

Food and Drug Administration Office of Regulatory Affairs

Summary Report

For Sample Number: 1146587

TD Sample Number:

Import Sample Number

This is an accurate reproduction of the original electronic record as of 04/05/2023

Sample Class: Normal Everyday Sample

Sample Origin: Domestic/Import

Sample Basis: Compliance

Sample Flag:

Sample Type: Domestic Import

Collecting District: PHRM1

Home District:

Orig C/R and Records To: PHRM1

Collection PACs: 56D800

Product Name: Carboxymethylcellulose Sodium, Emollient,Lubricant; Human - Non/Rx Single Ingredient; Sterile Liquid

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

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

Lab: IRVLMP **Split Num:** 0

Date Received: 02/07/2023

Date Out of Lab: 03/22/2023

**District
Conclusion:**

**District Conclusion
Made By:**

**District
Conclusion Date:**

**Disposition
Reason:**

**Disposition
Authorized By:**

**Disposition
Authorized Date:**

Performing Org	PAC	LID	PAF	Compliance No	Lab Class-Description	Laboratory Status
IRVMP-MIC	56D800		MDS		1 - In Compliance	Completed

Lab Conclusion

No growth was found in 1 out of 1 composite analyzed for sterility.
No microorganisms were found in 2 out of 2 subs analyzed for direct staining.
Method suitability was performed satisfactorily for USP <71>. See Sample 1146588.
QA/QC elements have been reviewed by management and verified to meet requirements.
All laboratory controls were satisfactory.

Lab Conclusion Date

Lab Conclusion Made By

03/22/2023

Kwan,Thao T