



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:  New Item

Final Version

Date: 10/28/2019

## PRODUCT INFORMATION

Company Name: TWI Pharmaceuticals USA, Inc Application: ANDA  
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 207206/S-001  
 DUNS: 080216652  
 Proprietary Name (If Applicable) and Established Name: Metoprolol Succinate Extended-Release Tablets USP  
 Selling Unit NDC: 24979-039-01 Individual Unit NDC: \_\_\_\_\_ UPC: 3 24979 03901 5  
 UDI: \_\_\_\_\_ CVX Code: \_\_\_\_\_ MVX Code: \_\_\_\_\_  
 Description: White, round tablets imprinted with: e701  
 Active Ingredient(s): Metoprolol Succinate  
 URL for Additional Product Information: \_\_\_\_\_  
 Address: 115 West Century Road Address 2: Suite 135  
 City: Paramus State: NJ Zip: 07652  
 Key Contact: Kari Olson Email: kari.olson@twipharmausa.com  
 Phone Number: 201-762-1409 Fax: 201-225-0051  
 Product Therapeutic Classification: Beta Blocker

### 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...  Unit of Use  
 If Unit Dose, is item bar coded to unit dose for hospital scanning?   
 If Unit Dose NDC, indicate NDC here: \_\_\_\_\_  
 Country of Origin: China  
 Is this product covered under the Trade Agreements Act (TAA)?  No

### PRODUCT DESCRIPTION INFORMATION

Size: 100 count  
 Strength: 100 mg  
 Dosage Form: Tablet  
 Product Shape: Round  
 Product Color: White  
 Product Imprint: e701

## 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?  No  
 Is this product to be shipped to customers on dry ice?  No  
 b. Contact for temperature excursion questions:  
 Name: Kari Olson  
 Number: 201-762-1409  
 Group E-mail: kari.olson@twipharmausa.com  
 c. Special regulations for product in any states?  No  
 Special returns requirements for this product?  No  
 d. Store product (unit of sale) upright?  No  
 Protect product (unit of sale) from light?  No  
 e. Shelf life:  Months  
 Initial shelf life at launch (if different): \_\_\_\_\_ Months

## ORDER INFORMATION

Unit of Sale:  Bottle  
 Box/Carton  
 Ampule  
 Glass  
 Tube  
 Vial Liquid Sgl  
 Vial Liquid Multi  
 Vial Powder Sgl  
 Vial Powder Multi  
 Other: Write In \_\_\_\_\_  
 What is the NDC selling unit?  
 1 bottle of 100 tablets  
 (Write-in, e.g. 1 Box of 10 Vials)  
 Minimum order quantity?  Yes  
 If Yes, how many of which package type?  
 Each  
 Inner/Carton/Pack  
 1 Case

## FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB  Authorized Generic \*If Authorized Generic, other section fields are not applicable  
 II. Generic Equivalent to What Brand?: Toprol XL

## PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? 1 Bottle  
 (Write-in, e.g. 1 Vial)  
 Rx billing unit to pharmacy:  
 1 Each  
 Gram  
 Milliliter

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

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

## ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.14	1.85	4.45	1.85	15.230125	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	3.8	11.6	4.4	7.9	403.216	24
Pallet:	760	46.6	44	39.5	80990.8	200
UPC:	Case:					
	Carton:					

## GTIN PRODUCT INFORMATION

Serialized? If not, when? Items aggregated?	Level	Item	Saleable Unit	Quantity	GTIN-14
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>		00324979039015
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Case	<input type="checkbox"/>		60324979039017
<input type="checkbox"/>		Pallet	<input type="checkbox"/>		
<input type="checkbox"/>			<input type="checkbox"/>		
<input type="checkbox"/>			<input type="checkbox"/>		
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<input type="checkbox"/>			<input type="checkbox"/>		
<input type="checkbox"/>			<input type="checkbox"/>		

## COST INFORMATION

Regular Cost \_\_\_\_\_ Vendor #: \_\_\_\_\_  
 Invoice Cost (WAC) (\$) \$18.00 Whsl. Code #: \_\_\_\_\_  
 Federal Excise Tax Per Unit of Sale \_\_\_\_\_  
 As of date: \_\_\_\_\_

## WHOLESALE USE ONLY:

Fineline Code: \_\_\_\_\_  
 Signature: \_\_\_\_\_