

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

Version 2021						Introduction T	Гуре:	New Item		Final Version			Date:	7/2/2	2024		
PRODUCT INFORMATION									SPECIAL HANDLING AND STORAGE F				E REQUIREMENTS*				
Company Name: SOLA Pharmaceuticals Application: ANDA									a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): A217904 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)																	
Medical Device Class, if applicable:																	
DUNS:	080121345								Oth	er Temperature Range I	Requirement						
Proprietary Name (If Applicable) a		Ofloxacin O	phthalmic Solution 0.3%	1						(write in)							
Selling Unit NDC:	70512-793-05		Unit of Use NDC:			UPC: MVX Code:	37051279	3050	No	les							
UDI			CVX Code:			MVX Code:											
Description:	Ofloxacin Ophthalmic Solution USP, 0.3%, 5 mL									his product to be shippe				No			
Active Ingredient(s): Ofloxacin										Is this product to be shipped to customers on dry ice?							
Active ingredient(s):	b. Contact for temperature excursion questions:																
URL for Additional Product Inform	nation:								Name:								
Address:	655 Highlandia Dr.						Address 2:							866-747-7365			
City:	Baton Rouge					LA Zip : 70810			Gre	oup E-mail:		info@sola	meds.us				
Key Contact:						il: info@solameds.us											
Phone Number:	866-747-7365					800-754-9550			c. Special regulat	No							
Product Therapeutic Classification	n: Fluoroqui	nolone antibiotic	cs	Spi	ecial returns requirement	ts for this product?			No								
	ADDITIONAL PRO	NOTICE INFORM	AATION			PRODUCT	DESCRIPT	ION INFORMATION		!4 - 61-1				V	ı		
	ADDITIONAL PRO			Di coli o		PRODUCTI	DESCRIPT	ION INFORMATION	11 '	unit of sale) upright?				Yes			
The product is?	Ne		the Product	Direct-Ship O Unit of Use	nly		5m	x1	e. Shelf life:	otect product (unit of sa	ale) from light?			Yes 24	Mantha		
a legend device? if yes, enter class #	No		rphan Drug Status	Offic of Ose		Size:	511	IL		ial shelf life at launch (if different):			24	Months Months		
a product kit?	No		ipilali biug Status				0.3	3%		iai sileli ille at laulicii (ii dillerelli).				WOILLIS		
if yes, list NDCs of	1	F	DA Approval Status			Strength:					ORDER INFORM	MATION					
component parts						Dosage Forn	n. So	lution; Ophthalmic									
reverse numbered?	No					Dosage i oili				it of Sale			NDC selling	unit?			
co-licensed?	No	A	llergens Present							x Bottle		1 Bottle					
latex-free? preservative-free?	Yes Yes	_				Product Sha	pe:			Box/Carton Ampule		(Write-in, e.	.g. 1 Box of 1	U Vials)			
correctional institution block?	No									Glass		Minimum o	rder quantity	12	Yes		
opioid?	No					Product Cold	or:			Tube		William C	ruor quuminy	· ·	103		
Cannabinoid?	No	C	ountry of Origin	India		Product Imp	rint:			Vial Liquid Sgl							
If Unit Dose, is item bar coded to	unit dose for				•	Product imp	TITIL.			Vial Liquid Multi				ich package t	type?		
hospital scanning?			this product covered un							Vial Powder Sql		48	Each				
If Unit Dose, indicate NDC here:		Tr	rade Agreements Act (Ta	4A)?	No					Vial Power Multi			Inner/Cartor	n/Pack			
		505	OFNEDIO DRUG BRO	PUCTO						Other: Write In			Case				
		FUF	R GENERIC DRUG PRO	DUCIS													
					Aı	thorized Generic	*If Author	ized Generic, other		PH	IARMACY ORDER	/ BILL UNIT					
I. Orange Book Rating: AT					anoneda Conono	anation fields are not applicable			Rec. sell unit to customer? Rx billing unit to pharmacy:								
II. Generic Equivalent to What Brand?: Ocuflox					··			1 Bottle			x Each						
conono Equitatori to tinat En									(Write-in, e.g. 1 V				Gram				
	DRL	IG SUPPLY CH	IAIN SECURITY ACT (D	SCSA) INFOR	MATION				1 ` ' ' '	,			Milliliter				
				_									-				
Does supplier meet DSCSA defin	ition of manufacturer?		Yes	-	GLN:	0370512000004				ITEN	I AND PACKING I	NFORMATIO	N				
Is product exempt from DSCSA?		N	10														
If yes, select exemption:					GCP:	0370512				Weight Lbs.		ons (US msn	•	Volume	Saleable #		
Other exemption - Write in:		N	lo.		16						Depth	Width	Height	(Cube)	Pieces		
Is product repackaged? Is product sold by manufacturer's	exclusive distributor?	IN	No		direct from n	riginal product pure	ciiasea		Item/Each:	0.056	1.4567	1.378	2.7953	5.6110968	1		
Has FDA granted waiver/exception			No			ce manufacturer fo	or repackad	ged product	Box/Carton/Bund	le/							
If yes, attach documentation fro				_					Inner Pack:					0			
									Case:	3,1288	9.0551	5.7087	6.1024	315.45044	48		
		GTIN AN	D HIBCC PRODUCT IN	FORMATION						0.1200	0.0001	0.7007	0.1021	010.10011			
Saleable Unit of Measure	0-1	antite	IDCC			N 44		luit of Llos OTIN 44	Pallet:	593.184	48	40	47.44	91084.8	8,640		
x Item/Each	Saleable Qu	iantity H	IBCC			N-14 70512793050		Jnit of Use GTIN-14									
Box/Carton/Bundle/Inner Pack	003/0312/93050						COST INFORMATION WHOLESALER USE ONLY:					Y:					
X Case	48 50370512793055						JJRIIIJAIIJOR										
Pallet									Regular Cost			Vendor #:					
									Invoice Cost (WA	C) (\$)	\$6.00	Whsl. Code					
									II	0.17/0005		Fineline Co	de:				
									As of date:	3/7/2025							
									1.1			1					
		Δtta	ch copy of SAFETY DA	TA SHEET (SD	S) or non haza	ard letter PACKAGE	INSERT I	_ABEL AND PHOTO OF I	PRODUCT PACKAGIN	IG and BARCODE		ļ					



