



Your Trusted Source for Generics

SDS NOT REQUIRED

August 30, 2016

Regarding your SDS Request:

Dear Valued Customer:


In response to your Safety Data Sheet (SDS) request, according to OSHA Hazard Communications Standards 1910.1200(b)(6)(vii) and 1910.1200(b)(5)(iii), an SDS is not required for the requested product(s), as they are exempt from the Hazard Communications Standard.

<u>NDC</u>	<u>DESCRIPTION</u>
51224-151-50	URSODIOL CAPSULES, USP 300 MG

Epic products are stored, prescribed, prepared, dispensed, administered, and disposed of according to the directions included within the product labeling and product packaging. The products are regulated by the Food and Drug Administration according to 21 CFR § 211.132.

If you have any questions or require additional product information, please contact Epic Customer Service via e-mail at cs@epic-pharma.com.

Sincerely,


Nekela Bornell
Manager, Customer Service
Epic Pharma, LLC
718-481-6164



227-15 N. Conduit Ave * Laurelton, NY 11413

(P) 718-276-8600 * (F) 718-276-1735 * www.epic-pharma.com



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014 Introduction Type: Post Launch Change Final Version Date: 9/18/2017

PRODUCT INFORMATION

Company Name: **TAQI Pharma, Inc.** Application: **ANDA**

Rx Product/Proprietary Name: **Ursodiol Capsules, USP** Application: **ANDA**

NDC: **51224-151-50** UPC: **MVX Code:**

CVX Code: **Ursodiol Capsules, USP 300mg**

Description: **Ursodiol**

Active Ingredients: **Ursodiol**

URL for Additional Product Information: **www.taqipharma.com**

Address: **722 Progressive Lane** Address 2: **Room 205**

City: **South Beloit** State: **IL** Zip: **61080**

Key Contact: **Melissa Bradley** Email: **mbradley@taqipharma.com**

Phone Number: **815-524-7685** Fax: **815-524-7014**

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: **AB** II. Brand Name: **Adyall**

III. Generic Equivalent for Brand: **Ursodiol HCl**

DRUG SUPPLY CHAIN SECURITY (ACT/DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes No **DUNS: 953322650**

If Yes, select exemption: Other exemption - Write in: _____

Is product exempt from DSCSA? No

Is product sold by manufacturer's exclusive distributor? No

Are any waivers granted for product ID/barcode? No

If Yes, attach documentation from FDA _____

ADDITIONAL PRODUCT INFORMATION

Is the Product... Direct Ship Item No Yes

Legend Device? No Yes

State Control? No Yes

ARCOS reportable? No Yes

Co-Licensed? No Yes

Controlled Substance? No Yes

Schedule No.? **N/A**

(Incl. N for non-narcotic)

Controlled Substance Code: N/A

Hazardous Material/Cytotoxic Agent? No

Is Item... Neither

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

Is it reverse numbered? No

ORDER INFORMATION

Unit of Sale Bottle Box/ Carton

What is the NDC selling unit? **1 Bottle**

(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes No

If Yes, how many of which package type? **12**

Each Inner/ Carton/ Pack Case

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Depth	Height	Width:	Volume (Cube)	# Pieces:
Box/ Carton:	3.06oz		3.75"	2"		
Case:	3.78lbs		4"	6.25"		
Pallet:						
Case:						
Carton:						

SPECIAL HANDLING AND STORAGE REQUIREMENTS

a. Temperature - Indicate the USP temperature range for this product.

I. Freezer - between -25 and -10 C (-13° - 14° F)

II. Cold - between 2 and 8 C (36° - 46° F)

III. Cool - between 8 and 15 C (46° - 59° F)

IV. Controlled Room - between 20 and 25 C (68° - 77° F)

allows for excursions between 15 and 30 C (59° - 86° F)

V. Avoid Excessive Heat - above 40 C (>104° F)

VI. Other Temperature Range Requirement (write in) _____

VII. No Requirement

b. Contact for temperature excursion questions: **Walk Freixen**

Name: **Walk Freixen**

Number: **815-524-7685**

Is this product to be shipped to customers on ice? No

Is this product to be shipped to customers on dry ice? No

c. Special regulations for product in certain 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

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? No Yes

(Write-in, e.g. 1 Vial)

Size/Strength/Form: **300mg Capsules**

Product Shape: **Capsule**

Product Color: **Opaque white and pink**

Product Imprint: **E503**

Other Product Information

COST INFORMATION

Regular Cost Per Unit of Sale (\$): **\$458.65**

Invoice Cost (WAC) (\$): _____

Federal Excise Tax Per Unit of Sale: _____

WHOLESALE/REUSE ONLY

Vendor #: _____

Whsl. Code #: _____

Finaline Code: _____

*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. Signature: **Kristin Loehr**

