



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

Version 2021

Introduction Type:  New Item

Final Version

Date:

## PRODUCT INFORMATION

Company Name: SOLA Pharmaceuticals Application:

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

Medical Device Class, if applicable:

DUNS: 080121345

Proprietary Name (if Applicable) and Established Name: Triple Antibiotic Ointment 28.4gm

Selling Unit NDC: 70512-102-30 Unit of Use NDC:  UPC: 705120102305

UDI:  CVX Code:  MVX Code:

Description: Triple Antibiotic Ointment 28.4gm

Active Ingredient(s): Bacitracin Zinc USP 400 Units, Neomycin Sulfate USP 5mg, Polymixin B Sulfate USP 5,000 Units

URL for Additional Product Information:

Address: 655 Highlandia Dr. Address 2:

City: Baton Rouge State: LA Zip: 70810

Key Contact:  Email: [info@solameds.us](mailto:info@solameds.us)

Phone Number: 866-747-7365 Fax: 800-754-9550

Product Therapeutic Classification: First Aid Antibiotic

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

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?  No

Is this product to be shipped to customers on dry ice?  No

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?  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):  Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class #	<input type="checkbox"/> No	Is the Product... Is the Product... Orphan Drug Status	<input type="checkbox"/> Direct-Ship Only
if yes, list NDCs of component parts reverse numbered?	<input type="checkbox"/> No	FDA Approval Status	<input type="text"/>
co-licensed?	<input type="checkbox"/> No	Allergens Present	<input type="text"/>
latex-free?	<input type="checkbox"/> Yes	Country of Origin	<input type="text" value="India"/>
preservative-free?	<input type="checkbox"/> Yes	Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> No
correctional institution block?	<input type="checkbox"/> No	Size:	<input type="text" value="28.4g"/>
opioid?	<input type="checkbox"/> No	Strength:	<input type="text" value="Bacitracin Zinc USP 400 Units, Neomycin Sulfate USP 5mg, Polymixin B Sulfate USP 5,000 Units"/>
Cannabinoid?	<input type="checkbox"/> No	Dosage Form:	<input type="text" value="Ointment"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/> No	Product Shape:	<input type="text"/>
If Unit Dose, indicate NDC here:	<input type="text"/>	Product Color:	<input type="text" value="White ointment"/>
		Product Imprint:	<input type="text"/>

## ORDER INFORMATION

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 tube of 28.4g"/>
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="checkbox"/> Yes
<input checked="" type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Multi	<input type="text" value="240"/> Each
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> Inner/ Carton/ Pack
<input type="checkbox"/> Vial Power Multi	<input type="text"/> Case
<input type="checkbox"/> Other: Write In	

## 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

Rec. sell unit to customer?

Rx billing unit to pharmacy:

Each

Gram

Milliliter

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?  Yes

Is product exempt from DSCSA?  Yes

If yes, select exemption: Other exemption: (Write in)

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

If yes, attach documentation from FDA.

GLN:

GCP:

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		
	0.1	1.125	3.625	5.87	23.938594	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	24	12.5	12.5	17.5	2734.375	240
Pallet:	768	46	45	55	113850	7680

## 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		00370512104603	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	240		50370512104608	
<input type="checkbox"/> Pallet				

## COST INFORMATION

Regular Cost

Invoice Cost (WAC) (\$)

As of date:

Vendor #:

Whsl. Code #:

Fineline Code:

\*Please provide any additional information on page 2.

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

See new p. 3 for Designated Drop Ship Only.

Signature: