



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:  New Item

Final Version

Date:

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:	24979-039-02
Individual Unit NDC:	
UPC:	3 24979 03902 2
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
City:	Paramus
Key Contact:	Kari Olson
Phone Number:	201-762-1409
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:	
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... Unit of Use	
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	China
Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION	
Size:	500 count
Strength:	100 mg
Dosage Form:	Tablet
Product Shape:	Round
Product Color:	White
Product Imprint:	e701

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 bottle of 500 tablets
<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" value="1"/> Each
	<input type="text" value="1"/> Inner/Carton/Pack
	<input type="text" value="1"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Toprol XL
<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	<input type="text" value="1"/> Each
(Write-in, e.g. 1 Vial)	<input type="text" value=""/> Gram
	<input type="text" value=""/> 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:	
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.59	2.9	5.1	2.9	42.891	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	7.13	12.3	6.1	9.3	697.779	12
Pallet:	748.65	43.5	45	36.3	71057.25	105
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit		Quantity	GTIN-14	If not, when? Items aggregated?
		Item	Case			
<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	00324979039022	
<input type="checkbox"/>	Case	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	60324979039024	
<input type="checkbox"/>	Pallet	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>		
<input type="checkbox"/>		<input type="checkbox"/>	<input type="text"/>	<input type="text"/>		
<input type="checkbox"/>		<input type="checkbox"/>	<input type="text"/>	<input type="text"/>		
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<input type="checkbox"/>		<input type="checkbox"/>	<input type="text"/>	<input type="text"/>		
<input type="checkbox"/>		<input type="checkbox"/>	<input type="text"/>	<input type="text"/>		

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$125.00	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

**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> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">a. EDI</td> <td style="width: 15%;"><input type="text"/></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 20%;"></td> </tr> <tr> <td>b. Autofax</td> <td><input type="text"/></td> <td>Fax Number:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> <tr> <td>c. Fax</td> <td><input type="text"/></td> <td>Fax Number:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> <tr> <td>d. Phone only</td> <td><input type="text"/></td> <td>Phone No.:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td><input type="text"/></td> <td>Site Address:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> </table> <p>Minimum Order Quantity: <input style="width: 80%;" type="text"/></p> <p>Supplier's Customer Service Number: <input style="width: 95%;" type="text"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td><input style="width: 80%;" type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input style="width: 80%;" type="text"/></td> </tr> </table>	a. EDI	<input type="text"/>					b. Autofax	<input type="text"/>	Fax Number:	<input type="text"/>			c. Fax	<input type="text"/>	Fax Number:	<input type="text"/>			d. Phone only	<input type="text"/>	Phone No.:	<input type="text"/>			e. Supplier Web Site only	<input type="text"/>	Site Address:	<input type="text"/>			Name:	<input style="width: 80%;" type="text"/>	Phone:	<input style="width: 80%;" type="text"/>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input style="width: 80%;" type="text"/></p> <p>Shipping lead time of PO: <input style="width: 15%;" type="text"/> Hours <input style="width: 15%;" type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p>
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Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																																		
<p>Expedited freight fees billed with each order: <input style="width: 80%;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 80%;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 80%;" type="text"/></p> <p>Comments: <input style="width: 95%; height: 60px;" type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt cut off time: <input style="width: 80%;" type="text"/></p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table> <p><b>Priority Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 80%;" type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 80%;" type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">Phone:</td> <td style="width: 15%;"><input style="width: 50%;" type="text"/></td> <td style="width: 15%;">Phone #:</td> <td style="width: 15%;"><input style="width: 50%;" type="text"/></td> </tr> <tr> <td>Fax:</td> <td><input style="width: 50%;" type="text"/></td> <td>Fax #:</td> <td><input style="width: 50%;" type="text"/></td> </tr> <tr> <td>EDI:</td> <td><input style="width: 50%;" type="text"/></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p>	<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday	Phone:	<input style="width: 50%;" type="text"/>	Phone #:	<input style="width: 50%;" type="text"/>	Fax:	<input style="width: 50%;" type="text"/>	Fax #:	<input style="width: 50%;" type="text"/>	EDI:	<input style="width: 50%;" type="text"/>														
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Class of Trade Restriction:	Return Instructions																																		
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input style="width: 95%; height: 60px;" type="text"/></p>	<p>Contact # if product is received damaged: <input style="width: 80%;" type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: <input style="width: 80%;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments?  <input style="width: 95%; height: 40px;" type="text"/></p>																																		
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION																																		
<p>Patient Procedure Date: <input style="width: 80%;" type="text"/></p> <p>Physician Name: <input style="width: 80%;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 80%;" type="text"/></p> <p>Physician State License #: <input style="width: 80%;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 80%;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 80%;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>																																		
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