

Time Kill Study Final Report


Test Article: 1 sample
 Study Number: 847108
 Study Received Date: 22 Sep 2015
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0158 Rev 02
 Protocol Detail Sheet (PDS) Number: 201503692 Rev 01

Summary: This report describes the procedure for the evaluation of products for anti-microbial activity against selected organisms at representative contact times. Products are evaluated in a liquid matrix. The test organisms and contact times are chosen by the sponsor. This is a quantitative test that allows the determination of the amount of organism reduction at pre-determined intervals. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results: Values are considered approximate (~) when plate counts were outside of the statistically accurate range of 25-250 colony forming units (CFU)/plate for bacteria and yeast and 8-80 CFU/plate for mold. Less than symbols (<) are applied to recovery values where no CFU were observed on the plates. This denotes the limit of detection (LOD) for the test.

Test Article:

Organism	Identification	Exposure Intervals	Average Control Titer (CFU/mL)	Average Test Article Titer (CFU/mL)	Percent Reduction (%)	LOG ₁₀ Reduction
Methicillin-Resistant <i>Staphylococcus aureus</i> , ATCC #33591	Control	30 minutes	5.0 x 10 ⁶	6.4 x 10 ⁶	-28	-0.11
		30 seconds		6.3 x 10 ⁶	-25	-0.10
	Test Article	15 minutes		6.1 x 10 ⁵	88	0.92
		30 minutes		1.6 x 10 ⁴	99.67	2.49
<i>Staphylococcus aureus</i> , ATCC #6538	Control	30 minutes	~5.4 x 10 ⁶	7.5 x 10 ⁶	~40	~-0.15
		30 seconds		~4.5 x 10 ⁶	~16	~-0.08
	Test Article	15 minutes		~4.9 x 10 ⁵	~90.8	~-1.04
		30 minutes		7.2 x 10 ³	~99.87	~-2.87
<i>Listeria monocytogenes</i> , ATCC #19111	Control	30 minutes	5.6 x 10 ⁶	~5.5 x 10 ⁶	~2	~-0.01
		30 seconds		~4.6 x 10 ⁶	~18	~-0.08
	Test Article	15 minutes		~1.0 x 10 ³	~99.982	~-3.74
		30 minutes		<2.0 x 10 ¹	>99.99964	>5.45


 Study Director

Wellance T. Naeata, B.S.


 Study Completion Date



Neutralization:

Organism	Average Test Article Counts (CFU)	Average Control Counts (CFU)	Percent Neutralization (%)
MRSA	18	22	82
<i>S. aureus</i>	10	12	83
<i>L. monocytogenes</i>	14	14	100