



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Zydus Pharmaceuticals USA Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	90-460
Rx Product/Proprietary Name:	Tramadol Hydrochloride & Acetaminophen Tablets, USP 37.5mg/325mg, 100ct
NDC:	68382-334-01
UPC:	368382334015
CVX Code:	
MVX Code:	
Description:	White-color, capsule-shaped, bevel, biconvex, film-coated tablet, debossing '334' on one side and plain on the other side.
Active ingredients:	Tramadol & Acetaminophen
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

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
<input type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<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)
<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input type="checkbox"/>	VI. Other Temperature Range Requirement (write in) <input type="text"/>
<input type="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
Name:	<input type="text"/>
Number:	<input type="text"/>
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
c. Special regulations for product in certain states?	
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
e. Shelf life:	
<input type="text" value="24"/> Months	
Initial shelf life at launch (if different):	<input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Brand Name:	Ultracet
III. Generic Equivalent for Brand:	Tramadol Hydrochloride & Acetaminophen Tablets, USP 37.5mg/325mg, 100ct

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input checked="" type="text" value="Yes"/> Yes <input type="text" value="No"/> No
DUNS:	156861945
Is product exempt from DSCSA?	<input type="text" value="No"/> No
If yes, select exemption:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	<input type="text" value="No"/> No <input type="text" value="Yes"/> Yes
If Yes, was original product purchased direct from mfr?	<input type="text" value="No"/> No <input type="text" value="Yes"/> Yes
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="No"/> No <input type="text" value="Yes"/> Yes
Are any waivers granted for product ID/barcode?	<input type="text" value="No"/> No <input type="text" value="Yes"/> Yes
If yes, attach documentation from FDA	<input type="text"/>

ADDITIONAL PRODUCT INFORMATION	
Is the Product... Direct Ship Item	<input type="text"/>
Legend Device?	<input type="text" value="No"/> No
State Control?	<input type="text" value="Yes"/> Yes
ARCOS reportable?	<input type="text" value="Yes"/> Yes
Co-Licensed?	<input type="text" value="No"/> No
Controlled Substance?	<input type="text" value="Yes"/> Yes
Schedule No.?	<input type="text" value="IV"/> IV
(incl. N for non-narcotic)	
Controlled Substance Code:	<input type="text"/>
Hazardous Material/Cytotoxic Agent?	<input type="text" value="No"/> No
Is Item...	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>
Is it reverse numbered?	<input type="text"/>

ORDER INFORMATION	
Unit of Sale	<input checked="" type="checkbox"/> Bottle
	<input type="checkbox"/> Box/Carton
	<input type="checkbox"/> Ampule
	<input type="checkbox"/> Glass
	<input type="checkbox"/> Tube
	<input type="checkbox"/> Vial Liquid Sgl
	<input type="checkbox"/> Vial Liquid Multi
	<input type="checkbox"/> Vial Powder Sgl
	<input type="checkbox"/> Vial Powder Multi
	<input type="checkbox"/> Other: Write In <input type="text"/>
What is the NDC selling unit?	<input type="text" value="Each"/> Each
(Write-in, e.g. 1 Box of 10 Vials)	
Minimum order quantity?	<input type="text" value="Yes"/> Yes
If Yes, how many of which package type?	
	<input type="text" value="1"/> 1 Each
	<input type="text"/> Inner/Carton/Pack
	<input type="text"/> Case

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	68.94 G		3.425	1.878	6.43215	
Box/ Carton:					0	
Case:	5.00LBS	8.7	4.45	12.95	501.35925	24
Pallet:		47.24	48.03	39.37	89328.0576	104
UPC:						
Case:						
Carton:						

WHOLESALE USE ONLY:	
Vendor #:	<input type="text"/>
Whsl. Code #:	<input type="text"/>
Fineline Code:	<input type="text"/>

PHARMACY ORDER / BILL UNIT	Other Product Information
Rec. sell unit to customer?	Size/Strength/Form:
<input type="text" value="1"/> 1 (Write-in, e.g. 1 Vial)	100ct/37.5/325mg/Tablets
Rx billing unit to pharmacy:	Product Shape:
<input checked="" type="checkbox"/> Each	Capsule
<input type="checkbox"/> Gram	Product Color:
<input type="checkbox"/> Milliliter	White
	Product Imprint:
	334

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$60.00	
As of date: <input type="text" value="9/10/2014"/>		

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:



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? No

Carcinogen
 Reproductive Toxicant
 Both
 Warning appears on label

c. Contact Hazard? No

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

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? 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#

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

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

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

Passenger
 Cargo
 Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization						
Serialized?	Yes	Level	How?	RFID	GTIN-14	
Serialized?	<input checked="" type="checkbox"/>	Item	2D	Linear	<input type="checkbox"/>	10368382334012
If not, when?	<input type="text"/>	Box/Carton	2D	Linear	<input type="checkbox"/>	
Items aggregated to case?	<input type="text"/>	Case	2D	Linear	<input type="checkbox"/>	
		Pallet	2D	Linear	<input type="checkbox"/>	

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?)

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic Inorganic
 Antineoplastic Steroid/Androgen
 Corrosive Oxidizer

Aerosol Class; Identify NFPA Storage Level:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 877-993-8779

Is product returnable for credit:

URL/Link to returns policy: www.zydususa.com

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

If so, which states? Other requirements? Comments?

