MILOUDA LABORATORIES מעבדות מילודע מילווע אשרת מילודע אשרת 25201, Israel 25201 איר נע אשרת 25201 מלפון 972-4-9853292, Fax: 972-4-9853291 04-9853291



# Study Name:

# Efficacy of antiseptic preparation for disinfection of surfaces for **Pharmacidal**

# **Report Number:**

MILOUDA #62935/1

# Sponsor:

Biological Industries

David Fiorentini

# **Sponsor Address:**

Kibbuts Beit Haemek

I Page of 7

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# Study Time Schedule:

Study initiation: 12.10

Study completion: 1.11

Report completion: 2,2011

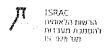
# **Authorized Signature:**

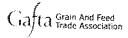
ד"ר דונית בן אביהם מנהלת מיקצועית. מעבדה מיקרוכיאלית

**Quality Assurance Signature:** 

2 Page of 7

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# **Table of Contents**

1.	STUDY OBJECTIVE	4
2.	TEST SOIL	2
3.	TEST ARTICLE AND CONTROLS	2
4.	GROWTH MEDIUM	
5.	RELATED DOCUMENTS	4
6.	STUDY OUTLINE	
	ASSAY OF BIOBURDEN.	
	CONCLUSIONS	
	REFERENCES	

3 Page of 7

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# 1. Study Objective

The objective of this short term study was to evaluate the microbiological aspects of the antiseptic sample to remove microorganisms from surfaces.

The microbiological study was conducted at Milouda Laboratories, Akko, Israel.

### 2. Test Soil

The soil is composed from fresh suspension of artificial test soil that comprises three different proteins (7% Bovine Albumin fraction 5; Porcine Mucin type 3; and Bovine Fibrogen frcation 1, in 1:1:1 ration, per Orzechowski and de Bruijn, AAMI TIR 30: 2003), as well as Gram-positive (Staphylococcus aureus ATCC 6538) and Gram-negative (E.coli) bacteria.

The bacterial concentration of the inoculum was 106 colony forming units (CFU) per 1 ml for each bacterium tested.

# 3. Sample description

Pharmacidal - Disinfection Solution for incubators for cell and tissue culture. Cat. No. 110100L.

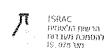
# 4. Growth Medium – Quality control

The following media were tested for their ability to support growth of microorganisms according to USP standards and found to be suitable.

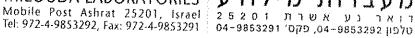
- 6.1 Bacterial Growth Medium: TSA (Milouda lots 6051, 591).
- 6.2 Buffer phosphate (Milouda lot 6028).

4 Page of 7

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# 5. Related Documents

5.1 Milouda SOP 200.04.01.

# 6. Study Outline

- 14 glass surfaces (50x50 mm) were inoculated with test soil (as defined in section 4).
- The devices were left to dry for 30 minutes at room temperature.
- Then ten glasses were disinfected according to manufactures instructions using Pharmacidal (spraying until the glass is completely covered with the disinfectant)
- 14 glasses were tested for bioburden.

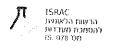
# 7. Assay of Bioburden

# 7.1 Viable Bioburden Assessment

- The glasses were quantitatively assessed using standard filtration procedure and pour plate technique.
- The glass was washed with buffer phosphate (100 ml) for 2 minutes by hand mixing.
- The eluent was filtered (100, 10 ml) or plated in Petri dishes (in dilutions ml). The filter papers were put on solid TSA.
- Warm TSA was poured in the Petri dishes and the plates were left to solidify.
- The plates were incubated at 35°C for 48-72 hours. The bacterial colonies were counted.

5 Page of 7

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### 7.2 Results

The table below summarizes the bioburden assay results.

Sample #	Colony Forming Units/Device
1	<1
2	<1
3	<1
44	<1
5	<1
6	<1
7	<1
8	<1
9	<1
10	<1
Average	<1
Control positive -1	1,020,000
Control positive -2	1,700,000
Control positive -3	1,600,000
Control positive -4	900,000
Average	1,305,000
Negative control 1	<1

Table 2: Bioburden Results

6 Page of 7

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### 8. Conclusions:

The preparation Pharmacidal reduced at least 6 magnitudes of bacteria tested with the presence of soil on surfaces.

## References:

ASTM International. Standard test method for determination of effectiveness of cleaning processes for reusable medical instruments using a microbiologic method (simulated use test). ASTM E2314:03. Philadelphia: ASTM International, 2003.

ASTM International. Standard test method to determine efficacy of disinfection processes for reusable medical devices (simulated use test). ASTM E1837:96. (reapproved 2002).

AAMI TIR 30: 2003. A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.

ISO 11737-1. Sterilization of medical devices-Microbiological methods-part 1: Estimation of population of microorganisms on products, 2006

EN 14561:2006 - Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area – Test method and requirements.

7 Page of 7

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