



REPORT

Eco Handle Testing – Dynamics of Contamination

Report for: Mr Matt Roberts

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Test Facility: Wickham Laboratories Limited
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REPORT AUTHORIZATION

Report approved by:

Principal Scientist

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Senior Technician, Pharmaceutical Microbiology QC

Date

16.02.17

Management

L Chisenga

L Chisenga, BSc MRSB
Laboratory Manager, Pharmaceutical Microbiology

Date

16/02/17

Eco Handle Testing – Dynamics of Contamination

KEY INFORMATION

Status of study: c GMP

Compliance: The experimentation was undertaken in compliance with current Good Manufacturing Practice requirements for contract analysis specified under the EU Guidelines to GMP for Medicinal products for Human and Veterinary Use, (cGMP). Wickham Laboratories Limited is registered with the Medicines and Healthcare Products Regulatory Agency (MHRA) and Food and Drug Administration (FDA) (registration number FEI 3009798720) as a facility for contract analysis in compliance with Good Manufacturing Practice. Inspection of the facility for compliance with current GMP requirements for contract analysis is made by the MHRA and FDA.

Testing commenced: 6th January 2017

Testing completed: 19th January 2017

SUMMARY

The intention was to assess the effectiveness and contamination levels of the Purehold Eco handle, a self-cleaning door handle cover, against standard stainless steel door handles that are used in many buildings. The Eco handle uses silver technology embedded into the handle surface to kill bacteria deposited onto the surface by user's hands.

The assessment was performed on a series of pre-production units which were affixed to three doors. These would be used by a population of around 85 employees on the site.

TEST SUMMARY

Three high use door locations were identified as suitable for testing. A male toilet door, a female toilet door and a canteen door. Each had a stainless steel pull door handle that users have to pull to open the door the door.

In week 1, swabs were undertaken on the stainless steel door handles after a period of 7 days. The duration of 7 days was chosen to allow sufficient bacteria to build up on the handle surface over the course of an entire week, therefore simulating a representative environment.

In week 2, once the stainless steel door handles were swabbed, Eco handles were installed and left in-site on each door for 7 days. Swabs were then taken after a period of 7 days.

APPARATUS

Swabs, sterile, dry
Fisher Scientific Disinfectant wipes
Swab area measuring apparatus
Tape
Vortex mixer
Pipettes, sterile disposable; 1 mL
Petri dishes, sterile, 90mm disposable
Incubators 30-35°C
Marker pen
Tryptone Soya Agar (TSA)

REAGENTS/MEDIA

The following reagents and media were prepared as described in WLL SOP MM003 (6.1):-
Tryptone Soya Agar (TSA) (Thermofisher CM131)
0.1% w/v Bacteriological Peptone in Saline (PES) (Thermofisher LP0037) in 9mL volumes.

METHODS

On day one (1), the three (3) stainless steel door handles identified for testing were wiped with Fisher Scientific Disinfectant wipes to remove all bacteria from the surface.

After a period of seven (7) days and early morning, a swab area measuring apparatus (see Appendix 1) was cleaned thoroughly using Fisher Scientific Disinfectant wipes and attached to the rear of each door handle. This apparatus contained two (2) small openings to allow two (2) sets of swabs to be obtained from the door handle, one swab for the top section of the handle and one for the bottom section. Each opening was thoroughly swabbed using a sterile disposable transwab moistened in diluent. The contents of the swabs were vortexed for 5 minutes and then the Total Aerobic Microbial Count (TAMC) was performed by plating out 1mL of the contents of the swabs in individual petri dishes according to Wickham Laboratories SOP: MM168-00. Further dilutions were performed from the contents of the swabs using PES diluent and the same plating out procedure was followed. The plates were then poured with approximately 15mL-20mL of molten Tryptone Soya Agar (TSA).

Following the swab testing of the stainless steel door handles, Eco handles were installed on the same test doors. Once installed, these were wiped with Fisher Scientific Disinfectant wipes to remove all bacteria from the surface.

After a period of seven (7) days and early morning, the same swab area measuring apparatus was cleaned thoroughly using Fisher Scientific Disinfectant wipes and attached to the rear of each Eco handle. This apparatus contained two (2) small openings to allow two (2) sets of swabs to be obtained from the door handle, one swab for the top section of the handle and one for the bottom section. Each opening was thoroughly swabbed using a sterile disposable transwab moistened in diluent. The Total Aerobic Microbial Count was carried out on the swabs as described above.

INCUBATION AND ENUMERATION OF PLATES

Allow the agar to set and incubate the TSA plates inverted at 30-35°C for 3-5 days. After incubation the colonies on each plate were counted and the number of colonies per swab obtained.

