



☐ Final Version

☒ New Item ☐ Promotion/Deal ☐ Open Stock ☐ Post Launch Change

Date: 7/28/2014

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*									
Company Name: Amneal Pharmaceuticals		<input type="checkbox"/> NDA <input checked="" type="checkbox"/> ANDA <input type="checkbox"/> BLA <input type="checkbox"/> Med Device #		a. Temperature – Indicate the USP temperature range for this product.									
Application number for NDA/ ANDA/ BLA, Med Device: 203638				<input type="checkbox"/> I. Freezer – between -25 and -10 C (-13° – 14° F)									
Rx Product / Proprietary Name: Oxycodone Hydrochloride Tablets, USP 30mg				<input type="checkbox"/> II. Cold – between 2 and 8 C (36° – 46° F)									
NDC: 65162-051-10		UPC: 3-6516205110-0		<input type="checkbox"/> III. Cool – between 8 and 15 C (46° – 59° F)									
CVX Code:		MVX Code:		<input checked="" type="checkbox"/> IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)									
Description: Blue, round, biconvex tablets debossed with "A" on the left and "51" on the right of the score on one side and plain on the other side.				<input type="checkbox"/> V. Avoid Excessive Heat – above 40 C (>104° F)									
Active ingredients: Oxycodone Hydrochloride				<input type="checkbox"/> VI. Other Temperature Range Requirement (write in) _____									
URL for additional product information:				<input type="checkbox"/> VII. No Requirement									
Address: 118 Beaver Trail		Address 2:		b. Contact for temperature excursion questions:									
City: Glasgow		State: KY		Name: _____ Number: 866-525-7270									
Key Contact:		Email:		Is this product to be shipped to customers on ice? <input type="radio"/> Yes <input checked="" type="radio"/> No									
Phone Number: 866-525-7270		Fax: 866-525-7271		Is this product to be shipped to customers on dry ice? <input type="radio"/> Yes <input checked="" type="radio"/> No									
FOR GENERIC DRUG PRODUCTS				c. Special regulations for this product in certain states? <input type="radio"/> *Yes <input checked="" type="radio"/> No									
I. Orange Book Rating: AB		II. Brand Name: Roxycodone		Special returns requirements for this product? <input type="radio"/> *Yes <input checked="" type="radio"/> No									
III. Generic Equivalent for Brand: Oxycodone Hydrochloride Tablets, USP 30mg				d. Store product (unit of sale) upright? <input checked="" type="radio"/> Yes <input type="radio"/> No									
ADDITIONAL PRODUCT INFORMATION				Protect product (unit of sale) from light? <input checked="" type="radio"/> Yes <input type="radio"/> No									
Serialized? <input checked="" type="radio"/> Yes <input type="radio"/> No		Level		How?		GTIN-14							
		<input type="checkbox"/> Item		<input type="checkbox"/> 2D <input type="checkbox"/> Linear <input type="checkbox"/> RFID		50365162051105							
		<input checked="" type="checkbox"/> Case		<input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear <input type="checkbox"/> RFID									
		<input type="checkbox"/> Pallet		<input type="checkbox"/> 2D <input type="checkbox"/> Linear <input type="checkbox"/> RFID									
Is the Product... <input checked="" type="checkbox"/> Direct Ship Item <input type="checkbox"/> Direct and Drop Ship <input type="checkbox"/> Drop Ship only item (See new page 3.)				e. Shelf life: 24 Months Initial shelf life at launch (if different): _____ Months									
a Legend Device? <input type="radio"/> Yes <input checked="" type="radio"/> No				ITEM AND PACKING INFORMATION									
a State Control? <input checked="" type="radio"/> Yes <input type="radio"/> No													
ARCOS reportable? <input checked="" type="radio"/> Yes <input type="radio"/> No													
Co-Licensed? <input type="radio"/> Yes <input checked="" type="radio"/> No													
Repackaged? <input type="radio"/> Yes <input checked="" type="radio"/> No													
Controlled Substance? <input checked="" type="radio"/> Yes <input type="radio"/> No													
Schedule No.? CII (incl. N for non-narcotic)													
Hazardous Material / Cytotoxic Agent? <input type="radio"/> *Yes <input type="radio"/> No													
Is Item... <input type="radio"/> Unit Dose <input type="radio"/> Unit of Use													
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="radio"/> Yes <input type="radio"/> No													
Is it reverse numbered? <input type="radio"/> Yes <input type="radio"/> No													
WHOLESALER USE ONLY:													
Vendor #:													
Whsl. Code #:													
Fineline Code:													
Order Information		Unit of Sale		What is the NDC selling unit?		Weight Lbs.		Dimensions (US msmts.)		Volume (Cube)		# Pieces:	
		<input checked="" type="checkbox"/> Bottle		1 Bottle of 100 tablets		Item: 22.68gm		Depth		Height		Width:	
		<input type="checkbox"/> Box / Carton		(Write-in, e.g. 1 Box of 10 Vials)		Box/ Carton:							
		<input type="checkbox"/> Ampule		Minimum order quantity? <input checked="" type="radio"/> Yes <input type="radio"/> No		Case: 1.95 lbs		10"		3.25"		6.75"	
		<input type="checkbox"/> Glass		If Yes, how many of which package type?		Pallet:		40"		48"		40"	
		<input type="checkbox"/> Tube		24 <input checked="" type="checkbox"/> Each								0 392	
		<input type="checkbox"/> Vial Liquid Sgl		<input type="checkbox"/> Inner / Carton		UPC:							
		<input type="checkbox"/> Vial Liquid Multil		<input type="checkbox"/> Case		Case:							
		<input type="checkbox"/> Vial Powder Sgl				Carton:							
		<input type="checkbox"/> Vial Powder Multi											
		<input type="checkbox"/> Other: Write In											
PHARMACY ORDER / BILL UNIT		Other Product Information		COST INFORMATION									
Rec. sell unit to customer?		Size/Strength/Form:		Regular Cost Per Unit of Sale (\$)		Invoice Cost (WAC) (\$)		Federal Excise Tax Per Unit of Sale					
(Write-in, e.g. 1 Vial)		100ct/30mg/Tablets											
		Product Shape: round											
Rx billing unit to pharmacy:		Product Color: blue											
<input type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter		Product Imprint: A 51											