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Version 2021 For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification No a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No x Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer No Does the product label bear a CA Prop 65 warning? Steroid/Androgen No Contact Hazard c. Contact Hazard? Does the product have an Aerosol class? If yes, No No identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No Is the product a NIOSH hazardous drug? No (if yes, answer a-e below and provide SDS) If yes, indicate which: a. UN/Identification Number b. Proper Shipping Name Hazardous Waste Identification c. DOT Hazard Class d. Packing Group EPA Hazardous Waste Code: Waste Characteristics e. Inhalation Hazard? No Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) **REMS or REGISTRY RESTRICTIONS** a. UN/Identification Number b. Proper Shipping Name Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? c. DOT Hazard Class No d. Packing Group Website URL: e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: Med Guide Required No No Passenger Limited Distribution Requirement No Comments / Details: (For example, iPledge program?) Cargo Passenger & Cargo Is this a reportable quantity? REMS: No Phone: RQ Threshold: REMS Program Manager Name: Is this a marine pollutant? Supplier Manages REMS registry exclusively: Wholesale distributor support: Is this product shipped utilizing an authorized DOT exception or Special Permit? Provider Name: (if yes, identify method below) DEA #: Limited Quantity Site Enrollment Number assigned NCPDP# Consumer Commodity, ORM-D by Supplier: NPI#: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry: Phone: Registry Program Contact Name: ADD'L STORAGE INFORMATION Comments Is the Product RETURN INSTRUCTIONS Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No 866-747-7365 ARCOS Reportable? No If yes, indicate which: Contact tel. # if product received damaged: Schedule No. Is it a scheduled listed chemical product?: Yes Is product returnable for credit: CLASS OF TRADE RESTRICTION: URL/Link to returns policy: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: No No Restricted from US territories? (explain in comments) If so, which states? Other requirements? Comments? No Comments:

MISCELLANEOUS NOTES and/or Image of Product Barcode



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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 b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	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:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday						
	Priority Overnight receipt available:						
Class of Trade Restriction:	PO Receipt Cut off time:						
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:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:						
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	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?						
	ADDITIONAL INFORMATION						
	Is product order for scheduled patient procedure? Is product order for restocking purposes?						