



Standard Pharmaceutical Product Information (Rx Product Only)

Final Version	Date:				
<input type="checkbox"/>	<input type="checkbox"/>	02/27/2019			
PRODUCT INFORMATION					
Company Name: TACB Pharma, Inc.					
Application: ANIDA					
Application Number for NDA/ANDA/BLA (drug): PMAJ510(k)(med device)					
Application Number for NDA/ANDA/BLA (drug): PMAJ510(k)(med device)					
Proprietary Name (if applicable) and Established Name: Meformin Hydrochloride Immediate-Release Tablets, USP					
Selling Unit NDC: 51224-120-70					
Individual Unit NDC: _____					
UPC: _____					
UDI: _____					
CVX Code: _____					
MYX Code: _____					
Description: Meformin IR 850mg 1000 count					
Active Ingredient(s): Meformin IR					
URL for Additional Product Information: www.lagpharma.com					
Address: 722 Progressive Lane					
City: South Beloit					
State: IL					
Room: 205					
Zip: 61080					
Key Contact: Melissa Bradley					
Phone Number: 815-624-7885					
Product Therapeutic Classification: _____					
PRODUCT DESCRIPTION INFORMATION					
Size: 1000					
Strength: 850mg					
Dosage Form: Tablet					
Product Shape: Round					
Product Color: White					
Product Imprint: _____					
FOR GENERIC DRUG PRODUCTS					
I. Orange Book Rating: AB					
II. Generic Equivalent to What Brand?: _____					
Authorized Generic: <input type="checkbox"/>					
*If Authorized Generic fields are not applicable					
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION					
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/>					
Is product exempt from DSCSA? <input type="checkbox"/>					
If yes, select exemption: _____					
Other exemption - Write in: _____					
Is product repackaged? <input type="checkbox"/>					
Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/>					
Has FDA granted waiver/exemption/exception for product? <input type="checkbox"/>					
GTIN PRODUCT INFORMATION					
Serialized? If not, when? Items aggregated? <input type="checkbox"/>					
Level: _____					
Unit: _____					
Item: <input checked="" type="checkbox"/> Linear					
Box/ Carton/ Bundle/ Inner Pack: <input checked="" type="checkbox"/> Linear					
Case: <input checked="" type="checkbox"/> Linear					
Pallet: <input checked="" type="checkbox"/> Linear					
Quantity: _____					
GTIN-14: 00351224120709					
GTIN-12: 30351224120700					
GTIN-8: 50351224120704					
GTIN-5: _____					
GTIN-2: _____					
GTIN-1: _____					
ORDER INFORMATION					
What is the NDC selling unit? (Write-in, e.g. 1 Box of 10 Vials) _____					
Minimum order quantity? _____					
Unit of Sale: <input checked="" type="checkbox"/> Bottle					
Box/Carton: _____					
Ampule: _____					
Glass: _____					
Tube: _____					
Vial Liquid Sgl: _____					
Vial Liquid Multi: _____					
Vial Powder Sgl: _____					
Vial Powder Multi: _____					
Inner/ Carton/ Pack: _____					
Other: Write in: _____					
If Yes, how many of which package type?					
Each: _____					
Each: _____					
Case: _____					
PHARMACY ORDER / BILL UNIT					
Rec. sell unit to customer? _____					
Rx billing unit to pharmacy: _____					
(Write-in, e.g. 1 Vial)					
Each: _____					
Gram: _____					
Milliliter: _____					
ITEM AND PACKING INFORMATION					
Weight Lbs. _____					
Dimensions (US in units.)					
Depth: _____					
Height: _____					
Width: _____					
Volume (Cube): _____					
# Pieces: _____					
Item: _____					
Box/Carton/Bundle/Inner Pack: _____					
Case: _____					
Pallet: _____					
UPC: _____					
Case: _____					
Carton: _____					
COST INFORMATION					
Regular Cost (WAC) (\$): _____					
Invoice Cost (WAC) (\$): \$63.11					
Federal Excise Tax Per Unit of Sale: _____					
As of date: 7/5/2019					
Vendor #: _____					
Whsl. Code #: _____					
Freight Code: _____					
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?
Is the product a CA Prop 65 reproductive toxicant?
Does the product label bear a CA Prop 65 warning?
 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

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#

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?
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 No

URL/link to returns policy:

Special regulations or returns requirements for this product in certain states? Yes No

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

Comments:

ADDITIONAL 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, hospitals, clinics and physician offices Yes No

Restricted to retail pharmacy only: No No

Restricted to hospital, clinics, and physician offices only: No No

Restricted from US territories? (explain in comments) No No

Comments:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE



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 No

b. Autofax Yes No

c. Fax Yes No

d. Phone only Yes No

e. Supplier Web Site only Yes No

Minimum Order Quantity: _____

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

Contracted 3PL company / contact #: _____

Name: _____

Phone: _____

Fax Number: 815-624-7687

Phone No.: 855-225-8244

Site Address: _____

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 Yes

Ships for second day receipt: No Yes

Ships regular ground for 3-10 days receipt: No Yes

Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order: Yes No

Drop Ship service fee billed with each order: Yes No

Drop Ship miscellaneous fees billed: Yes No

Comments: _____

Overnight and Priority Overnight PO Processing

Overnight receipt available: Yes No

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 No

Restricted to retail pharmacy only: Yes No

Restricted to hospital, clinics, and physician offices only: Yes No

Restricted from US territories? (explain in comments) Yes No

Comments: _____

Priority Overnight receipt available:

PO Receipt Cut off time: _____ 12:00pm

Saturday Overnight receipt available:

PO Receipt Cut off time: Yes No

Phone: 855-225-8244

Fax: 815-624-7687

Order receipt method:

Phone: Yes No

Fax: Yes No

EDI: Yes No

Overnight Fees apply:

Other fees apply: Yes No

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 No

URL/link to returns policy: _____

Special regulations or returns requirements for this product in certain states? Yes No

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