Food and Drug Administration Office of Regulatory Affairs

Summary Report

For Sample Number: 555157

TD Sample Number: **Import Sample Number**

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

Sample Class: Normal Everyday Sample
Sample Flag: Complaint Sample
Home District:

Sample Origin: Domestic/Import
Sample Type: Official
Orig C/R and Records To: PHRM1

Sample Basis: Compliance
Collecting District: PHRM4
Collection PACs: 56R801

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

Product Description: Lubricant Eye Drops in white plastic bottle with blue plastic cap.

Collection Reason: Follow up to Consumer Complaint #179044 for microbial analysis.

Lab: IRVLMP **Split Num:** 1 **Date Received:** 02/27/2023 **Date Out of Lab:** 04/06/2023

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	56R801		MIC		2 - Regulatory Action Not Indicated	Completed

Lab Conclusion

Two isolates were identified by Whole Genome Sequencing as follows:

555157-S001-001:
Kraken2 ID: Pseudomonas aeruginosa
Sendsketch ID: Pseudomonas aeruginosa, Pseudomonas spp.

555157-S001-007:
Kraken2 ID: Pseudomonas aeruginosa
Sendsketch ID: Pseudomonas aeruginosa, Pseudomonas spp.

All laboratory controls and 6-month MLST lookback performed satisfactorily.

Lab Conclusion Date	Lab Conclusion Made By
04/06/2023	Kwan,Thao T

Food and Drug Administration Office of Regulatory Affairs

Summary Report

For Sample Number: 555157

TD Sample Number: **Import Sample Number**

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

Lab: IRVLMP **Split Num:** 0 **Date Received:** 02/17/2023 **Date Out of Lab:** 03/17/2023

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	56R801		MIC		4 - No Classification Required	Completed

Lab Conclusion

Growth was found in 1 out of 1 sub analyzed for sterility. Isolates were identified as follows:

555157-1 FTM D4 TSA: Most homologous to Pseudomonas aeruginosa (99.98%, 99.86%, 99.8%)
555157-1 FTM D4 CET: Most homologous to Pseudomonas aeruginosa (99.97%, 99.87%, 99.87%)
555157-1 FTM D4 ana TSA: Most homologous to Pseudomonas aeruginosa (99.97%, 99.87%, 99.87%)
555157-1 FTM D4 ana CET: Most homologous to Pseudomonas aeruginosa (99.97%, 99.87%, 99.87%)
555157-1 TSB D4 TSA: Most homologous to Pseudomonas aeruginosa (99.97%, 99.86%, 99.86%)
555157-1 TSB D4 CET: Most homologous to Pseudomonas aeruginosa (99.97%, 99.87%, 99.87%)
555157-1 FTM D14 TSA: Most homologous to Pseudomonas aeruginosa (99.97%, 99.87%, 99.87%)
555157-1 FTM D14 CET: Most homologous to Pseudomonas aeruginosa (99.97%, 99.86%, 99.86%)
555157-1 FTM D14 ana TSA: Most homologous to Pseudomonas aeruginosa (99.97%, 99.87%, 99.87%)
555157-1 FTM D14 ana CET: Most homologous to Pseudomonas aeruginosa (99.98%, 99.87%, 99.87%)
555157-1 TSB D14 TSA: Most homologous to Pseudomonas aeruginosa (99.97%, 99.86%, 99.87%)
555157-1 TSB D14 CET: Most homologous to Pseudomonas aeruginosa (99.97%, 99.86%, 99.87%)

No microorganisms were found in 1 out of 1 sub analyzed for direct staining.
Method suitability was performed satisfactorily according to USP <71>. See sample 1174937.
QA/QC elements have been reviewed by management and verified to meet requirements.
All laboratory controls were satisfactory.

Update 04/06/23: Sub sample unit was not intact upon receipt as the tamper evident seal was observed to be broken; therefore, the classification of the sample is LC4.

Lab Conclusion Date	Lab Conclusion Made By
04/06/2023	Kwan,Thao T