

Food and Drug Administration Office of Regulatory Affairs
Collection Report

For Sample Number: 555156

This is an accurate reproduction of the original electronic record as of 04/17/2023

Flag	Flag Remarks				
Complaint Sample	Follow up to Consumer Complaint #179044				
Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic/Import	Compliance	Official	23326406	Completed
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3012323885	02/15/2023	64DAK01	Manufacturer	56R801	10
Compliance Num	Country of Origin				
	India				
Related Smpl Num	Position Class	Sampling Organization	NDC Number	Permit Number	Storage Rqrmnt.
	INV	PHRM4	79503-0101-15		Ambient
Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name	
Yes			179044	Erzicare Artificial Tears (10mg/ml)	

Product Description

Lubricant Eye Drops in white plastic bottle with blue plastic cap.

Product Label

See continuation.

Reason for Collection

Follow up to Consumer Complaint #179044 for microbial analysis.

MFG Codes

Printed on bottle "Lot No: PCMI 004"

Expiration Date

Aug-2024

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
Global Pharma Healthcare Private Limited	A - 9 Sidco Pharmaceutical Complex , Thiruporur Chennai, 609110 IN	Manufacturer	3012323885	
EZRICARE, LLC	1525 Prospect St Ste 204 Lakewood, NJ 08701-4662 US	Shipper	3022210898	

Size of Lot	Est. Value	Rcpt Type	Carrier Name	Date Shipped
4 bottles of eye drops	\$ 60.00	FDA484		

Description of Sample

1 - 15mL bottle of eye drops (open and partially used)

Method of Collection

See continuation.

How Prepared

See continuation.

Collector's Identification on Package and/or Label

"555156 2/15/2023 SMK"

Collector's Identification on Seal

"555156 2/15/2023 Sangeeta M. Khurana, Investigator"

Sample Delivered To

UPS " Tracking no."1Z A46 W83 01 9232 8324""

Date Delivered

02/16/2023

Orig C/R & Records To

PHRM1

Lab w/Split Sample

0

Lab

PSFFL

Document Number	Document Date	Document Type	Document Remarks
3	02/15/2023	Other	Photos of product Lot #PCMI004 -5 Pages
1	02/15/2023	Affidavit	Affidavit from (b) (6) 1 Page
2	02/15/2023	Other	FDA Form 484 Reciept for Samples - 1 Page

Remarks

See continuation.

Date: 04/17/2023

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Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
\$0.00	No Charge	No	No	Sangeeta M Khurana
Name of Signer	Date & Time of Signature			Meaning
Sangeeta M Khurana	03/29/2023 02:22 PM ET			Collector

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Continuation:

Product Label

Labeled in part: "EZRICARE Artificial Tears Lubricant Eye Drops 1/2 fl oz (15ml) NDC 79503-0101-15 Mfg
Lic No. TN0002176 73921 101 15 Lot No: PCMI 004 Exp. Date: AUG-2024 Active Ingredient Carboxymethylcellulose
Sodium 10 mg in 1 mL Distributed by EzriCare, LLC Lakewood NJ Non Rx"

Method of Collection

1 15 ml bottle of Ezri Care Artificial Tears (the bottle was opened and partially used) was provided by the consumer in a plastic bag. Product transported via POV to Seattle District Office.

How Prepared

The sample was in my possession and control under lock and key from the time of collection until shipped. The sample bottle was labelled with sample number and sealed with FDA seal and placed in Form FDA 525 envelope. It was then placed in a brown cardboard shipping container along with other three samples. The cardboard container was sealed with FDA seal and shipped via UPS.

Remarks

Related to samples 555157, 555158, and 555159

RES #91621 initiated on 2/2/2023

No 702(b) portion collected.

Official Sample - interstate documents can be collected as needed. The consumer name and address is in complaint #179044. A receipt of sample was provided to the consumer and an affidavit was signed by the consumer.