

Food and Drug Administration Office of Regulatory Affairs
Collection Report

For Sample Number: 1214088

This is an accurate reproduction of the original electronic record as of 02/08/2023

Flag	Flag Remarks
Episode Number	Origin
	Domestic/Import
FEI	Date Collected
3012323885	02/02/2023
Compliance Num	Country of Origin
	India
Related Smpl Num	Position Class
1146587	INV
Dealer is Consumer	Crx/DEA Schedule
No	
Sampling Organization	NDC Number
PHRM1	72570-121-15
Permit Number	Storage Rqrmnt.
	Ambient
Consumer Compl. Num	Brand Name
	Delsam Pharma's ARTIFICIAL TEARS

Product Description

Carboxymethylcellulose sodium 1% lubricant eye drops packed in white eye dropper bottle with cap

Product Label

See continuation.

Reason for Collection

Collected as per sampling assignment from CDER for the ongoing
Pseudomonas Aeruginosa Possibly Associated with Artificial
Tears/ML/May 2022 incident response.

MFG Codes

"PCMH003"

Expiration Date

"NOV-23"

Firm Legal Name

Global Pharma Healthcare Private
Limited

Address

A - 9 Sidco Pharmaceutical Complex ,
Thirunorur, Chennai, 609110 IN

Type of Firm

Manufacturer

Firm FEI

3012323885

FCE

(b) (4)

(b) (4)

Shipper

(b) (4)

DELSAM PHARMA LLC

55 E Gun Hill Rd Bronx, NY 10467-2103
US

Dealer

3014909559

Size of Lot

65 units of 15 mL bottle

Est. Value

\$ (b) (4)

Rcpt Type

FDA484

Carrier Name

Date Shipped

Description of Sample

See continuation.

Method of Collection

See continuation.

How Prepared

See continuation.

Collector's Identification on Package and/or Label

"1214088 02/02/2023 mc" Subs 1-29

Collector's Identification on Seal

"1214088 02/02/2023 Mindy Chou, Investigator"

Sample Delivered To

UPS 1ZA5V5820191744645

Date Delivered

02/07/2023

Orig C/R & Records To

PHRM1

Lab w/Split Sample

0

Lab

PSMPL

Document Number

Document Date

02/02/2023

Document Type

Other

Document Remarks

FDA 482 issued to (b) (6)
Manager, (b) (4) (3 pages)

Operations

Date: 02/08/2023

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	02/02/2023	Other	FDA 484 issued to (b) (6) Operations Manager, (b) (4) covering Sample # 1146587, 1146588, 1146589, 151732, 1214088, 1214089, 1214091 (2 pages)
	02/02/2023	Other	FDA 482 issued to Kuppusamy G. Arumugam, President, Delsam Pharma Llc (3 pages)
R/PCMH003/20	12/29/2020	Other	Certificate of Analysis
	08/01/2021	Other	Packing List for shipment covering Artificial Tears Lot # PCMH001, PCMH002, PCMH003, PCMH004, PCMH005, PCMH006, PCMH007, PMCH008 and Artificial Eye Ointment Lot # H29
		Other	(b) (4) distribution list (2 Excel files)
		Other	Online stores (Delsam Amazon, Delsam (b) (4) Delsam Manual, Delsam Squarespc) distribution list (1 Excel file)
STVP/2020/001	01/20/2020	Other	Global Pharma Healthcare PVT. LTD. Analytical Method Verification Protocol for Sterility Test

Remarks

See continuation.

Payment Amount
\$0.00

Payment Method
No Charge

704(d) Sample
No

702(b) Portion
Yes

Collector's Name
Mindy M Chou

Name of Signer

Date & Time of Signature

Meaning

ET

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Continuation:

Product Label

Finished product: Label on bottle reads in part, "****NDC 72570 121 15 Delsam Pharma's ARTIFICIAL TEARS***Lubricant Eye Drops***1/2 fl oz (15ml)***Active Ingredient Carboxymethylcellulose Sodium 10 MG IN 1 mL***Distributed By: Delsam Pharma Llc, Bronx, New York 10467***Lot No.: PCMH003 Exp. Date: NOV-2023****"

Paperboard carton reads in part, "****NDC 72570 121 15 Delsam Pharma's ARTIFICIAL TEARS***Carboxymethylcellulose Sodium 1% Lubricant Eye Drops***1/2 fl oz (15ml)***Active Ingredient Carboxymethylcellulose Sodium 10 MG in 1 mL***Lot No.: PCMH003 Exp. Date: NOV-2023***Distributed By: Delsam Pharma Llc, Bronx, New York 10467****"

Plastic wrap reads in part, "****X003258L8V Delsam Pharma's Artificial ...& Moisturize Dry Eyes (b) (4) New****"

Plastic bag reads in part, "****X0036BJWHN DELSAM Pharma's Artificial ...fresh & Moisturize (2-Pack) New****"

Description of Sample

Sub 1 consists of one pre-packed (plastic wrapped) pack of (b) (4) units of product without tamper evident seal on carton.

Subs 2-25: Each sub consists of one sealed plastic bag containing two units of product without tamper evident seal on carton.

Subs 26-29: Each sub consists of one individual units without tamper evident seal on carton.

Method of Collection

64 units of Artificial Tears (without tamper evident seal), each containing 15 mL bottle of Artificial Tears eye drop, were collected from the three cases of Artificial Tears available at the site, which contained comingled lots of products. Some units were observed packaged in sealed bags of 2 or 4 units each, some were plastic wrapped as pack of (b) (4) while other units were found as single units with no additional packaging.

Sub 1 consists of one pre-packed (plastic wrapped) pack of (b) (4) units of product without tamper evident seal on carton. 2

Subs 2-25: Each sub consists of one sealed plastic bag containing two units of product without tamper evident seal on carton. 3

Subs 26-29: Each sub consists of one individual unit without tamper evident seal on carton. One bottle (Sub 29) was removed from carton

to verify whether bottle is intact. No neckband was observed; however, the screw on cap appears to be a tamper-evident cap. The product label was observed not fully affixed on the bottle.

How Prepared

A stick-on label was affixed to the sample and identified as noted in 'Collector's Identification on Package and/or Label' field. The sample was placed in a double brown paper bag, taped closed with clear plastic tape and officially sealed with FDA 415a as in the 'Collector's ID on Seal' field. The paper bag was identified as "1214088 02/02/2023 mc" in black ink. The officially sealed bag was brought back to the White Plains R.P. on 02/02/2023 by CSO Chou and locked in the cabinet for storage until preparation for shipment.

On 02/06/2023, the sample was removed from the locked cabinet by CSO Chou and placed in a clear plastic bag with FDA 525, then placed in a brown, cardboard box with Sample # 1214089, # 1146587, # 1146588, # 1146589 packaged with brown paper as cushion. The box was taped shut with clear plastic tape. The samples were dropped off at The (b) (4) located at (b) (4)

(b) (4)

Remarks

- This is a domestic import sample. However, sample was collected without adding prefix "DI" to sample number.
- Note: Sample includes 702(b) portion not separately packed
- Analysis to be performed: Sterility testing per USP <71>, to include cetrimide agar for Pseudomonas aeruginosa detection

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Continuation:

- Other related sample numbers: 1146587, 1146588, 1146589, 1151732, 1214089, 1214091
- Point of Contact: Delsam Pharma LLC - Kuppusamy G. Arumugam, (b) (6)
- Point of Contact: GyftGo Inc. - (b) (6) Operations Manager, (b) (6)
- As per Delsam Pharma's website, the retail value of each 15 mL bottle is (b) (4)
- Lot Size: The amount of goods on hand before sampling. This is the quantity on-hand at the location where the sample was collected. There's possibly more inventory at another warehouse (b) (4) from (b) (4) fulfillment center where sample was collected). Made request to firm on 2/2/2023 and 2/6/2023 for lot inventory. Firm has not provided the information.
- Delsam Pharma LLC: On 2/2/2023, CSO Mindy Chou and CST Tantania Potts visited Delsam Pharma LLC's business location at 55 E Gun Hill Rd Bronx, NY which shares the same office space as (b) (4) (a pharmacy). Credentials were presented and FDA 482 was issued to Mr. Kuppusamy G. Arumugam who is the owner of Delsam Pharma and the Supervising Pharmacist of (b) (4). Mr. Arumugam stated they do not have any Delsam Pharma's Artificial Tears or Artificial Eye Ointment products on hand at the location. He stated all the products are stored at the (b) (4) warehouse located at (b) (4) (b) (4)
- (b) (4) where sample was collected: On 2/2/2023, credentials were presented and FDA 482 was issued to (b) (6) Operations Manager. (b) (6) stated Delsam Pharma's products were hand delivered by Delsam to the warehouse and there was no receipt or packing slip. He stated (b) (4) does not have ownership of the product, and everything was imported by Delsam. He also added that they have additional inventory at another warehouse (b) (4) away; however, an appointment is needed to access that warehouse. CSO Chou requested (b) (6) to provide a copy of the current inventory, but (b) (6) said he is not able to gather that information quickly. (b) (6) agreed to email the information to CSO Chou.