



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

Version 2021 Introduction Type:   Final Version Date:

PRODUCT INFORMATION	SPECIAL HANDLING AND STORAGE REQUIREMENTS*
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**Company Name:** CREEKWOOD PHARMACEUTICALS LLC **Application:** ANDA

**Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):** A218673

**Medical Device Class, if applicable:**

**DUNS:** 118582565

**Proprietary Name (If Applicable) and Established Name:** Metformin Hydrochloride Extended-Release Tablets, USP 500mg, 100 tablets per bottle

**Selling Unit NDC:** 82619-140-01 **Unit of Use NDC:** 82619-140-01 **UPC:** 382619140019

**UDI:** NA **CVX Code:** **MXV Code:** NA

**Description:** Metformin Hydrochloride Extended-Release Tablets, USP 500mg, 100 tablets per bottle  
[White to off white, oval (Modified Capsule) shaped tablet debossed with "M16" on one side and plain on another side. Tablets should be free from

**Active Ingredient(s):** Metformin Hydrochloride API

**URL for Additional Product Information:**

**Address:** 1130 US 46 W **Address 2:** Suite 21

**City:** Parsippany **State:** NJ **Zip:** 07054

**Key Contact:** Paul Thomas **Email:** paul@creekwoodpharma.com

**Phone Number:** 1-732-344-022 **Fax:**

**Product Therapeutic Classification:** Anti-hyperglycemic

**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:** SUJIT SAKPAL

**Number:** 551-303-9330

**Group E-mail:** sujit@creekwoodpharma.com

**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="No"/></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" value="No"/></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... Unit of Use</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> NA</p> <p><b>Country of Origin</b> INDIA</p> <p>Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/></p>
	<p><b>Size:</b> 100</p> <p><b>Strength:</b> 500mg</p> <p><b>Dosage Form:</b> Tablets</p> <p><b>Product Shape:</b> Oval (Modified Capsule) shaped</p> <p><b>Product Color:</b> White to off-white</p> <p><b>Product Imprint:</b> Debossed with "M16" on one side on one side and</p>

**ORDER INFORMATION**

<p><b>Unit of Sale</b></p> <p><input checked="" type="checkbox"/> Bottle</p> <p><input type="checkbox"/> Box/Carton</p> <p><input type="checkbox"/> Ampule</p> <p><input type="checkbox"/> Glass</p> <p><input type="checkbox"/> Tube</p> <p><input type="checkbox"/> Vial Liquid Sgl</p> <p><input type="checkbox"/> Vial Liquid Multi</p> <p><input type="checkbox"/> Vial Powder Sgl</p> <p><input type="checkbox"/> Vial Power Multi</p> <p><input type="checkbox"/> Other: Write In <input type="text"/></p>	<p><b>What is the NDC selling unit?</b> <input type="text" value="1 bottle of 100 Tablets"/></p> <p>(Write-in, e.g. 1 Box of 10 Vials)</p> <p><b>Minimum order quantity?</b> <input type="text" value="Yes"/></p> <p><b>If Yes, how many of which package type?</b></p> <p><input type="text" value="24"/> Each</p> <p><input type="text" value="1"/> Inner/ Carton/ Pack</p> <p><input type="text" value="1"/> Case</p>
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**FOR GENERIC DRUG PRODUCTS**

Authorized Generic \*If Authorized Generic, other section fields are not applicable

**I. Orange Book Rating:**

**II. Generic Equivalent to What Brand?:**

**PHARMACY ORDER / BILL UNIT**

<p><b>Rec. sell unit to customer?</b> <input type="text" value="1 bottle"/></p> <p>(Write-in, e.g. 1 Vial)</p>	<p><b>Rx billing unit to pharmacy:</b></p> <p><input checked="" type="checkbox"/> Each</p> <p><input type="checkbox"/> Gram</p> <p><input type="checkbox"/> Milliliter</p>
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**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

Does supplier meet DSCSA definition of manufacturer?

Is product exempt from DSCSA?

If yes, select exemption:

Other exemption - Write in:

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.