Attach copy of MATERIAL SAFETY DATA SHEET (MSDS) 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:

**MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION**

Is this product (check all that apply):

a. Cytotoxic?

☐ Yes ☒ No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?

☐ Yes ☒ No☐

Carcinogen

☐

Reproductive Toxicant

☐

Both

☐

Warning appears on label

c. Contact Hazard?

☐ Yes ☒ No

d. Does this product require special clean-up instructions?

☐ Yes ☒ No

(If yes, attach MSDS with special instructions.)

e. Does the product contain DEHP?

☐ Yes ☒ No**Hazardous Waste Identification**

EPA Hazardous Waste Code:

Is this product regulated for shipment by the DOT?

☐ Yes ☒ No

(if yes, answer a-d below and provide MSDS)

Is this a reportable quantity?

☐ Yes ☒ No

RQ Threshold:

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

☐ Yes ☒ No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

☐ Yes ☐ No

(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#

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.

☐

Organic

☐

Inorganic

☐

Antineoplastic

☐

Steroid/Androgen

☐

Corrosive

☐

Oxidizer

☐ Aerosol Class; Identify NFPA Storage Level:☐ Level 1☐ Level 2☐ Level 3☐ Listed Chemical (List I or II) (Indicate or Write-in below):☐

Ephedrine

☐

Pseudoephedrine

☐

Phenylpropanolamine

☐Iodine ($\geq 2.2\%$)☐

Other:

CLASS OF TRADE RESTRICTION:

No restriction: Sold to both 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:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

☐ Yes ☒ No

If Yes, is it managed with a pharmacy registry?

☐ Yes ☐ No

Website URL:

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

RETURN INSTRUCTIONS

Contact # if product recvd damaged: 866-525-7270

Is product returnable for credit:

☐ Yes ☐ No

URL/Link to returns policy:

Special regulations or returns requirements for this product

☐ Yes ☐ No

in certain states? If so, which states? Other requirements?

Comments:

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

MISCELLANEOUS NOTES and/or Image of Product Barcode: