



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

Version 2024

Introduction Type:  New Item Final VersionDate:  4/29/2025

| PRODUCT INFORMATION   |                                 |  |                          | SPECIAL HANDLING AND STORAGE REQUIREMENTS*  |                |                            |  |
|---|---------------------------------|--|--------------------------|---|----------------|----------------------------|--|
| <b>Company Name:</b> SOLA Pharmaceuticals   |                                 |  |                          | <b>Application:</b> ANDA  |                |                            |  |
| <b>Application Number for NDA/ANDA/BLA; PMA/510(k):</b> 209102                          |                                 |  |                          | <b>NDA 505(b) Type:</b>   |                |                            |  |
| <b>Medical Device Class, if applicable:</b>   |                                 |  |                          |   |                |                            |  |
| <b>DUNS:</b> 080121345  |                                 |  |                          |   |                |                            |  |
| <b>Proprietary Name (If Applicable) and Established Name:</b> Baclofen Tablets USP 10mg |                                 |  |                          |   |                |                            |  |
| <b>Selling Unit NDC:</b> 70512-782-10   |                                 |  |                          | <b>Unit of Use NDC:</b>   |                |                            |  |
| <b>UDI</b>  |                                 |  |                          | <b>UPC:</b> 370512782108  |                |                            |  |
| <b>CVX Code:</b>  |                                 |  |                          | <b>MVX Code:</b>  |                |                            |  |
| <b>Description:</b> Baclofen Tablets USP 10mg 100ct                                     |                                 |  |                          |   |                |                            |  |
| <b>Active Ingredient(s):</b> Baclofen   |                                 |  |                          |   |                |                            |  |
| <b>URL for Additional Product Information:</b>  |                                 |  |                          |   |                |                            |  |
| <b>Address:</b> 655 Highlandia Dr.  |                                 |  |                          | <b>Address 2:</b>   |                |                            |  |
| <b>City:</b> Baton Rouge  |                                 |  |                          | <b>State:</b> LA <b>Zip:</b> 70810  |                |                            |  |
| <b>Key Contact:</b>   |                                 |  |                          | <b>Email:</b> <a href="mailto:info@solameds.us">info@solameds.us</a>  |                |                            |  |
| <b>Phone Number:</b> 866-747-7365   |                                 |  |                          | <b>Fax:</b> 800-754-9550  |                |                            |  |
| <b>Product Therapeutic Classification:</b> Muscle Relaxant/Antispasmodic Agent          |                                 |  |                          |   |                |                            |  |
| ADDITIONAL PRODUCT INFORMATION  |                                 |  |                          | PRODUCT DESCRIPTION INFORMATION   |                |                            |  |
| <b>The product is?</b>  |                                 | <b>Is the Product...</b>   |                          | <b>Size:</b>  |                | <b>100ct</b>               |  |
| <b>a legend device?</b>   |                                 | <b>Is the Product...</b>   |                          | <b>Strength:</b>  |                | <b>10mg</b>                |  |
| <b>if yes, enter class #</b>  |                                 | <b>Orphan Drug Status</b>  |                          | <b>Dosage Form:</b>   |                | <b>Tablet; Oral</b>        |  |
| <b>a product kit?</b>   |                                 |  |                          | <b>Product Shape:</b>   |                | <b>Round</b>               |  |
| <b>if yes, list NDCs of component parts</b>   |                                 | <b>FDA Approval Status</b>   |                          | <b>Product Color:</b>   |                | <b>White</b>               |  |
| <b>reverse numbered?</b>  |                                 |  |                          | <b>Product Imprint:</b>   |                | <b>24</b>                  |  |
| <b>co-licensed?</b>   |                                 | <b>Allergens Present</b>   |                          |   |                |                            |  |
| <b>latex-free?</b>  |                                 |  |                          |   |                |                            |  |
| <b>preservative-free?</b>   |                                 | <b>Country of Origin</b>   |                          |   |                |                            |  |
| <b>correctional institution block?</b>  |                                 | <b>India</b>   |                          |   |                |                            |  |
| <b>opioid?</b>  |                                 |  |                          |   |                |                            |  |
| <b>Cannabinoid?</b>   |                                 |  |                          |   |                |                            |  |
| <b>If Unit Dose, is item bar coded to unit dose for hospital scanning?</b>              |                                 | <b>Is this product covered under the Trade Agreements Act (TAA)?</b> |                          |   |                |                            |  |
| <b>If Unit Dose, indicate NDC here:</b>   |                                 | <b>No</b>  |                          |   |                |                            |  |
| FOR GENERIC DRUG PRODUCTS   |                                 |  |                          |   |                |                            |  |
| <b>I. Orange Book Rating:</b> AB  |                                 |  |                          | <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable |                |                            |  |
| <b>II. Generic Equivalent to What Brand?:</b> Lioresal                                  |                                 |  |                          |   |                |                            |  |
| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION                                      |                                 |  |                          |   |                |                            |  |
| <b>Does supplier meet DSCSA definition of manufacturer?</b>                             |                                 |  |                          | <b>GLN:</b> 0370512000004   |                |                            |  |
| <b>Is product exempt from DSCSA?</b>  |                                 |  |                          |   |                |                            |  |
| <b>If yes, select exemption:</b>  |                                 |  |                          | <b>GCP:</b> 0370512   |                |                            |  |
| <b>Other exemption - Write in:</b>  |                                 |  |                          |   |                |                            |  |
| <b>Is product repackaged?</b>   |                                 |  |                          | <b>If yes, was original product purchased direct from mfr?</b>  |                |                            |  |
| <b>Is product sold by manufacturer's exclusive distributor?</b>                         |                                 |  |                          | <b>Provide source manufacturer for repackaged product</b>   |                |                            |  |
| <b>Has FDA granted waiver/exception/exemption for product?</b>                          |                                 |  |                          |   |                |                            |  |
| <b>If yes, attach documentation from FDA.</b>   |                                 |  |                          |   |                |                            |  |
| GTIN AND HIBCC PRODUCT INFORMATION  |                                 |  |                          |   |                |                            |  |
| <b>Saleable Unit of Measure</b>   |                                 | <b>RFID tag(Y/N)</b>   | <b>Saleable Quantity</b> | <b>HIBCC</b>  | <b>GTIN-14</b> | <b>Unit of Use GTIN-14</b> |  |
| <input checked="" type="checkbox"/>   | Item/Each                       |  | 24                       |   | 00370512782108 |                            |  |
| <input checked="" type="checkbox"/>   | Box/ Carton/ Bundle/ Inner Pack |  |                          |   |                |                            |  |
| <input checked="" type="checkbox"/>   | Case                            |  | 1                        |   | 50370512782103 |                            |  |
| <input type="checkbox"/>  | Pallet                          |  |                          |   |                |                            |  |
| <b>ITEM AND PACKING INFORMATION</b>   |                                 |  |                          |   |                |                            |  |
|   | <b>Weight Lbs.</b>              | <b>Dimensions (US msmts.)</b>  | <b>Volume (Cube)</b>     | <b>Saleable # Pieces</b>  |                |                            |  |
|   | <b>Depth</b>                    | <b>Width</b>   | <b>Height</b>            |   |                |                            |  |
| <b>Item/Each:</b>   | 1                               | 1.5  | 2.2                      | 4.7   | 15.51          | 1                          |  |
| <b>Box/ Carton/ Bundle/ Inner Pack:</b>   |                                 |  |                          |   |                |                            |  |
| <b>Case:</b>  | 2.43                            | 10.3   | 7.3                      | 4.7   | 353.393        | 24                         |  |
| <b>Pallet:</b>  | 514                             | 48   | 40                       | 45  | 86400          | 4416                       |  |
| COST INFORMATION  |                                 |  |                          | WHOLESALE USE ONLY:   |                |                            |  |
| <b>Regular Cost</b>   |                                 | \$648.72   |                          | <b>Vendor #:</b>  |                |                            |  |
| <b>Invoice Cost (WAC) (\$)</b>  |                                 | \$540.60   |                          | <b>Whsl. Code #:</b>  |                |                            |  |
| <b>As of date:</b> 4/29/2025  |                                 |  |                          | <b>Fineline Code:</b>   |                |                            |  |

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING AND BARCODE.

\*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



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Version 2024

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?  
(If yes, attach SDS with special instructions.) ☐ No
- e. Does the product contain DEHP? ☐ No

Is this product regulated for shipment by DOT?  
(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 this product regulated for shipment by IATA?  
(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 Substance Code
- Controlled by State(s)? ☐ No Listed Chemical (List I or II) ☐ No
- ARCOS Reportable? ☐ No If yes, indicate which:
- Schedule No.  Is it a scheduled listed chemical product?: ☐

### CLASS OF TRADE RESTRICTION:

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

☐ Yes

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

- ☒ Organic ☐ Corrosive
- ☐ Inorganic ☐ Oxidizer
- ☐ Steroid/Androgen ☐ Contact Hazard

Does the product have an Aerosol class? If yes,  
identify NFPA Storage Level:

☐ No

NFPA Storage Level:

Is the product a NIOSH hazardous drug?  
If yes, indicate which:

☐ No

### Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

☐ No

If Yes, is it managed with a pharmacy registry?

☐ No

Website URL:

Med Guide Required

☐ No

Limited Distribution Requirement

☐ No

Comments / Details: (For example, iPledge program?)

#### REMS:

☐ No

REMS Program Manager Name:

Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

DEA #:

Site Enrollment Number assigned

NCPDP#:

by Supplier:

NPI #:

Comments

#### Registry:

☐ No

Registry Program Contact Name:

Phone:

Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

866-747-7365

Is product returnable for credit:

☐ Yes

URL/Link to returns policy:

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

☐ No

If so, which states? Other requirements? Comments?

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

Release DATE



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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   |
|---|---|
| <p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="text"/></p> <p>b. Autofax <input type="text"/></p> <p>c. Fax <input type="text"/></p> <p>d. Phone only <input type="text"/></p> <p>e. Supplier Web Site only <input type="text"/></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>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>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="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>  |
| <p><b>Expedited Freight Charges or Other Designated Drop Ship Fees:</b></p> <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 type="text"/></p>   | <p><b>Overnight and Priority Overnight PO Processing</b></p> <p><b>Overnight receipt available:</b> <input type="text"/></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="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p> |
| <p><b>Class of Trade Restriction:</b></p> <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 type="text"/></p>  |   |
| <p><b>Other Data Information Required to Process PO:</b></p> <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><b>Return Instructions</b></p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></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="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>  |
| <p><b>Miscellaneous Notes:</b></p> <p><input type="text"/></p>  | <p><b>ADDITIONAL INFORMATION</b></p> <p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>  |