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?
 Carcinogen No
 Reproductive Toxicant
 Both

c. Contact Hazard? No
 Warning appears on label

d. Does this product require special clean-up instructions?
 (If yes, attach SDS with special instructions.) No
 Yes

e. Does the product contain DEHP? No

Hazardous Waste Identification

EPA Hazardous Waste Code: _____

Is this product regulated for shipment by the DOT? No

Is this a reportable quantity?
 RQ Threshold: _____ No

Is this a marine pollutant?
 Is this product shipped utilizing an authorized DOT exception or Special Permit?
 (If yes, identify method below) No

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# _____

Is the product restricted for air shipment? If so, indicate restriction:
 Passenger
 Cargo
 Passenger & Cargo

ADD'L STORAGE INFORMATION

Please check as appropriate for this product:

<input type="checkbox"/> Organic	<input type="checkbox"/> Inorganic
<input type="checkbox"/> Antineoplastic	<input type="checkbox"/> Steroid/Androgen
<input type="checkbox"/> Corrosive	<input type="checkbox"/> Oxidizer

Aerosol Class (Identify NFPA Storage Level: _____)

Listed Chemical (List I or II) (Indicate or Write-in below):
 Ephedrine _____
 Pseudoephedrine _____
 Phenylpropanolamine _____
 Iodine (2.2%) _____
 Other: _____

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospital, 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: _____

(If yes, answer a-d below and provide SDS)

a. DOT Hazard Class _____
 b. UN/ID Number _____
 c. Packing Group _____
 d. Inhalation Hazard? No

ADDITIONAL PRODUCT INFORMATION - Serialization

Serialized? <input type="checkbox"/> Yes	Level	2D	How? <input type="checkbox"/> Linear	RFID <input type="checkbox"/>
If not, when? <input type="checkbox"/> 11/12/08	Item	2D	Linear	RFID <input type="checkbox"/>
Items aggregated to case? <input type="checkbox"/>	Box/ Carton	2D	Linear	RFID <input type="checkbox"/>
	Case	2D	Linear	RFID <input type="checkbox"/>
	Pallet	2D	Linear	RFID <input type="checkbox"/>

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry? No

Website URL: _____

Comments / Details: (For example, IPledge program?) _____

REMS or REGISTRY RESTRICTIONS

Contact tel. # if product received damaged: 800-397-8228

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. Requester can be made via fax: 815-624-7687 or email: customercare@lagpharma.com

RETURN INSTRUCTIONS

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here: _____

MISCELLANEOUS NOTES and/or change of Product Barcode: _____

N/A

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. Autotax Yes No Fax Number: 815-624-7687

c. Fax Yes No Fax Number: 815-624-7687

d. Phone only Yes No Phone No.: 800-397-9228

e. Supplier Web Site only No Yes Site Address: _____

Minimum Order Quantity: 12 Bottles (1 Case) by Wholesaler

Supplier's Customer Service Number: 815-624-7685

Contracted 3PL company / contact #: _____

Name: _____

Phone: _____

Standard Order Receipt and Processing

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

Out of time: _____

Shipping lead time of P.O.: _____ 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

Overnight and Priority Overnight PO Processing

Expedited freight fees billed with each order: Yes No

Drop Ship service fee billed with each order: Yes No

Drop Ship miscellaneous fees billed: No Yes

Comments: _____

Overnight receipt available: Yes No

PO Receipt cut off time: 12:00 PM Central

Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday

Priority Overnight receipt available: Yes No

PO Receipt Cut off time: 12:00 PM

Saturday Overnight receipt available: No Yes

PO Receipt Cut off time: 8:00-397-9228

Order receipt method: Yes No Phone #: 815-624-7687

Fax: Yes No

EDI: Yes No

Overnight Fees apply: Yes No

Other fees apply: No Yes

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) No Yes

Comments: _____

REMS or Registry Restrictions

REMS: No Yes

REMS Program Manager Name: _____ Phone: _____

Supplier Manages REMS registry exclusively: Yes No

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 # if product is received damaged: 800-397-9228

Is product returnable for credit: Yes No

URL/link to return policy: N/A

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 _____

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure? Yes No

Is product order for restocking purposes? Yes No

Miscellaneous Notes:

Other Data Information Required to Process PO: _____

Patient Procedure Date: _____

Physician Name: _____

Physician/Clinic Phone #: _____

Physician State License #: _____

Physician/Clinic DEA #: _____

Physician/Clinic Specialty: _____