**GLN:** 850045940003

**GCP:** 850045940

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:	0.2998		2.63	4.13	10.84125	1
<b>Box/Carton/Bundle/ Inner Pack:</b>						
<b>Case:</b>	7.1991	11.22	8.06	9.842	890.044	24
<b>Pallet:</b>	480.4316	47.24	39.37	46.456	86400.7	60

**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		00382619140019	382619140019
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		20382619140013	
<input checked="" type="checkbox"/> Pallet	60			

**COST INFORMATION**

**Regular Cost**

**Invoice Cost (WAC) (\$)**

As of date:

**WHOLESALE USE ONLY:**

**Vendor #:**

**Whsl. Code #:**

**Fineline Code:**

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION	
<b>Is this product (check all that apply):</b>	
a. Cytotoxic?	<input type="checkbox"/> No
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	<input type="checkbox"/> No
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
c. Contact Hazard?	<input type="checkbox"/> No
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	<input type="checkbox"/> No
e. Does the product contain DEHP?	<input type="checkbox"/> No
<b>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)</b>	
a. UN/Identification Number	<input type="text"/>
b. Proper Shipping Name	<input type="text"/>
c. DOT Hazard Class	<input type="text"/>
d. Packing Group	<input type="text"/>
e. Inhalation Hazard?	<input type="checkbox"/> No
<b>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)</b>	
a. UN/Identification Number	<input type="text"/>
b. Proper Shipping Name	<input type="text"/>
c. DOT Hazard Class	<input type="text"/>
d. Packing Group	<input type="text"/>
e. Inhalation Hazard?	<input type="checkbox"/> No
<b>Is the product restricted for air shipment? If so, indicate restriction:</b>	
<input type="checkbox"/> Passenger	<input type="checkbox"/> No
<input type="checkbox"/> Cargo	
<input type="checkbox"/> Passenger & Cargo	
<b>Is this a reportable quantity? <input type="checkbox"/> No</b>	
RQ Threshold:	<input type="text"/>
<b>Is this a marine pollutant? <input type="checkbox"/> No</b>	
<b>Is this product shipped utilizing an authorized DOT exception or Special Permit?</b>	
<input type="checkbox"/> No (if yes, identify method below)	
<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"/>	
ADD'L STORAGE INFORMATION	
<b>Is the Product...</b>	
Controlled Substance?	<input type="checkbox"/> No
Controlled by State(s)?	<input type="checkbox"/> No
ARCOS Reportable?	<input type="checkbox"/> No
Schedule No.	<input type="text"/>
Controlled Substance Code	<input type="text"/>
Listed Chemical (List I or II)	<input type="checkbox"/> No
If yes, indicate which:	<input type="text"/>
Is it a scheduled listed chemical product?:	<input type="checkbox"/> No
CLASS OF TRADE RESTRICTION:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	<input type="checkbox"/> Yes
Restricted to retail pharmacy only:	<input type="text"/>
Restricted to hospital, clinics, and physician offices only:	<input type="text"/>
Restricted from US territories? (explain in comments)	<input type="text"/>
Comments:	<input type="text"/>
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
Does the product have an Aerosol class? If yes, identify NFPA Storage Level:	<input type="checkbox"/> No
NFPA Storage Level:	<input type="text"/>
Is the product a NIOSH hazardous drug? If yes, indicate which:	<input type="checkbox"/> No
	<input type="text"/>
Hazardous Waste Identification	
EPA Hazardous Waste Code:	<input type="text"/>
Waste Characteristics	<input type="text"/>
REMS or REGISTRY RESTRICTIONS	
<b>Is there a REMS on this product?</b>	
If Yes, is it managed with a pharmacy registry?	<input type="checkbox"/> No
Website URL:	<input type="text"/>
<b>Med Guide Required</b>	
Limited Distribution Requirement	<input type="checkbox"/> No
Comments / Details: (For example, iPledge program?)	<input type="text"/>
<b>REMS:</b>	
REMS Program Manager Name:	<input type="text"/>
Supplier Manages REMS registry exclusively:	<input type="checkbox"/> No
Wholesale distributor support:	<input type="text"/>
Provider Name:	<input type="text"/>
Site Enrollment Number assigned by Supplier:	<input type="text"/>
DEA #:	<input type="text"/>
NCPDP#:	<input type="text"/>
NPI #:	<input type="text"/>
Phone:	<input type="text"/>
Comments	<input type="text" value="IT IS NOT A REMS PRODUCT"/>
<b>Registry:</b>	
Registry Program Contact Name:	<input type="checkbox"/> No
Comments	<input type="text" value="IT IS NOT A REMS PRODUCT"/>
Phone:	<input type="text"/>
RETURN INSTRUCTIONS	
<b>Contact tel. # if product received damaged:</b>	
Is product returnable for credit:	<input type="text"/>
URL/Link to returns policy:	<a href="https://creekwoodpharma.com/wp-content/uploads/2023/07/Return-Goods-Policy.pdf">https://creekwoodpharma.com/wp-content/uploads/2023/07/Return-Goods-Policy.pdf</a>
<b>Special regulations or returns requirements for this product in certain states?</b>	
If so, which states? Other requirements? Comments?	<input type="text"/>
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"/> Yes b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Units Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: Name: <input type="text"/> Direct customer solutions (R & S) Phone: <input type="text"/> 1-800-655-7556 Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <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:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>