



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):	206534
DUNS:	156861945
Proprietary Name (If Applicable) and Established Name:	DILTIAZEM HYDROCHLORIDE EXTENDED-RELEASE CAPSULES, USP 180MG 90CT
Selling Unit NDC:	68382-596-16
Individual Unit NDC:	
UPC:	368382596161
UDI	
CVX Code:	
MVX Code:	
Description:	White to off white pellets filled in size "0" empty hard gelatin capsules with opaque light blue colored cap & opaque grey colored body imprinted with "596" in black ink.
Active Ingredient(s):	DILTIAZEM
URL for Additional Product Information:	
Address:	73 ROUTE 31 NORTH
City:	PENNINGTON
State:	NJ
Address 2:	
Zip:	08534
Key Contact:	
Email:	
Phone Number:	(609) 730 1900
Fax:	(609) 730 1998
Product Therapeutic Classification:	

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°)
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:	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

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 checked="" type="checkbox"/>
If Unit Dose NDC, indicate NDC here:	
Country of Origin	
Is this product covered under the Trade Agreements Act (TAA)?	<input checked="" type="checkbox"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	90 COUNT
Strength:	180MG
Dosage Form:	CAPSULES
Product Shape:	CAPSULES
Product Color:	OPAQUE LIGHT BLUE & OPAQUE GREY
Product Imprint:	"596"

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit? □
<input checked="" type="checkbox"/> Bottle	1 BOTTLE OF 90 CAPSULES
<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="text"/> Each
	<input type="text"/> Inner/Cartron/Pack
	<input checked="" type="checkbox"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	CARDIZEM CD
<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 90 CAPSULES"/>	<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?	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?	<input checked="" type="checkbox"/>
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	0.04	2.12	3.97	2.12	17.842768	1
Box/Cartron/Bundle/Inner Pack:					0	
Case:	5.24	13.26	8.85	5.11	599.66361	24
Pallet:	494.79	48	40	48	92160	2184
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	No	Level	Saleable Unit	Quantity	GTIN-14	
If not, when?	11/1/2018	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	1	00368382596161	
Items aggregated?	Yes	<input checked="" type="checkbox"/> Box/Cartron/Bundle/Inner Pack				
		<input checked="" type="checkbox"/> Case		24	40368382596169	
		<input checked="" type="checkbox"/> Pallet			80368382596167	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$76.18	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	9/7/2018		