



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	ZYDUS PHARMACEUTICALS (USA) INC.
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	205253
DUNS:	156861945
Proprietary Name (If Applicable) and Established Name:	TRAZODONE HYDROCHLORIDE TABLETS USP, 50MG
Selling Unit NDC:	6838280501
Individual Unit NDC:	
UPC:	368382805010
UDI	
CVX Code:	
MVX Code:	
Description:	white to off-white, round-shape, biconvex beveled tablets, bisect on one side and plain on other side. The bisected side of tablet is debossed with '8' on upper side of bisect and '05' on lower side of bisect.
Active Ingredient(s):	TRAZODONE
URL for Additional Product Information:	
Address:	73 ROUTE 31 NORTH
City:	PENNINGTON
Key Contact:	
Phone Number:	(609) 730 1900
Product Therapeutic Classification:	
State:	NJ
Address 2:	
Zip:	08534
Email:	
Fax:	(609) 730 1998

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	
Is this product to be shipped to customers on ice?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> No
b. Contact for temperature excursion questions:	
Name:	
Number:	
Group E-mail:	
c. Special regulations for product in any states?	<input type="checkbox"/> No
Special returns requirements for this product?	
d. Store product (unit of sale) upright?	<input type="checkbox"/> No
Protect product (unit of sale) from light?	<input type="checkbox"/> No
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	<input type="checkbox"/> No
reverse numbered?	<input type="checkbox"/> No
co-licensed?	<input type="checkbox"/> No
Is the Product... Direct-Ship Only?	<input type="checkbox"/>
Is the Product... Neither?	<input type="checkbox"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>
If Unit Dose NDC, indicate NDC here:	<input type="text"/>
Country of Origin	<input type="text"/>
Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	100 COUNT
Strength:	50MG
Dosage Form:	TABLETS
Product Shape:	ROUND
Product Color:	WHITE TO OFF-WHITE
Product Imprint:	"8" & "05"

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 BOTTLE OF 100 TABLETS
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<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	
	Minimum order quantity? <input type="checkbox"/> Yes
	If Yes, how many of which package type?
	<input type="checkbox"/> Each
	<input type="checkbox"/> Inner/Carton/Pack
	<input checked="" type="checkbox"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Desyrel
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="1 BOTTLE OF 100 TABLETS"/>	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="checkbox"/> Yes
Is product exempt from DSCSA?	<input type="checkbox"/> No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	<input type="checkbox"/> No
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> No
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> No
GLN:	036382000002
If Yes, was original product purchased direct from mfr?	<input type="checkbox"/>
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	0.06	1.609	2.982	1.609	7.72004314	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	3.8	9.84	4.45	6.69	292.94172	24
Pallet:	626	48	40	48	92160	3840
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit	Quantity	GTIN-14		
No	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	1	00368382805010		
If not, when? 3/1/2018	<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="checkbox"/>				
Items aggregated? Yes	<input checked="" type="checkbox"/> Case	<input type="checkbox"/>	24	40368382805018		
	<input checked="" type="checkbox"/> Pallet	<input type="checkbox"/>		80368382805016		
		<input type="checkbox"/>				
		<input type="checkbox"/>				
		<input type="checkbox"/>				
		<input type="checkbox"/>				
		<input type="checkbox"/>				
		<input type="checkbox"/>				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$6.65	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	2/8/2018		



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Company Name:	ZYDUS PHARMACEUTICALS (USA) INC.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	205253
DUNS:	156861945
Proprietary Name (If Applicable) and Established Name:	TRAZODONE HYDROCHLORIDE TABLETS USP, 50MG
Selling Unit NDC:	6838280505
Individual Unit NDC:	
UDI	
CVX Code:	
UPC:	368382805058
MXV Code:	
Description:	white to off-white, round-shape, biconvex beveled tablets, bisect on one side and plain on other side. The bisected side of tablet is debossed with '8' on upper side of bisect and '05' on lower side of bisect.
Active Ingredient(s):	TRAZODONE
URL for Additional Product Information:	
Address:	73 ROUTE 31 NORTH
City:	PENNINGTON
State:	NJ
Address 2:	
Zip:	08534
Key Contact:	
Phone Number:	(609) 730 1900
Fax:	(609) 730 1998
Product Therapeutic Classification:	

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	No
reverse numbered?	No
co-licensed?	No
Is the Product... Direct-Ship Only	
Is the Product... Neither	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>
If Unit Dose NDC, indicate NDC here:	
Country of Origin	
Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	500 COUNT
Strength:	50MG
Dosage Form:	TABLETS
Product Shape:	ROUND
Product Color:	WHITE TO OFF-WHITE
Product Imprint:	"8" & "05"

