

Food and Drug Administration Office of Regulatory Affairs

Summary Report

For Sample Number: 1105520

TD Sample Number:

Import Sample Number

This is an accurate reproduction of the original electronic record as of 08/02/2019

Sample Class: Quality Assurance

Sample Origin: Domestic

Sample Basis: Compliance

Sample Flag:

Sample Type: Investigational

Collecting District: PHRM2

Home District:

Orig C/R and Records To: FLA-DO

Collection PACs: 56D017

Product Name: Miscellaneous Patent Medicines, Etc.; Human - Rx/Single Ingredient; Active Pharm Ingreed/Chems for Rx

Product Description: Environmental Sampling (b) (4) plates, swabs, sponges, material)

Collection Reason: CDER directed sample collection initiated during EI at Pacifico National, Inc. dba AmEx Pharmacy; Please analyze for sterility.

Summary Report

For Sample Number: 1105520

TD Sample Number:

Import Sample Number

This is an accurate reproduction of the original electronic record as of 08/02/2019

Lab: NMPL

Split Num: 0

Date Received: 05/04/2019

Date Out of Lab: 07/05/2019

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
WEAC-BIOE	56D017		NAR		4 - No Classification Required	Completed

Lab Conclusion

One (1) fungal isolate sequenced:

Sub 68 6/14/19 SH: Most homologous to *Hamigera avellanea*, *H. insecticola* and *H. paravellanea*;

Six (6) bacterial isolates sequenced:

Sub 75 BAP 5-10: Most homologous to *Paenibacillus* spp.;Sub 79 MLA 5-7: Most homologous to *Staphylococcus hominis novobiosepticus* and *S. hominis hominis*;Sub 79 SDA 5-7: Most homologous to *Staphylococcus hominis novobiosepticus* and *S. hominis hominis*;Sub 79 MLA 5-10: Most homologous to *Staphylococcus hominis novobiosepticus* and *S. hominis hominis*;Sub 79 MLA 5-18: Most homologous to *Staphylococcus hominis novobiosepticus* and *S. hominis hominis*;Sub 89 BAP 5-18: Most homologous to *Cohnella* spp.

All controls were satisfactory.

Lab Conclusion Date**Lab Conclusion Made By**

07/05/2019

Silverman,Matthew D

Performing Org	PAC	LID	PAF	Compliance No	Lab Class-Description	Laboratory Status
NMPL-LAB-G	56D017		NAR		3 - Adverse Findings	Completed

Lab Conclusion

Growth was detected in subs 68,75,77,79,81 and 89.

1.0 CFU was detected on RODAC sub no. 68. Isolate sent to WEAC for further fungal identification.

Paenibacillus glucoanolyticus/(*Bacillus circulans*), *Paenibacillus lautus*, and *Bacillus megaterium* were isolated from sub 75. In addition, one isolate sent to WEAC for further bacterial identification from Sub 75.

Staphylococcus haemolyticus, *Staphylococcus hominis* ssp. *hominis*, *Staphylococcus epidermidis* and *Staphylococcus warneri* were isolated from Sub 77.

Staphylococcus epidermidis and *Staphylococcus hominis* ssp. *hominis*, were isolated from Sub 79. In addition, four isolates sent to WEAC for further bacterial identification from Sub 79.

Micrococcus luteus was isolated from sub 81, and *Paenibacillus macerans* was isolated from sub 89. In addition, one isolate sent to WEAC for further bacterial identification from Sub 89.

No growth was detected in subs no. 1-67, 69-74, 76,78,80,82-88 & 90-105 after 14 days of incubation.

Collector's controls: A, B, C, D, E F and G were negative for growth after 14 days of incubation.

All controls gave valid results.

Lab Conclusion Date**Lab Conclusion Made By**

06/20/2019

Romero,Haydee B