

Food and Drug Administration Office of Regulatory Affairs

Summary Report

For Sample Number: 1214092

TD Sample Number:

Import Sample Number

This is an accurate reproduction of the original electronic record as of 04/10/2023

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: Emollient, Lubricant, N.E.C.; Human - Non/Rx Combination Ingredient; Sterile Ointment

Product Description: See "Remarks" section.

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

Food and Drug Administration Office of Regulatory Affairs**Summary Report****For Sample Number: 1214092****TD Sample Number:****Import Sample Number**

This is an accurate reproduction of the original electronic record as of 04/10/2023

Lab: IRVLMF Split Num: 0**Date Received: 02/07/2023****Date Out of Lab: 03/16/2023****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		MIC		3 - Adverse Findings	Completed

Lab Conclusion

Growth was found in composites 3 and 4 analyzed for sterility. No growth was found in composites 1, 2, and 5-10. Isolates were identified as follows:

Composite 3:1214092-3TSB D7 TSA: Most homologous to *Bacillus kochii* (99.80%)1214092-3TSB D14 TSA: Most homologous to *Bacillus kochii* (99.82%)**Composite 4:**1214092- 4FTM D2 TSA: Most homologous to *Burkholderia multivorans* (99.69%), *Burkholderia cepacia* (99.53%), and *Burkholderia cenocepacia* (99.48%)1214092- 4FTM D2 BAP: Most homologous to *Burkholderia multivorans* (99.71%), *Burkholderia cepacia* (99.57%), and *Burkholderia cenocepacia* (99.49%)1214092- 4FTM D2 ana TSA: Most homologous to *Burkholderia multivorans* (99.64%), *Burkholderia cepacia* (99.59%), and *Burkholderia cenocepacia* (99.43%)1214092-4TSB D7 TSA: Most homologous to *Burkholderia multivorans* (99.70%), *Burkholderia cepacia* (99.53%), and *Burkholderia cenocepacia* (99.49%)1214092-4FTM D14 TSA: Most homologous to *Burkholderia multivorans* (99.66%), *Burkholderia cepacia* (99.61%), and *Burkholderia cenocepacia* (99.46%)1214092-4FTM D14 CET: Most homologous to *Burkholderia multivorans* (99.70%), *Burkholderia cepacia* (99.53%), and *Burkholderia cenocepacia* (99.49%)1214092-4FTM D14 ana TSA: Most homologous to *Burkholderia multivorans* (99.65%), *Burkholderia cepacia* (99.60%), and *Burkholderia cenocepacia* (99.45%)1214092-4TSB D14 TSA: Most homologous to *Burkholderia multivorans* (99.69%), *Burkholderia cepacia* (99.56%), and *Burkholderia cenocepacia* (99.49%)1214092-4TSB D14 CET: Most homologous to *Burkholderia multivorans* (99.70%), *Burkholderia cepacia* (99.56%), and *Burkholderia cenocepacia* (99.49%)

Method suitability was performed satisfactorily according to USP <71>.

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**

03/16/2023

Kwan,Thao T

Food and Drug Administration Office of Regulatory Affairs

Summary Report

For Sample Number: 1214092

TD Sample Number:

Import Sample Number

This is an accurate reproduction of the original electronic record as of 04/10/2023

Lab: IRVLMP Split Num: 1

Date Received: 03/10/2023

Date Out of Lab: 04/08/2023

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		MIC		2 - Regulatory Action Not Indicated	Completed

Lab Conclusion

Two isolates were analyzed and identified by Whole Genome Sequencing as follows:

1214092-S003-002

Kraken2 ID: Cytobacillus kochii

Sendsketch ID: Cytobacillus kochii

1214092-S004-005

Kraken2 ID: Burkholderia vietnamiensis

Sendsketch ID: Burkholderia spp., Burkholderia vietnamiensis, Burkholderia ubonensis

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

Lab Conclusion Date

Lab Conclusion Made By

04/08/2023

Kwan,Thao T