

Food and Drug Administration Office of Regulatory Affairs

Summary Report

For Sample Number: 555156

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 Origin:** Domestic/Import **Sample Basis:** Compliance
Sample Flag: Complaint Sample **Sample Type:** Official **Collecting District:** PHRM4
Home District: **Orig C/R and Records To:** PHRM1 **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: IRVLHAF **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:

555156-1 FTM D4 TSA: Most homologous to Pseudomonas aeruginosa (99.97%, 99.87%, 99.87%)
555156-1 FTM D4 CET: Most homologous to Pseudomonas aeruginosa (99.97%, 99.87%, 99.87%)
555156-1 FTM D4 ana TSA: Most homologous to Pseudomonas aeruginosa (99.98%, 99.88%, 99.88%)
555156-1 FTM D4 ana CET: Most homologous to Pseudomonas aeruginosa (99.98%, 99.86%, 99.86%)
555156-1 TSB D4 TSA: Most homologous to Pseudomonas aeruginosa (99.97%, 99.87%, 99.87%)
555156-1 TSB D4 CET: Most homologous to Pseudomonas aeruginosa (99.97%, 99.86%, 99.86%)
555156-1 FTM D14 TSA: Most homologous to Pseudomonas aeruginosa (99.97%, 99.86%, 99.86%)
555156-1 FTM D14 CET: Most homologous to Pseudomonas aeruginosa (99.98%, 99.88%, 99.88%)
555156-1 FTM D14 ana TSA: Most homologous to Pseudomonas aeruginosa (99.97%, 99.86%, 99.86%)
555156-1 FTM D14 ana CET: Most homologous to Pseudomonas aeruginosa (99.97%, 99.87%, 99.87%)
555156-1 TSB D14 TSA: Most homologous to Pseudomonas aeruginosa (99.97%, 99.87%, 99.87%)
555156-1 TSB D14 CET: Most homologous to Pseudomonas aeruginosa (99.97%, 99.86%, 99.86%)

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: Note: 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

Food and Drug Administration Office of Regulatory Affairs

Summary Report

For Sample Number: 555156

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: 1

Date Received: 02/27/2023

Date Out of Lab: 04/07/2023

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 analyzed and identified by Whole Genome Sequencing as follows:

555156-S001-001

Kraken2 ID: Pseudomonas aeruginosa

Sendsketch ID: Pseudomonas aeruginosa, Pseudomonas spp.

555156-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

04/07/2023

Kwan,Thao T