

Report for:

Mr. Quality Control EMLab P&K (QA) 1150 Bayhill Drivé Suite 100 San Bruno, CA 94066

Eurofins EPK Built Environment Testing, LLC

Regarding: Project: Sample Report

EMĹ ID: 1350490

Approved by:

**Technical Manager** Murali Putty

Dates of Analysis:

USP 797 Count & ID 26-30C: 04-10-2015 USP 797 Count & ID 33-37C: 04-10-2015

Service SOPs: USP 797 Count & ID 26-30C (EM-USP-S-2082, EM-USP-S-2081, EM-BT-S-1576), USP 797 Count & ID 33-37C (EM-USP-S-2082, EM-USP-S-2081, EM-BT-S-1576)

All samples were received in acceptable condition unless noted in the Report Comments portion in the body of the report. Due to the nature of the analyses performed, field blank correction of results is not applied. The results relate only to the samples as received and tested. Information supplied by the client which can affect the validity of results: sample air volume.

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Client: EMLab P&K (QA) C/O: Mr. Quality Control Re: Sample Report Date of Sampling: 04-03-2015 Date of Receipt: 04-03-2015 Date of Report: 04-10-2015

# **USP 797 - Summary of Sample Analysis Results**

The summary information for each sample includes a Pass/Fail result with respect to the USP 797 action level guidelines for concentration of colony forming units (see *Table 1*) and actionable microorganisms (United States Pharmacopeia, 2014). Actionable microorganisms are defined here as Gram-negative bacteria, coagulase-positive Staphylococcus, molds, and yeasts.

Table 1: Recommended Action Levels for Viable Particles in Air and from Surfaces

ISO Class	Active Airborne (cfu*/m3)	Inanimate Surfaces** (cfu/plate)
5	>1	>3
7	>10	>5
8+	>100	>100

<sup>\*</sup> cfu = colony forming units

Pass Acceptable concentrations and absence of actionable microorganisms

Fail Unacceptable concentrations and/or presence of actionable microorganisms

N/A Not applicable. Blank Sample, insufficient sample volume and/or no ISO Class area designation provided<sup>4</sup>

Location	Media	Туре	Total CFU†	Colony Identification§	ISO Class	Performance vs. USP 797 Guidelines‡
1:	MEA	Air	< 1	No colonies detected	5	Pass
2:	TSA	Air	2	Micrococcus Staphylococcus Coagulase (+)	5	Fail

Reason for fail result: Total CFU result exceeds action level concentration and actionable microorganism/s detected.

	3:	MEA	Air	3	Penicillium	7	Fail
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Reason for fail result: Actionable microorganism/s detected.

4:	TSA	Air		Gram-positive cocci Micrococcus	7	Pass
5:	MEA	Surface	3	Aspergillus ochraceus Yeasts	5	Fail

Reason for fail result: Actionable microorganism/s detected.

**REFERENCE:** United States Pharmacopeia and National Formulary Chapter <797> (USP 35-NF 30). Rockville, MD: United States Pharmacopeial Convention; 2014:40-84.

<sup>\*\*</sup> Contact plate areas vary from 24 to 30 cm2. When swabbing is used in sampling, the area covered should be at least 24 cm2 but no larger than 30 cm2.

<sup>¥</sup> Samples that would otherwise pass in relationship to concentration and actionable microorganisms will always report as N/A when one or more bacterial colonies in the sample are identified as Other Bacteria.

<sup>†</sup> The Total CFU value reported in this column is the Total CFU/unit value for the entire sample. For details, refer to the detailed results page of each sample in this report. In order to calculate Total CFU/unit values for air sample types, an air volume must be provided. Air samples without air volumes provided are reported as N/A (Not Applicable). A reported value of ND indicates none detected. § Actionable microorganisms reported in Bold font when detected.

<sup>‡</sup> As stated in USP 797, the recommended action level table and actionable microorganism list are for guidance purposes only.

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# USP 797 - Summary of Sample Analysis Results

Location	Media	Туре	Total CFU†	Colony Identification§	ISO Class	Performance vs. USP 797 Guidelines;
6:	TSA	Surface	3	Bacillus Gram-negative rods	5	Fail
Reason for fail result: Actionable micro	oorganism/s	detected.				
7:	MEA	Surface	2	Aspergillus niger Non-sporulating fungi	7	Fail
Reason for fail result: Actionable micro	oorganism/s	detected.				
8:	TSA	Surface	ND	No colonies detected	7	Pass
9:	MEA	Surface	ND	No colonies detected	5	Pass
10:	TSA	Surface	10	Bacillus Gram-negative rods Micrococcus	5	Fail
Reason for fail result: Total CFU resul	exceeds ac	ction level co	oncentration	on and actionable microorganism/s	s detected	l.
11:	MEA	Surface	5	Aspergillus niger Cladosporium Penicillium	7	Fail
Reason for fail result: Actionable micro	oorganism/s	detected.				
12:	TSA	Surface	1	Staphylococcus Coagulase (-)	7	Pass
13:	MEA	Air	N/A	No colonies detected	None	N/A
14:	MEA	Surface	ND	No colonies detected	None	N/A
15:	MEA	Surface	ND	No colonies detected	None	N/A

REFERENCE: United States Pharmacopeia and National Formulary Chapter <797> (USP 35-NF 30). Rockville, MD: United States Pharmacopeial Convention; 2014:40-84.

<sup>¥</sup> Samples that would otherwise pass in relationship to concentration and actionable microorganisms will always report as N/A when one or more bacterial colonies in the sample are identified as Other Bacteria.

<sup>†</sup> The Total CFU value reported in this column is the Total CFU/unit value for the entire sample. For details, refer to the detailed results page of each sample in this report. In order to calculate Total CFU/unit values for air sample types, an air volume must be provided. Air samples without air volumes provided are reported as N/A (Not Applicable). A reported value of ND indicates none detected.

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## **USP 797 - Detail Sample Analysis Results**

Location:	1:		2:		3:		4:	
Comments (see below)	None		None		None		None	
Area Designation	ISO C	Class 5	ISO (	Class 5	ISO C	Class 7	ISO C	Class 7
Sample type	Anderse	n sample	Anderse	n sample	Anderse	n sample	Anderse	n sample
Media used	M	EA	T	SA	M	EA	TS	SA
Lot#/Expiration date	123456/8	3-25-2015	475869/6	5-24-2015	123456/8	3-25-2015	475869/6	5-24-2015
Lab ID-Version‡:	6185	527-1	6185	528-1	6185	529-1	6185	530-1
Analysis Date	4-10-	-2015	4-10	-2015	4-10-	-2015	4-10-	2015
Incubation		30°C	33° - 37°C		26° - 30°C		33° - 37°C	
	for 5-	7 days	for 2-3 days		for 5-7 days		for 2-3 days	
	raw ct.	cfu*/m3	raw ct.	cfu*/m3	raw ct.	cfu*/m3	raw ct.	cfu*/m3
BACTERIA								
Gram-positive cocci							2	2
Micrococcus			1	1			3	3
Staphylococcus Coagulase (+)			1	1				
FUNGI								
Penicillium					3	3		
§Total	ND	< 1	2	2	3	3	5	5
Sample size	1000 liter		1000 liter		1000 liter		1000 liter	
Positive Hole		00		00	400		400	

\*cfu = colony forming units **Comments:** 

Positive hole correction chart used for all calculations

ND = none detected

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Identifiers listed without a count or data entry were not detected during the course of the analysis for the respective sample.

Note: Interpretation is left to the company and/or persons who conducted the field work. Some rare strains of Staphylococcus produce free (unbound) coagulase exclusively. The applied coagulase test only measures bound coagulase.

<sup>‡</sup> A "Version" indicated by -"x" after the Lab ID# with a value greater than 1 indicates a sample with amended data. The revision number is reflected by the value of "x".

<sup>§</sup> Total cfu/unit has been rounded to two significant figures to reflect analytical precision.

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## **USP 797 - Detail Sample Analysis Results**

Location:	13:							
Comments (see below)	No	None						
Area Designation	No	one						
Sample type	Anderse	n sample						
Media used	MI	EA						
Lot#/Expiration date	123456/8	123456/8-25-2015						
Lab ID-Version‡:	6185542-1							
Analysis Date	4-10-	4-10-2015						
Incubation	26° - for 5-'							
	raw ct.	cfu*/m3						
§Total	ND N/A							
Sample size	0 1	ter						
Positive Hole	400							

\*cfu = colony forming units

Positive hole correction chart used for all calculations

ND = none detected

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**Comments:** 

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## **USP 797 - Detail Sample Analysis Results**

Location:	5:		6:		7:		8:	
Comments (see below)	None		None		None		None	
Area Designation	ISO C	Class 5	ISO C	Class 5	ISO C	Class 7	ISO Class 7	
Sample type	Contac	ct plate	Conta	ct plate	Contac	ct plate	Contac	ct plate
Media used	M	ΕĀ	$T^{s}$	SA	M	ΕĀ	TS	SA
Lot#/Expiration date	258369/6	5-25-2015	142536/6	5-13-2015	258369/6	5-25-2015	142536/6	5-13-2015
Lab ID-Version‡:	6185	531-1	6185	532-1	6185	533-1	6185	534-1
Analysis Date	4-10-	-2015	4-10-	-2015	4-10-	-2015	4-10-	-2015
Incubation	26° -		33° - 37°C		26° - 30°C		33° - 37°C	
	for 5-	7 days	for 2-3 days		for 5-7 days		for 2-3 days	
	raw ct.	cfu*/plate	raw ct.	cfu*/plate	raw ct.	cfu*/plate	raw ct.	cfu*/plate
BACTERIA								
Bacillus			2	2				
Gram-negative rods			1	1				
FUNGI								
Aspergillus ochraceus	2	2						
Aspergillus niger					1	1		
Yeasts	1	1						
Non-sporulating fungi					1	1		
§Total	3	3	3	3	2	2	ND	ND

\*cfu = colony forming units

**Comments:** 

ND = none detected

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## **USP 797 - Detail Sample Analysis Results**

Location:	9:		10:		11:		12:	
Comments (see below)	None		None		None		None	
Area Designation	ISO C	Class 5	ISO C	Class 5	ISO C	Class 7	ISO Class 7	
Sample type	Swab	sample	Swab	sample	Swab	sample	Swab	sample
Media used	M	EA	TS	SA	M	EA	TS	SA
Lot#/Expiration date	789456/6	5-15-2015	461379/7	7-19-2015	789456/6	5-15-2015	461379/7	7-19-2015
Lab ID-Version‡:	6185	535-1	6185	536-1	6185	537-1	6185	538-1
Analysis Date	4-10-	-2015	4-10-	-2015	4-10-	-2015	4-10-	-2015
Incubation		30°C	33° - 37°C		26° - 30°C		33° - 37°C	
	10r 5-	7 days	for 2-3 days		for 5-7 days		for 2-3 days	
	raw ct.	cfu*/swab	raw ct.	cfu*/swab	raw ct.	cfu*/swab	raw ct.	cfu*/swab
BACTERIA								
Bacillus			5	5				
Gram-negative rods			3	3				
Micrococcus			2	2				
Staphylococcus Coagulase (-)							1	1
FUNGI								
Aspergillus niger					1	1		
Cladosporium					2	2		
Penicillium					2	2		
§Total	ND	ND	10	10	5	5	1	1

\*cfu = colony forming units

Comments:

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## **USP 797 - Detail Sample Analysis Results**

Location:	1.	4:	15:		
Comments (see below)	No	one	None		
Area Designation	No	one	No	one	
Sample type	Contac	et plate	Swab sample		
Media used	M	EA	MEA		
Lot#/Expiration date	258369/6	5-25-2015	789456/6-15-2015		
Lab ID-Version‡:	6185	543-1	6185550-1		
Analysis Date	4-10-	-2015	4-10-2015		
Incubation	26° - for 5-	30°C 7 days	26° - 30°C for 5-7 days		
	raw ct.	cfu*/plate	raw ct.	cfu*/swab	
§Total	ND	ND	ND	ND	

\*cfu = colony forming units

**Comments:** 

ND = none detected

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