



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:  Final Version  Date: 02/27/2019

**PRODUCT INFORMATION**

Company Name: TAGI Pharma, Inc. Application: ANDA

Application Number for NDA/ANDA/BLA (drug): PMA/510(K)(med device): A205096

Proprietary Name (if Applicable) and Established Name: Metformin Hydrochloride Immediate-Release Tablets, USP

Selling Unit NDC: 51224220-70 Individual Unit NDC: UPC: MXV Code:

Description: Metformin IR 1000mg 1000 count

Active Ingredient(s): Metformin IR

URL for Additional Product Information: www.tagipharma.com

Address: 722 Progressive Lane State: IL Room 205 Zip: 61080

City: South Beloit Email: mbradley@tagipharma.com

Key Contact: Melissa Bradley 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  No  
 Neither  No

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

If Unit Dose NDC, indicate NDC here:  No

Country of Origin: China

Is this product covered under the Trade Agreements Act (TAA)?  No

**PRODUCT DESCRIPTION INFORMATION**

Size: 1000

Strength: 1000mg

Dosage Form: Tablet

Product Shape: Round

Product Color: White

Product Imprint:

**FOR GENERIC DRUG PRODUCTS**

I. Orange Book Rating:  AB  Authorized Generic  \*If Authorized Generic, other section fields are not applicable

II. Generic Equivalent to What Brand?:

Does supplier meet DSCSA definition of manufacturer?  No  Yes

Is product exempt from DSCSA?  No  Yes

GLN:  No  Yes

If Yes, was original product purchased direct from mfr?  No  Yes

If Yes, attach documentation from FDA.

**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

Serialized?  Yes  No

If not, when?  No  Yes

Items aggregated?  No  Yes

**GTIN PRODUCT INFORMATION**

Item	Level	Quantity	GTIN-14
<input checked="" type="checkbox"/>	Box/ Carton/ Bundle/ Inner Pack	<input type="text"/>	00351224220706
<input checked="" type="checkbox"/>	Case	<input type="text"/>	30351224220707
<input checked="" type="checkbox"/>	Pallet	<input type="text"/>	50351224220701
<input type="checkbox"/>	Level	<input type="text"/>	
<input type="checkbox"/>	Unit	<input type="text"/>	

**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:

b. Contact for temperature excursion questions:  
 Is this product to be shipped to customers on ice?  No  Yes  
 Is this product to be shipped to customers on dry ice?  No  Yes

Name: Mel Mathis  
 Number: 815-624-7685  
 Group E-mail: dmgriffin@tagipharma.com

c. Special regulations for product in any states?  
 Special returns requirements for this product?  No  Yes

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

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

**ORDER INFORMATION**

Unit of Sale:  Bottle  Box/ Carton  Ampule  Glass  Tube  Vial Liquid Sgl  Vial Liquid Multi  Vial Powder Sgl  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  No

If Yes, how many of which package type?  
 Each  Inner/ Carton/ Pack  Case

**PHARMACY ORDER / BILL UNIT**

Rx sell unit to customer?  Each  Gram  Milliliter

Rx billing unit to pharmacy:

**ITEM AND PACKING INFORMATION**

Item:	Weight Lbs.	Depth	Height	Width	Volume (Cubes)	# Pieces:
Box/ Carton/ Bundle/ Inner Pack:	2.83		4.078	2.625		1
Case:	8.79					3
Pallet:	35.27	9.84	20.47	15.35		12
UPC:	Case:	Carton:				

**COST INFORMATION**

Regular Cost  Vendor #:

Invoice Cost (WAC) (\$)  Whal. Code #: 582.35

Federal Excise Tax Per Unit of Sale  Finline Code:

As of date: 7/5/2019

**WHOLESALE USE ONLY:**

Signature:  Melissa Bradley

\*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL and PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship Only.



# 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?  
 (If yes, attach SDS with special instructions.)  No

e. Does the product contain DEHP?  No

Is this product regulated for shipment by DOT or IATA?  
 (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  No

Cargo  No

Passenger & Cargo  No

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  Corrosive

Inorganic  Oxidizer

Steroid/Androgen  Contact Hazard

Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug?  
 If yes, indicate which:

EPA Hazardous Waste Code:

Hazardous Waste Identification

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  
 If Yes, is it managed with a pharmacy registry?  
 Website URL:

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

REMS:  No

REMS Program Manager Name:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

Phone:

DEA #:

PCPDF #:

NPI #:

Comments

Registry:

Registry Program Contact Name:

Comments

Phone:

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?  
 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

ADD'L STORAGE INFORMATION

Is the Product...  No

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)

If yes, indicate which:

Is it a scheduled listed chemical product?:  No

CLASS OF TRADE RESTRICTION:

No restriction:  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:



# 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	Standard Order Receipt and Processing										
Purchase orders may be accepted by: a. EDI <input type="checkbox"/> Yes <input type="checkbox"/> No b. Autofax <input type="checkbox"/> Yes <input type="checkbox"/> No c. Fax <input type="checkbox"/> Yes <input type="checkbox"/> No d. Phone only <input type="checkbox"/> Yes <input type="checkbox"/> No e. Supplier Web Site only <input type="checkbox"/> Yes <input type="checkbox"/> No Minimum Order Quantity: _____ Supplier's Customer Service Number: 855-225-8244 Contracted 3PL company / contact #: _____ Name: _____ Phone: _____	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:	Overnight and Priority Overnight PO Processing										
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 receipt available: _____ Yes _____ PO Receipt cut off time: 12:00pm _____ Central _____ Days of week overnight is available: <table border="1" style="margin-left: 20px;"> <tr><td>Monday</td><td><input checked="" type="checkbox"/></td></tr> <tr><td>Tuesday</td><td><input checked="" type="checkbox"/></td></tr> <tr><td>Wednesday</td><td><input checked="" type="checkbox"/></td></tr> <tr><td>Thursday</td><td><input checked="" type="checkbox"/></td></tr> <tr><td>Friday</td><td><input type="checkbox"/></td></tr> </table> Priority Overnight receipt available: _____ Yes _____ PO Receipt Cut off time: 12:00pm _____ Saturday Overnight receipt available: _____ No _____ PO Receipt Cut off time: _____ Phone: 855-225-8244 Fax: 815-624-7687 EDI: _____ Other fees apply: _____	Monday	<input checked="" type="checkbox"/>	Tuesday	<input checked="" type="checkbox"/>	Wednesday	<input checked="" type="checkbox"/>	Thursday	<input checked="" type="checkbox"/>	Friday	<input type="checkbox"/>
Monday	<input checked="" type="checkbox"/>										
Tuesday	<input checked="" type="checkbox"/>										
Wednesday	<input checked="" type="checkbox"/>										
Thursday	<input checked="" type="checkbox"/>										
Friday	<input type="checkbox"/>										
Class of Trade Restriction:	Return Instructions										
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: _____	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 email										
Other Data Information Required to Process PO:	Additional Information										
Patient Procedure Date: _____ Physician Name: _____ Physician/Clinic Phone #: _____ Physician State License #: _____ Physician/Clinic DEA #: _____ Physician/Clinic Specialty: _____ Miscellaneous Notes: _____	Is product order for scheduled patient procedure? _____ Is product order for restocking purposes? _____										

# SAFETY DATA SHEET

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

Trade name : Metformin Tablets

Company Identification: CSPC OUYI PHARMACEUTICAL CO., LTD.

Emergency tel: 0311-87896581

Issue Date : 12/10/2015.

## 2. HAZARDS IDENTIFICATION

Risk Phrases : Harmful in contact with skin and if swallowed. - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Adverse human health effects : Damage to liver. This material may induce blood disorders and/or aggravate pre-existing blood disorders. Cardiac disorders. Exposure may produce an allergic reaction. Hypoglycaemia. Gastrointestinal disorders.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Components : This product is hazardous.

Substance name Contents CAS No EC No Annex No Classification

Metformin hydrochloride: 1115-70-4214-230-6-----Xn; R21/22R52-53

CSPC OUYI PHARMACEUTICAL CO., LTD.  
石药集团欧意药业有限公司

## 4. FIRST AID MEASURES

First aid measures

- Inhalation: Assure fresh air breathing. Rest. If you feel unwell, seek medical advice. - Skin contact: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. - Eye contact: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking, tears or redness persist. - Ingestion: Rinse mouth. If swallowed, seek medical advice immediately and show this container or label. In case of reactions described in hazards identification or other severe, immediate or persisting symptoms seek medical advice and call the nearest poison centre. Show the label and this safety data sheet.

## 5. FIRE FIGHTING MEASURES

Extinguishing media- Suitable extinguishing media: Water spray. Carbon dioxide. Dry powder.

- Unsuitable extinguishing media: Do not use a heavy water stream. Surrounding fires: Use water spray or fog for cooling exposed containers. Protection against fire: Do not enter fire area without proper protective equipment, including respiratory protection. Hazardous combustion products: Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases.

## 6. ACCIDENTAL RELEASE MEASURES

General precautions: Remove ignition sources. Evacuate area. Personal precautions: Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection. Clean up methods: To clean the floor and all objects contaminated by this material, use : Water. /Detergent. Avoid dust production. Ensure adequate ventilation.

## 7. HANDLING AND STORAGE

Personal protection: Avoid all unnecessary exposure. Ensure prompt removal from eyes, skin and clothing. Technical protective measures: Material should be handled in a laboratory hood whenever possible.

Handling: Handle in accordance with good industrial hygiene and safety procedures.

Storage: METFORMIN HYDROCHLORIDE CRS is not intended for long-term storage.

Keep container tightly closed in a cool, well ventilated place. Storage - away from: All heat sources, including direct sunlight. Open flame. Sources of ignition. Sparks. Incompatible materials, see §10

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal protection= 8 :- Respiratory protection: Wear approved mask. (P2) In case of insufficient ventilation, wear suitable respiratory equipment. - Hand protection: Wear suitable gloves resistant to chemical penetration. -

Skin protection: Wear suitable protective clothing. - Eye protection: Chemical goggles or safety glasses. Industrial

hygiene:Provide local exhaust or general room ventilation.

#### 9. PHYSICAL AND CHEMICALS PROPERTIES

Chemical formula:C<sub>4</sub>H<sub>12</sub>N<sub>5</sub>Molecular weight:165.6Physical state at 20 °C:Crystals.Colour:White.pH value:6.68 (1%)Melting point [°C]:222 - 226Boiling point [°C]:No data available.

Solubility in water:Complete.Flash point [°C]:No data available.Log P octanol / water at 20°C:-2.64

#### 10 STABILITY AND REACTIVITY

Stability and reactivity:Stable under normal conditions.Materials to avoid:Alkali. Strong oxidizers.Conditions to avoid:None known.Hazardous decomposition products:Carbon monoxide. Carbon dioxide. Nitrogen oxides. Chlorides.When heated to decomposition, emits dangerous fumes.Hazardous reactions:None under normal conditions.Hazardous polymerization:Will not occur.

#### 11. TOXICOLOGICAL INFORMATION

RTECS nr:DU1800000 ( See actual entry in RTECS for complete information. )Rat oral LD<sub>50</sub> [mg/kg]:1770Rabbit dermal LD<sub>50</sub> [mg/kg]:No data available.Rat inhalation LC<sub>50</sub> [mg/L/4h]:No data available.Acute toxicity:Cardiac disorders. Hypoglycaemia. Gastrointestinal disorders. This material may induce blood disorders and/or aggravate pre-existing blood disorders.Chronic toxicity:Damage to liver.Sensitization:No data available.

#### 12. ECOLOGICAL INFORMATION

Ecological effects information:Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.LC<sub>50</sub>-96 Hour - fish [mg/L]:No data available.EC<sub>50</sub>-48 Hour-Daphnia magna [mg/L]:52IC<sub>50</sub>-72h-Algae [mg/L]:No data available.Biodegradation [%]:No data available.Persistence - degradability:Partially biodegradable.Log P octanol / water at 20°C:-2.64 (metformin)Bioaccumulative potential:No data available.

#### 13. DISPOSAL CONSIDERATIONS

General:Dispose of this material and its container at hazardous or special waste collection point.Dispose in a safe manner in accordance with local/national regulations.

#### 14. TRANSPORT INFORMATION

Transport regulation UN Classification: UN number shipping name – Class (other risk)– PG

IATA/ICAO (air) Not classified

ADR/RID (road/railway) Not classified

IMDG (sea) Not classified

Marine pollutant: None-hazardous for sea transport.

#### 15. REGULATORY INFORMATION

Symbol(s):Xn : HarmfulR Phrase(s):R21/22 : Harmful in contact with skin and if swallowed.R52/53 : Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.S Phrase(s):S24 : Avoid contact with skin.S36/37 : Wear suitable protective clothing and gloves.S51 : Use only in well-ventilated areas.S59 : Refer to manufacturer/supplier for information on recovery/recycling.S61 : Avoid release to the environment. Refer to special instructions/Safety datasheets.

#### 16. OTHER INFORMATION

Further information:Revision - See : \*List of relevant R phrases:R21/22 : Harmful in contact with skin and if swallowed.R52/53 : Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**EXPIRY DATE: 01/24/2018**

CSPC OUYI PHARMACEUTICAL CO.,LTD.  
石药集团欧意药业有限公司