



# 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: 24979-037-03 Individual Unit NDC: \_\_\_\_\_ UPC: 3 24979 03703 5  
 UDI: \_\_\_\_\_ CVX Code: \_\_\_\_\_ MVX Code: \_\_\_\_\_  
 Description: White, oval tablets imprinted with: e7  
 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

### 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

### 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: 1000 count  
 Strength: 25 mg  
 Dosage Form: Tablet  
 Product Shape: Oval  
 Product Color: White  
 Product Imprint: e7

### 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

### FOR GENERIC DRUG PRODUCTS

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

### PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?   
 (Write-in, e.g. 1 Vial)  
 Rx billing unit to pharmacy:  
 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:	0.3	2.083	4.75	2.083	20.6097228	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	3.82	13.1	4.1	4.5	241.695	12
Pallet:	1260.6	45	45.1	39.3	79759.35	330
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"/>		00324979037035
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Case	<input type="checkbox"/>		60324979037037
<input type="checkbox"/>		Pallet	<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"/>			<input type="checkbox"/>		
<input type="checkbox"/>			<input type="checkbox"/>		

### COST INFORMATION

Regular Cost: \_\_\_\_\_ Vendor #: \_\_\_\_\_  
 Invoice Cost (WAC) (\$): \$230.00 Whsl. Code #: \_\_\_\_\_  
 Federal Excise Tax Per Unit of Sale: \_\_\_\_\_  
 As of date: \_\_\_\_\_

### WHOLESALE USE ONLY:

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

**For Designated Drop Ship Only Products, Please Use Page 3**  
**MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION**

Is this product (check all that apply):

a. Cytotoxic? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?

Is the product a CA Prop 65 carcinogen? No

Is the product a CA Prop 65 reproductive toxicant? No

Does the product label bear a CA Prop 65 warning? No

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No  
 (If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT or IATA? No  
 (if yes, answer a-e below and provide SDS)

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard? No

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

Is this a reportable quantity? No  
 RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?  
 No (if yes, identify method below)

Limited Quantity

Consumer Commodity, ORM-D

Small Quantity (49 CFR 173.4)

Special Permit; DOT-SP

Special Provision (listed in Column 7 of 49 CFR 172.101);  
 SP#

**ADD'L STORAGE INFORMATION**

Is the Product...

Controlled Substance? No

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic)

Controlled Substance Code

Listed Chemical (List I or II) No  
 If yes, indicate which:

Is it a scheduled listed chemical product? No

**CLASS OF TRADE RESTRICTION:**

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

SDS Hazard Classification	
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
<input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input type="text"/>	
Is the product a NIOSH hazardous drug? <span style="float: right;">No</span>	
If yes, indicate which: <input type="text"/>	

Hazardous Waste Identification	
EPA Hazardous Waste Code:	<input type="text"/>

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? <span style="float: right;">No</span>	
If Yes, is it managed with a pharmacy registry? <input type="text"/>	
Website URL: <input type="text"/>	
Comments / Details: (For example, iPledge program?) <input type="text"/>	
<b>REMS:</b> <input type="text"/>	
REMS Program Manager Name: <input type="text"/>	Phone: <input type="text"/>
Supplier Manages REMS registry exclusively: <input type="text"/>	
Wholesale distributor support: <input type="text"/>	
Provider Name: <input type="text"/>	
Site Enrollment Number assigned by Supplier: <input type="text"/>	DEA #: <input type="text"/>
	PCPDP #: <input type="text"/>
	NPI #: <input type="text"/>

Comments:

**Registry:**

Registry Program Contact Name:  Phone:

Comments:

**RETURN INSTRUCTIONS**

Contact tel. # if product received damaged:

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?

**MISCELLANEOUS NOTES and/or Image of Product Barcode:**

**FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.**

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p style="margin-left: 20px;">Name: <input type="text"/></p> <p style="margin-left: 20px;">Phone: <input type="text"/></p> <p style="margin-left: 20px;">Fax Number: <input type="text"/></p> <p style="margin-left: 20px;">Fax Number: <input type="text"/></p> <p style="margin-left: 20px;">Phone No.: <input type="text"/></p> <p style="margin-left: 20px;">Site Address: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 80px;" type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="checkbox"/> Phone: <input type="text"/> Phone #: <input type="text"/></p> <p style="margin-left: 20px;">Fax: <input type="text"/> Fax #: <input type="text"/></p> <p style="margin-left: 20px;">EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	Return Instructions
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input style="width: 100%; height: 80px;" type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 80px;" type="text"/></p>
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>
Miscellaneous Notes:	
<input style="width: 100%; height: 100px;" type="text"/>	