

20 August, 2013

PSI New Zealand Limited
PO Box 28563
Remuera
Auckland 1050
NEW ZEALAND

Attention: Simon Wright

Dear Simon,

Sample Information

Number of samples	1
Number of tests	10
Project number	13NZAK0050169.2
Sample number	3424722 - 3424731
Laboratory testing started	Tuesday, 30 July, 2013
Test	Antimicrobial testing
Methodology	As directed by the client

Introduction

As requested, the microbiological challenge test for antimicrobial effectiveness was performed on the Medigene sample as submitted.

All documentation is kept in accordance with ISO 17025:1999. Laboratory personnel involved with this testing, have the appropriate training and experience to perform all necessary methodology.

Selection of Product for testing

Sample was chosen for testing by the client.

Selection of cultures and culture conditions

Cultures were maintained in accordance with the recommendations of the Curator of the Culture Collections Centre NZ Communicable Disease Centre and New Zealand Laboratory Services quality control systems.

As requested, the following organisms were used in the test:

<i>Escherichia coli</i>	(NZRM 916)
<i>Salmonella Menston</i>	(NZRM 383)
<i>Bacillus cereus</i>	(NZRM 5)
<i>Listeria monocytogenes</i>	(NZRM 44)
<i>Pseudomonas aeruginosa</i>	(NZRM 918)

Selection of Technique

Product was reconstituted as directed by the client.

Separate 10ml portions of the sample liquid were inoculated with an aliquot of the test organism. Mixed and left for 30 seconds and 300 seconds. An enumeration was then performed to determine the level of any viable test organisms remaining in the product under test.

Enumeration performed using the pour plate method.

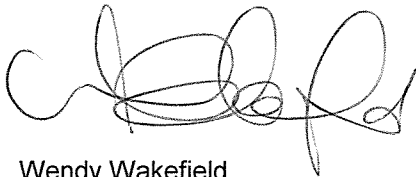
Results

The results apply to the samples as received at the laboratory. Please refer to the Sample Identification and Result table for all results.

Please contact us should you require any further information.

Yours faithfully,

EUROFINS NZ LABORATORY SERVICES LIMITED



Wendy Wakefield
Team Leader – Pharmaceutical Micro Services



Ganga Jayawickrama
Laboratory Technician – Pharmaceutical Micro Services

This report must not be altered or reproduced except in full.

Sample Identification and Results Table

Product Name	Medigene					Log	Count after 30 seconds (cfu/ml)	Log	Log Difference between starting inoculum and count after 30 seconds	% Reduction between starting inoculum and count after 30 seconds
Organism Name	NZRM Number	Starting inoculum (cfu/ml)	Log	Sample number	Count after 30 seconds (cfu/ml)	Log	Log Difference between starting inoculum and count after 30 seconds	% Reduction between starting inoculum and count after 30 seconds		
<i>Escherichia coli</i>	916	3.4×10^7	7.5	3424722	<1 (NR)	0.0	7.5	100.0		
<i>Salmonella Menston</i>	383	1.1×10^8	8.0	3424724	<1 (NR)	0.0	8.0	100.0		
<i>Bacillus cereus</i>	5	7.6×10^7	7.9	3424726	<1 (NR)	0.0	7.9	100.0		
<i>Listeria monocytogenes</i>	44	1.4×10^8	8.1	3424728	<1 (NR)	0.0	8.1	100.0		
<i>Pseudomonas aeruginosa</i>	918	4.6×10^7	7.7	3424730	<1 (NR)	0.0	7.7	100.0		

Key:	
NZRM	New Zealand Reference Culture Collection, Medical Section
<	Less than
NR	No recovery of the test organism

This report must not be altered or reproduced except in full.

Sample Identification and Results Table

Product Name	Medigene					Log	Count after 300 seconds (cfu/ml)	Log	Log Difference between starting inoculum and count after 300 seconds	% Reduction between starting inoculum and count after 300 seconds
	Organism Name	NZRM Number	Starting inoculum (cfu/ml)	Log	Sample number					
<i>Escherichia coli</i>	916	3.4×10^7	7.5	3424723	7.5	<1 (NR)	0.0	7.5	100.0	
<i>Salmonella Menston</i>	383	1.1×10^8	8.0	3424725	8.0	<1 (NR)	0.0	8.0	100.0	
<i>Bacillus cereus</i>	5	7.6×10^7	7.9	3424727	7.9	<1 (NR)	0.0	7.9	100.0	
<i>Listeria monocytogenes</i>	44	1.4×10^8	8.1	3424729	8.1	<1 (NR)	0.0	8.1	100.0	
<i>Pseudomonas aeruginosa</i>	918	4.6×10^7	7.7	3424731	7.7	<1 (NR)	0.0	7.7	100.0	

Key:	
NZRM	New Zealand Reference Culture Collection, Medical Section
<	Less than
NR	No recovery of the test organism

This report must not be altered or reproduced except in full.