MILOUDA LABORATORIES
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מעבדות מילודע
דואר נע אשרת 25201
טלפון 04-9853292, פקס' 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

Remarks:

1. The laboratory operates under organized working procedures which correlate to the international standard ISO/IEC 17025 in those disciplines where accreditation has been granted.
2. The microbiological tests are within the recognition framework of the Ministry of Health as published in the registrations.
3. The results are related only to the tested sample.
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5. Sampling was provided by and is the sole responsibility of the customer.
6. The Israel Laboratory Accreditation Authority is not responsible for the test results.
7. The valid results are those of the most updated report.

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Study Time Schedule:

Study initiation: 12.10

Study completion: 1.11

Report completion: 2.2011

Authorized Signature:

ד"ר רונית בן אברהם
מנהלת מיקרוביולוגית · מעבדה מיקרוביאלית

Quality Assurance Signature:

ד"ר לילך סומך

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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 10^6 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).

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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 35ºC for 48-72 hours. The bacterial colonies were counted.

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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
4	<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

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8. *Conclusions:*

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

9. *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.

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