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine
 Pseudoephedrine
 Phenylpropanolamine
 Iodine (≥2.2%)
 Other:

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

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:

MISCELLANEOUS NOTES and/or Image of Product Barcode:



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PRODUCT INFORMATION	
Company Name:	Zydus Pharmaceuticals USA Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	90-460
Rx Product/Proprietary Name:	Tramadol Hydrochloride & Acetaminophen Tablets, USP 37.5mg/325mg, 500ct
NDC:	68382-334-05
UPC:	368382334053
CVX Code:	
MVX Code:	
Description:	White-color, capsule-shaped, bevel, biconvex, film-coated tablet, debossing '334' on one side and plain on the other side.
Active ingredients:	Tramadol & Acetaminophen
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North
City:	Pennington
State:	NJ
Zip:	08534
Key Contact:	
Phone Number:	(609) 730 1900
Address 2:	
Email:	
Fax:	(609) 730 1991

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
<input type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<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)
<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input type="checkbox"/>	VI. Other Temperature Range Requirement (write in) <input type="text"/>
<input type="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
Name:	<input type="text"/>
Number:	<input type="text"/>
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
c. Special regulations for product in certain states?	
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
e. Shelf life:	
<input type="text" value="24"/> Months	
Initial shelf life at launch (if different):	<input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Brand Name:	Ultracet
III. Generic Equivalent for Brand:	Tramadol Hydrochloride & Acetaminophen Tablets, USP 37.5mg/325mg, 500ct

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="text" value="Yes"/>
DUNS:	156861945
Is product exempt from DSCSA?	<input type="text" value="No"/>
If yes, select exemption:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	<input type="text" value="No"/>
If Yes, was original product purchased direct from mfr?	<input type="text"/>
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="No"/>
Are any waivers granted for product ID/barcode?	<input type="text" value="No"/>
If yes, attach documentation from FDA	<input type="text"/>

ADDITIONAL PRODUCT INFORMATION	
Is the Product... Direct Ship Item	<input type="text"/>
Legend Device?	<input type="text" value="No"/>
State Control?	<input type="text" value="No"/>
ARCOS reportable?	<input type="text" value="No"/>
Co-Licensed?	<input type="text" value="No"/>
Controlled Substance?	<input type="text" value="No"/>
Schedule No.?	<input type="text"/>
(incl. N for non-narcotic)	
Controlled Substance Code:	<input type="text"/>
Hazardous Material/Cytotoxic Agent?	<input type="text" value="No"/>
Is Item...	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>
Is it reverse numbered?	<input type="text"/>

ORDER INFORMATION	
Unit of Sale	<input checked="" type="checkbox"/> Bottle
	<input type="checkbox"/> Box/Carton
	<input type="checkbox"/> Ampule
	<input type="checkbox"/> Glass
	<input type="checkbox"/> Tube
	<input type="checkbox"/> Vial Liquid Sgl
	<input type="checkbox"/> Vial Liquid Multi
	<input type="checkbox"/> Vial Powder Sgl
	<input type="checkbox"/> Vial Power Multi
	<input type="checkbox"/> Other: Write In <input type="text"/>
What is the NDC selling unit?	Each
(Write-in, e.g. 1 Box of 10 Vials)	<input type="text"/>
Minimum order quantity?	<input type="text" value="Yes"/>
If Yes, how many of which package type?	
	<input type="text"/> Each
	<input type="text"/> Inner/Carton/Pack
	<input type="text"/> Case
	<input type="text" value="1"/>

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	278.70 G		5.1	2.88	14.688	
Box/ Carton:					0	
Case:	8.70LBS	9.41	6.1	12.48	716.36448	12
Pallet:		47.24	48.03	39.37	89328.0576	84
UPC:	Case:					
	Carton:					

WHOLESALE USE ONLY:	
Vendor #:	<input type="text"/>
Whsl. Code #:	<input type="text"/>
Fineline Code:	<input type="text"/>

PHARMACY ORDER / BILL UNIT	Other Product Information
Rec. sell unit to customer?	Size/Strength/Form:
<input type="text"/>	500ct/37.5/325mg/Tablets
(Write-in, e.g. 1 Vial)	Product Shape:
Rx billing unit to pharmacy:	Capsuled
<input checked="" type="checkbox"/> Each	Product Color:
<input type="checkbox"/> Gram	White
<input type="checkbox"/> Milliliter	Product Imprint:
	334

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$285.00	
As of date: <input type="text" value="9/10/2014"/>		

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:



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? No

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

c. Contact Hazard? No

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

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? 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#

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

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

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

Passenger

Cargo

Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization						
Serialized?	Yes	Level	How?	RFID	GTIN-14	
Serialized?	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	10368382334050
If not, when?	<input type="text"/>	<input checked="" type="checkbox"/> Box/ Carton	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	<input type="text"/>
Items aggregated to case?	<input type="text"/>	<input checked="" type="checkbox"/> Case	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	<input type="text"/>
		<input checked="" type="checkbox"/> Pallet	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	<input type="text"/>

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product?	<u>No</u>
If Yes, is it managed with a pharmacy registry?	<input type="text"/>
Website URL:	<input type="text"/>
Comments / Details: (For example, iPledge program?)	
<input type="text"/>	

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic Inorganic

Antineoplastic Steroid/Androgen

Corrosive Oxidizer

Aerosol Class; Identify NFPA Storage Level:

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged:	<u>877-993-8779</u>
Is product returnable for credit:	<input type="text"/>
URL/Link to returns policy:	<u>www.zydususa.com</u>
Special regulations or returns requirements for this product in certain states?	<u>No</u>
If so, which states? Other requirements? Comments?	<input type="text"/>

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, 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:

ADDITIONAL INFORMATION	
If Unit Dose NDC, indicate NDC here:	<input type="text"/>

MISCELLANEOUS NOTES and/or Image of Product Barcode:

