

PRODUCT INFORMATION

Company Name: TAGI Pharma, Inc. Application: ANDA

DUNS: A205066

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

Selling Unit NDC: 51224-020-50 Individual Unit NDC: UPIC: MXX Code:

Description: Metformin IR 500mg 500 count

Active Ingredient(s): Metformin IR

URL for Additional Product Information: www.tagipharma.com

Address: 722 Progressive Lane, South Bekit, State: IL, Room 205, Zip: 61080

Key Contact: Melissa Bradley, Email: mbradley@tagipharma.com, Phone Number: 815-624-7885, Fax: 815-624-7887

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?

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: 500 count

Strength: 500mg

Dosage Form: Tablet

Product Shape: Round

Product Color: White

Product Imprint:

ORDER INFORMATION

Unit of Sale: Box/ Carton

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? Each

Inner/ Carton/ Pack:

Case:

FOR GENERIC DRUG PRODUCTS

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

2. Generic Equivalent to What Brand?

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? No Yes

Is product exempt from DSCSA? No Yes

If yes, select exemption: If Yes, was original product purchased direct from mfr? No Yes

Is product repackaged? No Yes

Is product sold by manufacturer's exclusive distributor? No Yes

Has FDA granted waiver/exception/exemption for product? No Yes

GTIN PRODUCT INFORMATION

Level	Item	Unit	Quantity
2D	Linear	2D	03351224020803
2D	Linear	2D	30351224020804
2D	Linear	2D	50351224020808
2D	Linear	2D	
2D	Linear	2D	
2D	Linear	2D	
2D	Linear	2D	
2D	Linear	2D	
2D	Linear	2D	

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?

Re. billing unit to pharmacy: Each

Gram

Milliliter

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US mmts.)	Height	Width	Volume (Cubes)	# Pieces:
Box/ Carton/ Bundle/ Inner Pack:	0.78	4.078	2.625			1
Case:	4.56					6
Pallet:	55.11	12.89	18.89	18.89		72
UPC:						

COST INFORMATION

Regular Cost (WAC (\$))

Invoice Cost

Federal Excise Tax Per Unit of Sale

As of date: 7/5/2019

WHOLESALE USE ONLY:

Vendor #:

Whst. Code #:

Fineline Code:

Signature: Melissa Bradley



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?
 No
 No
 No

c. Contact Hazard?
d. Does this product require special clean-up instructions?
(if yes, attach SDS with special instructions.)
e. Does the product contain DEHP?
 No
 No
 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
 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) _____
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, hospital, clinic and physician offices
Restricted to retail pharmacy only: Yes
Restricted to hospital, clinics, and physician offices only: No
Restricted from US territories? (explain in comments) No
Comments: _____

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: _____

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: _____ Phone: _____
Registry Program Contact Name: _____
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@acipharma.com

MISCELLANEOUS NOTES and/or Image of Product Barcode: _____



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 No 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: _____

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier: _____ 12:00pm Central

Cut off time: _____

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:

<input checked="" type="checkbox"/>	Monday
<input checked="" type="checkbox"/>	Tuesday
<input checked="" type="checkbox"/>	Wednesday
<input checked="" type="checkbox"/>	Thursday
<input type="checkbox"/>	Friday

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: _____

Priority Overnight receipt available:

PO Receipt Cut off time: _____ 12:00pm

Saturday Overnight receipt available: No

PO Receipt Cut off time: _____

Order receipt method: Phone: _____ Phone #: 855-225-8244

Fax: _____ Fax #: 815-624-7687

EDI: _____

Overnight Fees apply: Yes

Other fees apply: Yes

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: 815-624-7687 or email)

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 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:C₄H₁₂N₅Molecular 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 LD50 [mg/kg]:1770Rabbit dermal LD50 [mg/kg]:No data available.Rat inhalation LC50 [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.LC50-96 Hour - fish [mg/L]:No data available.EC50-48 Hour-Daphnia magna [mg/L]:52IC50-72h-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