



# Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021 Introduction Type:  New Item  Final Version Date:

PRODUCT INFORMATION	SPECIAL HANDLING AND STORAGE REQUIREMENTS*
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<b>Company Name:</b> <input type="text" value="Xiromed LLC"/>		<b>Application:</b> <input type="text" value="ANDA"/>	
<b>Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):</b> <input type="text" value="211783"/>			
<b>Medical Device Class, if applicable:</b> <input type="text"/>			
<b>DUNS:</b> <input type="text" value="080228637"/>			
<b>Proprietary Name (If Applicable) and Established Name:</b> <input type="text" value="ESTRADIOL"/>			
<b>Selling Unit NDC:</b> <input type="text" value="70700-143-35"/>	<b>Unit of Use NDC:</b> <input type="text"/>	<b>UPC:</b> <input type="text" value="370700143353"/>	
<b>UDI</b>	<b>CVX Code:</b> <input type="text"/>	<b>MXV Code:</b> <input type="text"/>	
<b>Description:</b> <input type="text" value="Estradiol Gel 0.1% 0.25mg 30 packets"/>			
<b>Active Ingredient(s):</b> <input type="text" value="ESTRADIOL"/>			
<b>URL for Additional Product Information:</b> <input type="text" value="www.xiromed.com"/>			
<b>Address:</b> <input type="text" value="180 Park Ave"/>		<b>Address 2:</b> <input type="text" value="Suite 101"/>	
<b>City:</b> <input type="text" value="Florham Park"/>		<b>State:</b> <input type="text" value="NJ"/>	
<b>Key Contact:</b> <input type="text" value="Xiromed Regulatory"/>		<b>Zip:</b> <input type="text" value="07932"/>	
<b>Phone Number:</b> <input type="text" value="973-803-5520"/>		<b>Email:</b> <input type="text" value="usregulatory@xiromed.com"/>	
<b>Product Therapeutic Classification:</b> <input type="text"/>		<b>Fax:</b> <input type="text" value="862-286-0932"/>	

**a. Temperature – Indicate the USP temperature range for this product.**

Temperature Range:

Other Temperature Range Requirement (write in):

Notes:

Is this product to be shipped to customers on ice?

Is this product to be shipped to customers on dry ice?

**b. Contact for temperature excursion questions:**

Name:

Number:

Group E-mail:

**c. Special regulations for product in any states?**

Special returns requirements for this product?

**d. Store product (unit of sale) upright?**

Protect product (unit of sale) from light?

**e. Shelf life:**  Months

Initial shelf life at launch (if different):  Months

ADDITIONAL PRODUCT INFORMATION	PRODUCT DESCRIPTION INFORMATION
<p>The product is a legend device? <input type="text" value="No"/></p> <p>if yes, enter class # <input type="text"/></p> <p>a product kit? <input type="text" value="No"/></p> <p>if yes, list NDCs of component parts reverse numbered? <input type="text"/></p> <p>co-licensed? <input type="text" value="No"/></p> <p>latex-free? <input type="text" value="Yes"/></p> <p>preservative-free? <input type="text" value="Yes"/></p> <p>correctional institution block? <input type="text" value="Yes"/></p> <p>opioid? <input type="text" value="No"/></p> <p>Cannabinoid? <input type="text" value="No"/></p> <p>If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/></p> <p>If Unit Dose, indicate NDC here: <input type="text"/></p>	<p><b>Is the Product... Direct-Ship Only</b> <input type="text"/></p> <p><b>Is the Product... Neither</b> <input type="text"/></p> <p><b>Orphan Drug Status</b> <input type="text"/></p> <p><b>FDA Approval Status</b> <input type="text"/></p> <p><b>Allergens Present</b></p> <p><input checked="" type="checkbox"/> Not made with natural rubber latex.</p> <p><b>Country of Origin</b> <input type="text" value="Spain"/></p> <p>Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="Yes"/></p>
	<p><b>Size:</b> <input type="text" value="30x0.25mg packets"/></p> <p><b>Strength:</b> <input type="text" value="0.1%"/></p> <p><b>Dosage Form:</b> <input type="text" value="GEL"/></p> <p><b>Product Shape:</b> <input type="text"/></p> <p><b>Product Color:</b> <input type="text"/></p> <p><b>Product Imprint:</b> <input type="text"/></p>

**ORDER INFORMATION**

**Unit of Sale**

<input checked="" type="checkbox"/>	Bottle
<input type="checkbox"/>	Box/Carton
<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 Power Multi
<input type="checkbox"/>	Other: Write In

**What is the NDC selling unit?**   
(Write-in, e.g. 1 Box of 10 Vials)

**Minimum order quantity?**

**If Yes, how many of which package type?**

<input type="text" value="24"/>	Each
<input type="text"/>	Inner/ Carton/Pack
<input type="text"/>	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:**

<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?**

**Is product exempt from DSCSA?**

**GLN:**

**If yes, select exemption:**

**Other exemption - Write in:**

**GCP:**

**Is product repackaged?**

**Is product sold by manufacturer's exclusive distributor?**

**Has FDA granted waiver/exception/exemption for product?**

**If yes, attach documentation from FDA.**

**If yes, was original product purchased direct from mfr?**

**Provide source manufacturer for repackaged product**

**ITEM AND PACKING INFORMATION**

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.013	4.016	3.031	1.89	23.006017	1
<b>Box/Carton/Bundle/ Inner Pack:</b>					0	
<b>Case:</b>	1	14.375	10.875	8.25	1289.707	24
<b>Pallet:</b>					0	

**GTIN AND HIBCC PRODUCT INFORMATION**

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00370700143353	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		10370700143350	
<input type="checkbox"/> Pallet				

COST INFORMATION	WHOLESALE USE ONLY:
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<b>Regular Cost</b> <input type="text"/>	<b>Vendor #:</b> <input type="text"/>
<b>Invoice Cost (WAC) (\$)</b> <input type="text" value="\$126.43"/>	<b>Whsl. Code #:</b> <input type="text"/>
<b>As of date:</b> <input type="text"/>	<b>Fineline Code:</b> <input type="text"/>

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?            Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No            Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/> No            Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions?            (If yes, attach SDS with special instructions.) <input type="checkbox"/> Yes</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT?            (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by IATA?            (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger  <input type="checkbox"/> Cargo  <input type="checkbox"/> Passenger &amp; Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No            RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit?  <input type="checkbox"/> No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity  <input type="checkbox"/> Consumer Commodity, ORM-D  <input type="checkbox"/> Small Quantity (49 CFR 173.4)  <input type="checkbox"/> Special Permit; DOT-SP  <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);            SP# <input type="text"/></p>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; margin: 0;"><b>SDS Hazard Classification</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input type="checkbox"/> Organic</td> <td style="width: 50%; border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input checked="" type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p style="margin-top: 5px;">Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text"/> No</p> <p>NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? <input type="checkbox"/> Yes            If yes, indicate which: <input type="text"/> Group 2 items (non-antineoplastic that meets a hazard criterion)</p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; margin: 0;"><b>Hazardous Waste Identification</b></p> <p>EPA Hazardous Waste Code: <input type="text"/> Waste Characteristics: <input type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; margin: 0;"><b>REMS or REGISTRY RESTRICTIONS</b></p> <p>Is there a REMS on this product? <input type="checkbox"/> No            If Yes, is it managed with a pharmacy registry? <input type="checkbox"/>            Website URL: <input type="text"/></p> <p>Med Guide Required <input type="checkbox"/> No            Limited Distribution Requirement <input type="checkbox"/> No            Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p><b>REMS:</b></p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="checkbox"/>            Wholesale distributor support: <input type="checkbox"/></p> <p>Provider Name: <input type="text"/> DEA #: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/> NCPDP#: <input type="text"/>            NPI #: <input type="text"/></p> <p>Comments <input type="text"/></p> <p><b>Registry:</b></p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/>            Comments <input type="text"/></p> </div>	<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive	<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer	<input checked="" type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive						
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer						
<input checked="" type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard						
ADD'L STORAGE INFORMATION							
<p>Is the Product...</p> <p>Controlled Substance? <input type="checkbox"/> No      Controlled Substance Code <input type="text"/></p> <p>Controlled by State(s)? <input type="checkbox"/> No      Listed Chemical (List I or II) <input type="checkbox"/> No</p> <p>ARCOS Reportable? <input type="checkbox"/> No      If yes, indicate which: <input type="text"/></p> <p>Schedule No. <input type="text"/>      Is it a scheduled listed chemical product?: <input type="checkbox"/> No</p>							
CLASS OF TRADE RESTRICTION:							
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</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 type="text"/></p>							
RETURN INSTRUCTIONS							
<p>Contact tel. # if product 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 type="text"/></p>							
MISCELLANEOUS NOTES and/or Image of Product Barcode:							
<input type="text"/>							



# Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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