



# 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):	205005
DUNS:	156861945
Proprietary Name (If Applicable) and Established Name:	NITROFURANTOIN CAPSULES, USP (MACROCRYSTALS) 100MG 100CT
Selling Unit NDC:	68382-560-01
Individual Unit NDC:	
UPC:	368382560018
UDI	
CVX Code:	
MVX Code:	
Description:	light yellow to yellow powder filled in size "2" empty hard gelatin capsules with blue opaque colored cap and blue opaque colored body imprinted with '560' in black ink.
Active Ingredient(s):	NITROFURANTOIN
URL for Additional Product Information:	
Address:	73 ROUTE 31 NORTH
City:	PENNINGTON
State:	NJ
Zip:	08534
Address 2:	
Key Contact:	
Email:	
Phone Number:	(609) 730 1900
Fax:	(609) 730 1998
Product Therapeutic Classification:	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
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>b. Contact for temperature excursion questions:</b>	
Name:	
Number:	
Group E-mail:	
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	No
<b>e. Shelf life:</b>	
Initial shelf life at launch (if different):	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 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:	100 COUNT
Strength:	100MG
Dosage Form:	CAPSULES
Product Shape:	CAPSULES
Product Color:	BLUE/BLUE
Product Imprint:	560

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit? <input type="checkbox"/>
<input checked="" type="checkbox"/> Bottle	1 BOTTLE OF 100 CAPSULES
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? Yes
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Multi	<input type="checkbox"/> Each
<input type="checkbox"/> Other: Write In	<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?:	MACRODANTIN
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer? <input type="checkbox"/>	Rx billing unit to pharmacy:
(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?	<input type="checkbox"/>
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.03	1.88	3.43	1.88	12.122992	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	4.8	11.29	7.51	4.33	367.131607	24
Pallet:	632	48	40	48	92160	3072
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit	Quantity	GTIN-14		
				2D	Linear	GTIN-14
No	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	1	<input checked="" type="checkbox"/>		00368382560018
If not, when?	<input type="checkbox"/> Box/Carton/Bundle/Inner Pack			<input type="checkbox"/>		
Items aggregated?	<input checked="" type="checkbox"/> Case		24	<input checked="" type="checkbox"/>		40368382560016
Yes	<input checked="" type="checkbox"/> Pallet			<input checked="" type="checkbox"/>		80368382560014
	<input type="checkbox"/>			<input type="checkbox"/>		
	<input type="checkbox"/>			<input type="checkbox"/>		
	<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) (\$)	\$166.11	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	9/10/2018		

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: