HDA

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

Version 2024

Introduction Type: ____ | ☐ Final Version | Date: 16/05/2025

PRODUCT INFORMATION

Field	Value	Field	Value
Company Name:	CREEKWOOD PHARMACEUTICALS LLC	Application:	ANDA
Application Number for NDA/ANDA/BLA; PMA/510(k):	A040150	NDA 505(b) Type:	
Medical Device Class, if applicable:			
DUNS:	118582565		
Proprietary Name (If Applicable) and Established Name:	Hydroxychloroquine Sulfate Tablets, USP 200 mg 500's		
Selling Unit NDC:	82619-131-02	Unit of Use NDC:	82619-131-02
		UPC:	382619131024
UDI:		CVX Code:	MVX Code:

Description: Hydroxychloroquine sulfate tablets, USP 200 mg is white, capsule shaped film-coated tablets debossed with "III" on one side and plain on other side.

Active Ingredient(s): Hydroxychloroquine sulfate, USP

URL for Additional Product Information:

Field	Value		
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: Antimalarial and Antirheumatic

ADDITIONAL PRODUCT INFORMATION

Field	Value
The product is?	
a legend device?	No
if yes, enter class #	
a product kit?	No
if yes, list NDCs of component parts	
reverse numbered?	No
co-licensed?	No
latex-free?	Yes
preservative-free?	Yes
correctional institution block?	No
opioid?	No
Cannabinoid?	No
If Unit Dose, is item bar coded to unit dose for hospital scanning?	No
If Unit Dose, indicate NDC here:	

Field	Value
Is the Product...	Direct-Ship Only
Is the Product...	Unit of Use
Orphan Drug Status	
FDA Approval Status	
Allergens Present	Not present
Country of Origin	INDIA
Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION

Field	Value
Size:	13 mm
Strength:	200 mg
Dosage Form:	Tablet
Product Shape:	Capsule shaped
Product Color:	White
Product Imprint:	"III" on one side and plain on other side

FOR GENERIC DRUG PRODUCTS

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

Field	Value
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	PLAQUENIL

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Field	Value	Field	Value
Does supplier meet DSCSA definition of manufacturer?	Yes	GLN:	850045940003
Is product exempt from DSCSA?		GCP:	850045940
If yes, select exemption:			
Other exemption - Write in:			
Is product repackaged?	No	If yes, was original product purchased direct from mfr?	
Is product sold by manufacturer's exclusive distributor?	No		
Has FDA granted waiver/exception/exemption for product?	No	Provide source manufacturer for repackaged product	
If yes, attach documentation from FDA.			

GTIN AND HIBCC PRODUCT INFORMATION

	Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
x	Item/Each		1		00382619131024	382619131024
	Box/Carton/Bundle/Inner Pack					
x	Case		12		20382619131028	
x	Pallet		96			

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

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

Field	Value
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
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:

Field	Value
Name:	SUJIT SAKPAL
Number:	551-303-9330
Group E-mail:	sujit@creekwoodpharma.com

Field	Value
c. Special regulations for product in any states?	No
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:	24 Months
Initial shelf life at launch (if different):	24 Months

ORDER INFORMATION

Unit of Sale		What is the NDC selling unit?
x	Bottle	1 bottle of 500 Tablets
	Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
	Ampule	
	Glass	Minimum order quantity? Yes
	Tube	
	Vial Liquid Sgl	If Yes, how many of which package type?
	Vial Liquid Multi	
	Vial Powder Sql	12 Each
	Vial Power Multi	Inner/Carton/Pack
	Other: Write In	1 Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?	Rx billing unit to pharmacy:
1 bottle of 500 tablets	x Each
(Write-in, e.g. 1 Vial)	Gram
HCPCS J-Code:	Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	0.5	2.61	2.61	4.83	32.90	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	7.07	11.023	8.26	6.1	555.40	12
Pallet:	678.43	44.09	33.07	36.61	53379.44	96

(Dimensions in US msmts.)

COST INFORMATION

Field	Value
Regular Cost	
Invoice Cost (WAC) ($)	
As of date:	

WHOLESALER USE ONLY:

Field	Value
Vendor #:	
Whsl. Code #:	
Fineline Code:	

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

Is this product regulated for shipment by DOT?	No
(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?	No
(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:	No
☐ 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#	

SDS Hazard Classification

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

Does the product have an Aerosol class? If yes, identify	No
NFPA Storage Level:	
NFPA Storage Level:	
Is the product a NIOSH hazardous drug?	No
If yes, indicate which:	

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?	
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	IT IS NOT A REMS PRODUCT		

Registry: No

Registry Program Contact Name:		Phone:
Comments	IT IS NOT A REMS PRODUCT	

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?:	No

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:	
Is product returnable for credit:	
URL/Link to returns policy:	https://creekwoodpharma.com/wp-content/uploads/2023/07/Return-Goods-Policy.pdf

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes
Restricted to retail pharmacy only:	
Restricted to hospital, clinics, and physician offices only:	
Restricted from US territories? (explain in comments)	
Comments:	

Special regulations or returns requirements for this product in certain states?	
If so, which states? Other requirements? Comments?	

MISCELLANEOUS NOTES and/or Image of Product Barcode:

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Version 2024   FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:

a. EDI		
b. Autofax	Fax Number:	
c. Fax	Fax Number:	
d. Phone only	Phone No.:	
e. Supplier Web Site only	Site Address:	

Minimum Order Quantity:

Supplier's Customer Service Number:

Contracted 3PL company / contact #: Name: Direct customer solutions (R & S)
Phone: 1-800-655-7556

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier

Cut off time:

Shipping lead time of PO: Hours   Days

Ships same day for next day receipt:

Ships for second day receipt:

Ships regular ground for 3-10 days receipt:

Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order:

Drop Ship service fee billed with each order:

Drop Ship miscellaneous fees billed:

Comments:

Overnight and Priority Overnight PO Processing

Overnight receipt available:

PO Receipt cut off time:

Days of week overnight is available:
- [ ] Monday
- [ ] Tuesday
- [ ] Wednesday
- [ ] Thursday
- [ ] Friday

Priority Overnight receipt available:

PO Receipt Cut off time:

Saturday Overnight receipt available:

PO Receipt Cut off time:

Order receipt method:	Phone:		Phone #:	
	Fax:		Fax #:	
	EDI:			

Overnight Fees apply:

Other fees apply:

Class of Trade Restriction:

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

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

Other Data Information Required to Process PO:

Patient Procedure Date:

Physician Name:

Physician/Clinic Phone #

Physician State License #

Physician/Clinic DEA #:

Physician/Clinic Specialty:

Return Instructions

Contact # if product is received damaged:

Is product returnable for credit:

URL/Link to returns policy:

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

If so, which states? Other requirements? Comments?

Miscellaneous Notes:

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?

Is product order for restocking purposes?