

Food and Drug Administration Office of Regulatory Affairs

Summary Report

For Sample Number: 1214088

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

District Conclusion

District

Conclusion:

Made By:

Conclusion Date:

Disposition

Disposition

Disposition

Reason:

Authorized By:

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 10 out of 10 composites analyzed for sterility.
No microorganisms were found in 20 out of 20 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 performed satisfactorily.

Lab Conclusion Date

Lab Conclusion Made By

03/22/2023

Kwan,Thao T