:	1/2/2020

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: Pierce Dewey

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?

Is the product a CA Prop 65 reproductive toxicant?

Does the product label bear a CA Prop 65 warning?

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?

No (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? No

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)624-0608 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)624-0608
c. Fax	Yes	Fax Number:	(815)624-0608
d. Phone only		Phone No.:	(855)225-8244
e. Supplier Web Site only	No	Site Address:	

Minimum Order Quantity: 12 Bottles

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

Contracted 3PL company / contact #: Name:

Phone:

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

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:

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)624-0608
EDI:	Yes		

Overnight Fees apply: Yes

Other fees apply:

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:

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)624-0608 or em

Miscellaneous Notes:

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: Azithromycin Tablets

Trade Name: Azithromycin

Chemical Family: Mixture

Intended Use: Pharmaceutical product used as antibiotic agent

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:

Red, modified oval-shaped, film-coated tablets, debossed with "OE" on one side and "250","500" or "600" on the other side.

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

Short Term: Dust may cause irritation if tablets are crushed or broken. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

Known Clinical Effects: May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain.

EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

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

Ingredient CAS Number EU EINECS/ELINCS List Classification %

Azithromycin dihydrate 117772-70-0 Not listed Not Listed 56

Starch, pregelatinized 9005-25-8 232-679-6 Not Listed *

Sodium lauryl sulfate 151-21-3 205-788-1 Not Listed *

Magnesium stearate 557-04-0 209-150-3 Not Listed *

Ingredient CAS Number EU EINECS/ELINCS List Classification %

Calcium phosphate dibasic, anhydrous 7757-93-9 231-826-1 Not Listed *

Croscarmellose sodium 74811-65-7 Not listed Not Listed *

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

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 determined

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 Large Spills:

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: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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 as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Analytical Method: Analytical method available for Azithromycin. Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

10 mg/m$_3$ TWA

Spain OEL - TWA Listed

Calcium phosphate dibasic, anhydrous

Latvia OEL - TWA Listed

Australia TWA 10 mg/m3

Sodium lauryl sulfate

Azithromycin dihydrate

Pfizer OEL TWA-8 Hr: 0.3 mg/m³

Belgium OEL - TWA

Magnesium stearate

Listed

ACGIH Threshold Limit Value (TWA) 10 mg/m3 TWA

Australia TWA 10 mg/m3

Bulgaria OEL - TWA Listed

Belgium OEL - TWA Listed

Ireland OEL - TWAs Listed

Pfizer OEL TWA-8 Hr:

Lithuania OEL - TWA Listed

Czech Republic OEL - TWA Listed

Portugal OEL - TWA Listed

500µg/m3

Spain OEL - TWA Listed

Greece OEL - TWA

Sweden OEL - TWAs Listed

Listed

Ireland OEL - TWAs Listed

Starch, pregelatinized

Revision date: 08-Sep-2009

OSHA - Final PELS - TWAs: 15 mg/m3 total

5 mg/m3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal

protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: 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

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

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)

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)

Rat Oral LD50 1288 mg/kg

Color: White to off-white

Azithromycin dihydrate

Mouse (F) Oral LD50 4000 mg/kg

Molecular Formula: Mixture

Mouse (M) Oral LD50 3000 mg/kg

Rat Oral LD50 > 2000 mg/kg

Molecular Weight: Mixture

Magnesium stearate

Sodium lauryl sulfate

Rat Oral LD50 > 2000 mg/kg

Eye Irritation Rabbit Severe

Rat Inhalation LC50 > 2000 mg/m3

Physical State: Film-coated tablets

Sodium lauryl sulfate

11. TOXICOLOGICAL INFORMATION

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

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

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

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

12. ECOLOGICAL INFORMATION

Environmental Overview: In the environment, the active ingredient in this formulation is expected to mainly reside in the aquatic environment and slowly degrade.

Mobility, Persistence and

Degradability:

Azithromycin half life < 28 days (Aerobic Biodegredation - Water)

Bioaccumulation and Toxicity: The active ingredient in this formulation has low potential to bioaccumulate and long-term adverse effects to aquatic organisms are not expected. See aquatic toxicity data, below.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

Bacterial Inhibition: (Species, Method, End Point, Duration, Result)

In Vitro Cytogenetics Human Lymphocytes Negative

1 Month(s) Rat Intravenous 5 mg/kg/day NOEL Liver

1 Month(s) Dog Intravenous 5 mg/kg/day NOEL Liver

Antigenicity- Passive cutaneous anaphylaxis Rabbit Negative

Azithromycin dihydrate

Antigenicity- Passive cutaneous anaphylaxis Mouse Negative

Reproductive & Fertility Rat Oral 10 mg/kg/day NOEL Fertility

Skin Irritation Rabbit Severe

Prenatal & Postnatal Development Mouse Oral 40 mg/kg/day NOEL Not Teratogenic

Azithromycin dihydrate

Prenatal & Postnatal Development Rat Oral 40 mg/kg/day NOEL Not Teratogenic

Daphnia Magna OECD EC50 48 Hours 120 mg/L

Azithromycin dihydrate

Hyallela azteca OECD LC50 96 Hours > 120 mg/L

Azithromycin dihydrate

Rainbow Trout OECD LC50 96 Hours > 84 mg/L

Azithromycin dihydrate

Green Algae OECD EC50 72 Hours 0.0037 mg/L

6 Month(s) Rat Oral 10 mg/kg/day LOEL Liver

Bacterial Mutagenicity (Ames) *Salmonella* Negative

In Vivo Cytogenetics Mouse Lymphoma Negative

6 Month(s) Dog Oral 10 mg/kg/day LOEL Liver

In Vitro Cytogenetics Mouse Negative

Antigenicity- Active anaphylaxis Guinea Pig Negative

12. ECOLOGICAL INFORMATION

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: 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.

Starch, pregelatinized

Inventory - United States TSCA - Sect. 8(b) Listed

Trichoderma viride (Fungus) OECD MIC > 1000 mg/L

Australia (AICS): Listed

Material Name: Azithromycin Tablets

REACH - Annex IV - Exemptions from the obligations of Register:

Present

Clostridium perfingens (Bacterium) OECD MIC 2.0 mg/L

EU EINECS/ELINCS List 232-679-6

Calcium phosphate dibasic, anhydrous

Bacillus subtilis (Bacterium) OECD MIC2.0 mg/L

Azithromycin dihydrate

Aspergillus niger (Fungus) OECD MIC > 1000 mg/L

15. REGULATORY INFORMATION

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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