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	Controlled Room – between 20 and 25 C (68° – 77°)
Temperature Range	
Other Temperature Range Requirement (write in)	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
b. Contact for temperature excursion questions:	
Name:	
Number:	
Group E-mail:	
c. Special regulations for product in any states?	No
Special returns requirements for this product?	
d. Store product (unit of sale) upright?	No
Protect product (unit of sale) from light?	No
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 BOTTLE OF 500 TABLETS
<input type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<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	
	Minimum order quantity? Yes
	If Yes, how many of which package type?
	<input type="checkbox"/> Each
	<input type="checkbox"/> Inner/ Carton/ Pack
	<input checked="" type="checkbox"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Desyrel
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="(Write-in, e.g. 1 Vial)"/>	<input checked="" type="checkbox"/> Each
	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
GLN:	036382000002
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/ Carton/ Bundle/ Inner Pack:	0.22	2.21	3.97	2.21	19.389877	1
Case:	5.54	9.06	6.81	7.09	437.443074	12
Pallet:	682	48	40	48	92160	1440
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION			
Serialized?	No		
If not, when?	3/1/2018		
Items aggregated?	Yes		
Level	Unit	Quantity	GTIN-14
<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	1	00368382805058
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	<input type="checkbox"/>		
<input checked="" type="checkbox"/> Case	<input type="checkbox"/>	12	40368382805056
<input checked="" type="checkbox"/> Pallet	<input type="checkbox"/>		80368382805054

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$30.40	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	2/8/2018		



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PRODUCT INFORMATION	
Company Name:	ZYDUS PHARMACEUTICALS (USA) INC.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	205253
DUNS:	156861945
Proprietary Name (If Applicable) and Established Name:	TRAZODONE HYDROCHLORIDE TABLETS USP, 50MG
Selling Unit NDC:	6838280510
Individual Unit NDC:	
UDI	
CVX Code:	
UPC:	368382805102
MXV Code:	
Description:	white to off-white, round-shape, biconvex beveled tablets, bisect on one side and plain on other side. The bisected side of tablet is debossed with '8' on upper side of bisect and '05' on lower side of bisect.
Active Ingredient(s):	TRAZODONE
URL for Additional Product Information:	
Address:	73 ROUTE 31 NORTH
City:	PENNINGTON
State:	NJ
Address 2:	
Zip:	08534
Key Contact:	
Phone Number:	(609) 730 1900
Fax:	(609) 730 1998
Product Therapeutic Classification:	

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	No
reverse numbered?	No
co-licensed?	No
Is the Product... Direct-Ship Only	
Is the Product... Neither	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>
If Unit Dose NDC, indicate NDC here:	
Country of Origin	
Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	1000 COUNT
Strength:	50MG
Dosage Form:	TABLETS
Product Shape:	ROUND
Product Color:	WHITE TO OFF-WHITE
Product Imprint:	"8" & "05"

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	Controlled Room – between 20 and 25 C (68° – 77°)
Temperature Range	
Other Temperature Range Requirement (write in)	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
b. Contact for temperature excursion questions:	
Name:	
Number:	
Group E-mail:	
c. Special regulations for product in any states?	No
Special returns requirements for this product?	
d. Store product (unit of sale) upright?	No
Protect product (unit of sale) from light?	No
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 BOTTLE OF 1000 TABLETS
<input type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<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	
	Minimum order quantity? Yes
	If Yes, how many of which package type?
	<input type="checkbox"/> Each
	<input type="checkbox"/> Inner/ Carton/ Pack
	<input checked="" type="checkbox"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Desyrel
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="(Write-in, e.g. 1 Vial)"/>	<input checked="" type="checkbox"/> Each
	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
GLN:	036382000002
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/ Carton/ Bundle/ Inner Pack:	0.43	2.643	4.971	2.643	34.724667	1
Case:	9.5	10.75	8.11	8.46	737.56395	12
Pallet:	825	48	40	48	92160	1020
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION			
Serialized?	No		
If not, when?	3/1/2018		
Items aggregated?	Yes		
Level	Unit	Quantity	GTIN-14
<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	1	00368382805102
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	<input checked="" type="checkbox"/>		
<input checked="" type="checkbox"/> Case	<input checked="" type="checkbox"/>	12	40368382805100
<input checked="" type="checkbox"/> Pallet	<input checked="" type="checkbox"/>		80368382805108

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$60.33	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	2/8/2018		