



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Item Final VersionDate:

PRODUCT INFORMATION	
Company Name:	Encube Ethicals Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	212438
DUNS:	11-698-2244
Proprietary Name (If Applicable) and Established Name:	Clindamycin Phosphate Gel USP, 1%
Selling Unit NDC:	21922-027-05
UDI	Individual Unit NDC: _____ CVX Code: _____ MVX Code: _____
UPC:	32192202705
Description:	Clear transparent gel, free from lumps and foreign particles. Packed in laminated tube with standup cap and legible label.
Active Ingredient(s):	Clindamycin Phosphate USP
URL for Additional Product Information:	
Address:	200 Meredith Avenue, Suite 101A
City:	Durham
Key Contact:	Kamesh Venugopal
Phone Number:	1-919-767-3292
Product Therapeutic Classification:	In the treatment of acne vulgaris
State:	NC
Zip:	27713
Address 2:	
Email:	Kamesh.V@encubeethicals.com
Fax:	984-439-2761

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)	Store at controlled room temperature
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:	Dipti Kamani
Number:	919-767-3292
Group E-mail:	usreg@encubeethicals.com
c. Special regulations for product in any states?	
Special returns requirements for this product?	
d. Store product (unit of sale) upright?	No
Protect product (unit of sale) from light?	No
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	No
reverse numbered?	
co-licensed?	
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?	
If Unit Dose NDC, indicate NDC here:	21922-027-05
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	

PRODUCT DESCRIPTION INFORMATION	
Size:	30 g tube
Strength:	1%
Dosage Form:	Topical Gel
Product Shape:	
Product Color:	Clear Transparent Gel
Product Imprint:	

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	21922-027-05
<input checked="" type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass Tube	Minimum order quantity?
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="checkbox"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="checkbox"/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<input type="checkbox"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	CLEOCIN T (Clindamycin Phosphate Gel USP, 1%)
<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="(Write-in, e.g. 1 Vial)"/>	<input type="checkbox"/> Each
	<input type="checkbox"/> Gram
	<input checked="" type="checkbox"/> 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:	8906005273444
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:	0.08816	4.3307087	1.3779528	1.1811024	7.04824244	1
Box/ Carton/ Bundle/ Inner Pack:	2.46848	7.4015748	4.5275591	5.7086614	191.303335	24
Case:	16.00104	13.976378	7.992126	11.811024	1319.30284	144
Pallet:	622.98264	43.346457	40.15748	36.889764	64213.4393	5184
UPC:	Case:					
	Carton:	32192202705				

GTIN PRODUCT INFORMATION						
Serialized?	Yes	Level		Unit	Quantity	GTIN-14
		Item	Saleable			
If not, when?		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	2D	1	00321922027051
Items aggregated?	Yes	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	2D	24	10321922027058
		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	2D	144	30321922027052
		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	2D	5184	50321922027056
				2D		
				2D		
				2D		
				2D		

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