TEST RESULTS

A microbiological assessment was made of the impact of the Eco handles with regard to contamination levels of the handle compared to stainless steel handles. The levels of bacteria on the Eco handle were compared to the levels of bacteria on the stainless steel handles. A summary table of results can be seen below.

For full results see Appendix 2.

Location	Standard Door Handle	Purehold Eco Handle	CFU Reduction
Male Toilet – Top Part of Handle	1,130 cfu/swab	150 cfu/swab	86.7%
Male Toilet – Bottom Part of Handle	1,580 cfu/swab	30 cfu/swab	98.1%
Female Toilet – Top Part of Handle	5,900 cfu/swab	10 cfu/swab	99.8%
Female Toilet – Bottom Part of Handle	6,300 cfu/swab	10 cfu/swab	99.8%
Canteen Door – Top Part of Handle	2,080 cfu/swab	80 cfu/swab	96.2%
Canteen Door – Bottom Part of Handle	3,450 cfu/swab	60 cfu/swab	98.3%
Overall	20,440 cfu/swab	340 cfu/swab	98.3%

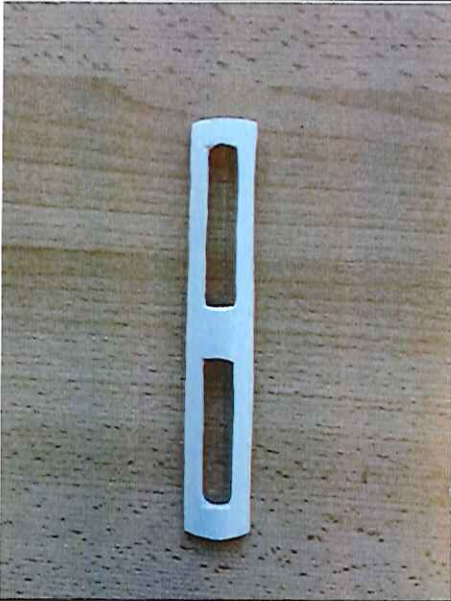
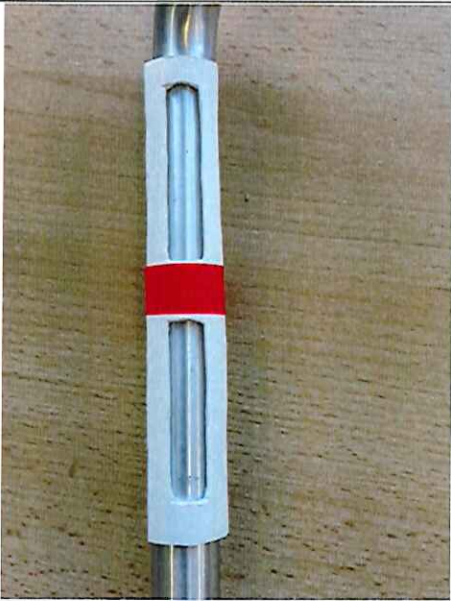
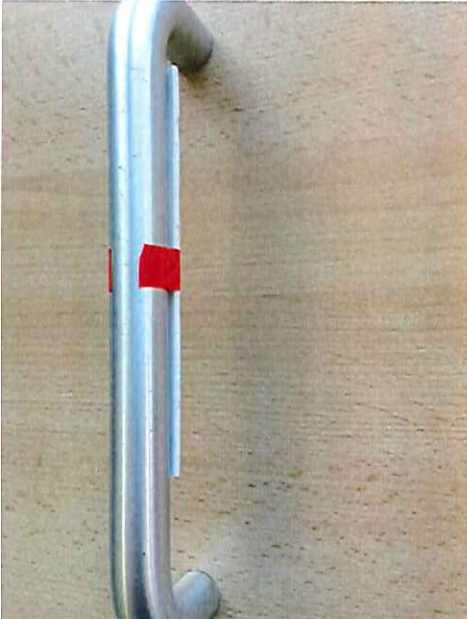
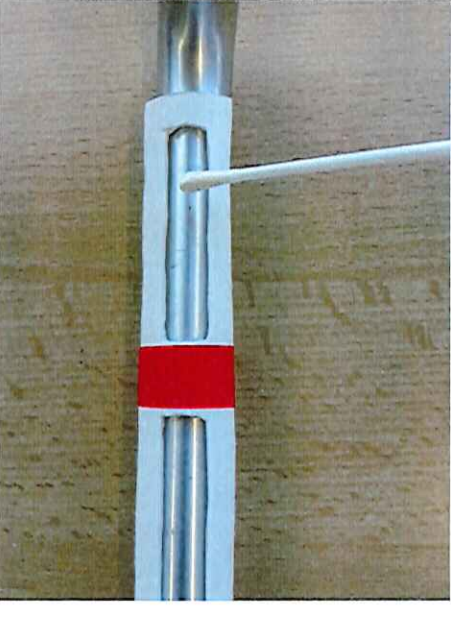
CONCLUSIONS

The results showed that counts from the Eco handles were significantly lower than those from the stainless steel door handles. On average the Eco handle was shown to be 98.3% cleaner, proving that there is a much lower risk to users of cross contamination by using the Eco handle compared to using stainless steel door handles.

REFERENCES

Wickham Laboratories Limited Standard Operating Procedure
MM003-21: Media and Reagent Preparation.
MM168-00: Environmental swab enumeration by plate count procedure

Appendix 1

 A white plastic measuring apparatus with two vertical slots, standing upright on a wooden surface.	 A close-up view of the white plastic apparatus attached to the rear of a metal door handle. A red band is visible around the handle.
<p>1. Swab area measuring apparatus</p>	<p>2. Swab area measuring apparatus affixed to rear of door handle [REAR VIEW]</p>
 A close-up view of the white plastic apparatus attached to the front of a metal door handle. A red band is visible around the handle.	 A close-up view of the white plastic apparatus attached to the rear of a metal door handle. A white swab is being inserted into the upper slot of the apparatus.
<p>3. Swab area measuring apparatus affixed to rear of door handle [FRONT VIEW]</p>	<p>4. Example of swab being used within swab measuring apparatus</p>

<p>1. Eco handle affixed to Female Toilet Door</p>	<p>2. Eco handle affixed to Male Toilet Door</p>
<p>3. Eco handle affixed to Canteen Door</p>	

Appendix 2
Stainless Steel Door Handle Test Results

At: M Bichard
Pine Hall Ltd
Unit 1, Colchester Business Park
Colchester Lane
Hornchurch
PCB GAQ

Date Received: 13 Jun 2017
Date Tested: 13 Jun 2017
Date Test Completed: 16 Jun 2017
Purchase Order:

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: Q03292/1
Test Requested: Enumeration of Swabs
Date Received: 13/06/2017
Test Article: Environmental Monitoring Swab
Sample Code: O Mole Top
Batch Ref: -
Qty Received: 1 Swab

Test	Method Used	Result
Total Aerobic Microbial Count of Swab	4841:AFCC	1.20 x10 ⁶ /swab
Product Standard Data Sheet	POG47/past	ENFC3

Report generated by Wickham Systems, for users and printed from LabView

Date: 17 Jun 2017 12:13:37

M K.A. Bichard
Business Manager - Projects

Certificate of Analysis - Client
Component tested
Part number tested
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Mr. M. Roberts
 Pure View Ltd
 Unit 1, Colphampton Business Park
 Colphampton Lane
 Colphampton
 Hampshire
 PO8 5AG

Date Received: 13 Jun 2017
 Date Tested: 13 Jun 2017
 Date Test Completed: 14 Jun 2017
 Purchase Order:

CERTIFICATE OF ANALYSIS

Laboratory Reference Number	0032042
Test Requested	Examination of Swab
Date Received	13/06/2017
Test Article	Environmental Monitoring Swab
Sample Code	Q Swab Surface
Batch Ref	
Qty Received	1 Swab
Test	Swabbed Area
Total Aerobic Microbial Count of Swab	None detected
Product Standard Data Sheet	PO047/psd

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Date: 17 Jun 2017 12:33

M. A. Baker
 Business Manager - Projects

Certificate of Analysis - Client
 Configuration: 000000
 File Number: 000000
 Version: 1.0.0

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Mr. M Roberts
 Pure Hand Ltd
 Unit 1, Colchester Business Park
 Colchester Lane
 Colchester
 Essex
 CO1 0AG

Date Received: 13 Jun 2017
 Date Tested: 13 Jun 2017
 Date Test Completed: 16 Jun 2017
 Purchase Order:

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 003262/A
 Test Description: Enumeration of Yeast
 Date Received: 13/06/2017
 Test Address: Environmental Monitoring Yeast
 Sample Code: 5 Sample Top
 Batch Ref: -
 Qty Received: 1 Yeast

Test	Method Name	Result
Total Aerobic Microbial Count of Yeast	MM160/3	3,100 CFU/yeast
Product Standard Daily Sheet	PO647/pad	EN903

Date: 17 Jun 2017 12:13:37

M F A, Baker
 Business Manager - Projects

Certificates of Analysis - Online
 Compliance verified
 PQR Number: 00000004
 Please Refer: GMP GLP FDS Company Registered & Inspected No. 72941



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Mr. M Roberts
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 PO8 5UG

Date Received: 13 Jun 2017
 Date Tested: 13 Jun 2017
 Date Test Completed: 14 Jun 2017
 Purchase Order:

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 00000226
 Test Description: Enumeration of Swab
 Date Received: 13/06/2017
 Test Article: Pharmaceutical Manufacturing Swab
 Sample Code: 3 Female Softform
 Batch Ref: -
 Qty Received: 1 Swab

Test	Method Item	Result
Total Aerobic Microbial Count of Swab	MS1 (M/10)	6,300 c.f.u./swab
Product Sterilant Residue Swab	POC47 (pH)	ENVD

Approved for release by: [Signature] Date: 17 Jun 2017 12:13:37

Mr K.A. Butler
 Business Manager - Projects

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Date Received: 13 Jun 2017
 Date Issued: 13 Jun 2017
 Date Test Completed: 16 Jun 2017
 Purchase Order:

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 003306273
 Test Requested: Enumeration of Swabs
 Date Received: 13/06/2017
 Test Address: Environmental Monitoring Swab
 Sample Code: F Container Top
 Batch Ref: -
 Qty Received: 1 Swab

Test	Method Name	Result
Total Aerobic Microbial Count of Swab	AM1 (M73)	2,000 c.f.u./swab
Product (Standard) Data Sheet	FG04 (1)ed	EN129

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Date Received: 13 Jun 2017
 Date Issued: 13 Jun 2017
 Date Test Completed: 14 Jun 2017
 Purchase Order:

CERTIFICATE OF ANALYSIS

Laboratory Reference Number: 0333424
 Test Requested: Enumeration of Swab
 Date Received: 13/06/2017
 Test Address: Environmental Monitoring Swab
 Sample Code: F Cottenham Boreham
 Sublot Ref: -
 Qty Received: 1 Swab

Test	Method Used	Result
Total Aerobic Microbial Count of Swab	MH145/03	3,420 cfu/swab
Product/Standard Data Sheet	FG04/food	EN137

Approved by: Date: 17 Jun 2017 12:13:37

Mr P.A. Barker
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Certificate of Analysis - Class
 Configuration: 000001
 Part Number: P000001
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Eco Handle Test Results



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CERTIFICATE OF ANALYSIS

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 PO8 0AQ

Purchase Order:

Test: Enumeration of Swab

LabRef	Test Article	Method Item	Sample Code	Batch Ref	Date Received
Test			Result	Date Tested	Date Completed
0033352/1	Swab		G Male Top		19 Jan 2017
	Total Aerobic Microbial Count of Swab	NM168/00	150 cfu/swab	19 Jan 2017	23 Jan 2017
	Product Standard Data Sheet	FG047/psd	BIIV03	19 Jan 2017	23 Jan 2017
0033352/2	Swab		G Male Bottom		19 Jan 2017
	Total Aerobic Microbial Count of Swab	NM168/00	30 cfu/swab	19 Jan 2017	23 Jan 2017
	Product Standard Data Sheet	FG047/psd	BIIV03	19 Jan 2017	23 Jan 2017
0033352/3	Swab		F Canleen Top		19 Jan 2017
	Total Aerobic Microbial Count of Swab	NM168/00	80 cfu/swab	19 Jan 2017	23 Jan 2017
	Product Standard Data Sheet	FG047/psd	BIIV03	19 Jan 2017	23 Jan 2017
0033352/4	Swab		F Canleen Bottom		19 Jan 2017
	Total Aerobic Microbial Count of Swab	NM168/00	60 cfu/swab	19 Jan 2017	23 Jan 2017
	Product Standard Data Sheet	FG047/psd	BIIV03	19 Jan 2017	23 Jan 2017
0033352/5	Swab		S Female Top		19 Jan 2017
	Total Aerobic Microbial Count of Swab	NM168/00	10 cfu/swab	19 Jan 2017	23 Jan 2017
	Product Standard Data Sheet	FG047/psd	BIIV03	19 Jan 2017	23 Jan 2017

Certificate of Analysis - MSMM
 Consignment: 0033352
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CERTIFICATE OF ANALYSIS

0033352/6	Swab		S Female Bottom		19 Jan 2017	19 Jan 2017
Total Aerobic Microbial Count of Swab		MW1.68/00	10 cfu/swab		19 Jan 2017	23 Jan 2017
Product Standard Data Sheet		FG047/psd	ENV03		19 Jan 2017	23 Jan 2017

Approval is provided by Electronic Signature. Their name is shown below.

L. Bailey

Date: 24 Jan 2017 10:45:34

L Bailey

Laboratory Manager - Pharmaceutical Microbiology

Certificate of Analysis - MCMV
Consignment: 0033352
Print Number: P0040069
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