CHDMA

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:	New Item	☐ **Final Version** **Date:** 8/25/2014

PRODUCT INFORMATION

Company Name:	Zydus Pharmaceuticals USA Inc.
	Application: ANDA
Application Number for NDA/ANDA/BLA, Med Device:	77-290
Rx Product/Proprietary Name:	Oxycodone Hydrochloride Tablets, USP 10 mg, 100 ct
NDC: 68382-794-01	**UPC:** 368382794017
CVX Code:	**MVX Code:**
Description:	Pink round, flat face, bevel edge tablets, debossed "NP" (closed P) with a partial bisect on one side and "12" on the other.
Active ingredients:	Oxycodone
URL for Additional Product Information:	www.zydususa.com
Address: 73 Route 31 North	**Address 2:**
City: Pennington	**State:** NJ **Zip:** 08534
Key Contact:	**Email:**
Phone Number: (609) 730 1900	**Fax:** (609) 730 1991

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB	**II. Brand Name:** Roxicodone
III. Generic Equivalent for Brand:	Oxycodone Hydrochloride Tablets, USP 10 mg, 100 ct

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes
DUNS:	156861945
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
If Yes, was original product purchased direct from mfr?	
Is product sold by manufacturer's exclusive distributor?	No
Are any waivers granted for product ID/barcode?	No
If yes, attach documentation from FDA	

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)
x	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:
- **Name:**
- **Number:**

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?	No
e. Shelf life: 24 **Months**	
Initial shelf life at launch (if different):	**Months**

ADDITIONAL PRODUCT INFORMATION

Is the Product…	Direct Ship Item
Legend Device?	No
State Control?	Yes
ARCOS reportable?	Yes
Co-Licensed?	No
Controlled Substance?	Yes
Schedule No.? (incl. N for non-narcotic)	II
Controlled Substance Code:	
Hazardous Material/Cytotoxic Agent?	No
Is Item…	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
Is it reverse numbered?	

ORDER INFORMATION

Unit of Sale

	Unit	**What is the NDC selling unit?**
x	Bottle	Each
	Box/Carton	
	Ampule	(Write-in, e.g. 1 Box of 10 Vials)
	Glass	
	Tube	**Minimum order quantity?** Yes
	Vial Liquid Sgl	
	Vial Liquid Multi	**If Yes, how many of which package type?**
	Vial Powder Sql	
	Vial Power Multi	Each
	Other: Write In	Inner/Carton/Pack
		1 Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

x	Each
	Gram
	Milliliter

Other Product Information

Size/Strength/Form:	100ct/10mg/Tablets
Product Shape:	Round
Product Color:	Pink
Product Imprint:	NP 12

ITEM AND PACKING INFORMATION

	Weight Lbs.	Depth	Height	Width:	Volume (Cube)	# Pieces:
Item:	22.95 G		3.23	1.77	5.7171	
Box/Carton:					0	
Case:	0.67LBS	5.6	4.75	7.5	199.5	12
Pallet:		48	44	40	84480	344
UPC:	**Case:**					
	Carton:					

Dimensions (US msmts.)

COST INFORMATION

Regular Cost Per Unit of Sale ($)	Invoice Cost (WAC) ($)	Federal Excise Tax Per Unit of Sale
	$50.00	

As of date: 9/10/2014

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:**