



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: 24979-038-01 Individual Unit NDC: _____ UPC: 3 24979 03801 8
 UDI: _____ CVX Code: _____ MVX Code: _____
 Description: White, round tablets imprinted with: e71
 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: 50 mg
 Dosage Form: Tablet
 Product Shape: Round
 Product Color: White
 Product Imprint: e71

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

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

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?

 (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
 Case

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.

PHARMACY ORDER / BILL UNIT

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

GTIN PRODUCT INFORMATION

Serialized?	Level	Saleable Unit	Quantity	GTIN-14
<input checked="" type="checkbox"/> Yes	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/> 2D	Linear	00324979038018
If not, when?	<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="checkbox"/> 2D	Linear	
Items aggregated?	<input checked="" type="checkbox"/> Case	<input type="checkbox"/> 2D	Linear	60324979038010
	<input type="checkbox"/> Pallet	<input type="checkbox"/> 2D	Linear	
		<input type="checkbox"/> 2D	Linear	
		<input type="checkbox"/> 2D	Linear	
		<input type="checkbox"/> 2D	Linear	
		<input type="checkbox"/> 2D	Linear	

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:	
		Depth	Height	Width			
Item:	0.09	1.7	4	1.7	11.56	1	
Box/Carton/Bundle/Inner Pack:					0		
Case:	2.55	10.6	3.9	7.2	297.648	24	
Pallet:	703.8	46.7	52.8	39.5	97397.52	276	
UPC:	Case:						
	Carton:						

COST INFORMATION

Regular Cost: _____ Vendor #: _____
 Invoice Cost (WAC) (\$): \$15.00 Whsl. Code #: _____
 Federal Excise Tax Per Unit of Sale: _____
 As of date: _____

WHOLESALE USE ONLY:

Fineline Code: _____
 Signature: _____