

# 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 &amp; 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