

Time Kill Study Final Report

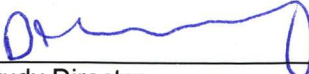
Test Article: Curoxen Lot 2018 02 10
 Purchase Order: PO11401
 Study Number: 915448-S01
 Study Received Date: 08 Sep 2016
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0158 Rev 02
 Protocol Detail Sheet (PDS) Number: 201602182 Rev 01
 Protocol Amendment Number(s) (PAN): PAN-161104

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
Methicilin Resistant <i>Staphylococcus aureus</i> , ATCC #33591	Positive Control	60 minutes	1.9 x 10 ⁷	1.8 x 10 ⁷	6	0.03
	Test Article			<2.0 x 10 ²	>99.9990	>4.99
<i>Staphylococcus aureus</i> , ATCC #6538	Positive Control	60 minutes	1.6 x 10 ⁷	1.1 x 10 ⁷	32	0.17
	Test Article			<2.0 x 10 ²	>99.9987	>4.90
<i>Pseudomonas aeruginosa</i> , ATCC #9027	Positive Control	60 minutes	1.6 x 10 ⁷	1.8 x 10 ⁷	-7	-0.03
	Test Article			<2.0 x 10 ²	>99.9988	>4.91
<i>Escherichia coli</i> , ATCC #8739	Positive Control	60 minutes	1.3 x 10 ⁷	9.4 x 10 ⁶	28	0.15
	Test Article			<2.0 x 10 ²	>99.9985	>4.82


 Study Director

Danielle Greening

03 Oct 2016
 Study Completion Date



Organism	Identification	Exposure Intervals	Average Control Titer (CFU/mL)	Average Test Article Titer (CFU/mL)	Percent Reduction (%)	LOG ₁₀ Reduction
<i>Enterococcus faecalis</i> , ATCC #4082	Positive Control	60 minutes	2.5 x 10 ⁷	2.9 x 10 ⁷	-14	-0.06
	Test Article			~2.0 x 10 ²	~99.99921	~5.10
<i>Candida albicans</i> , ATCC #10231	Positive Control	60 minutes	7.3 x 10 ⁶	1.3 x 10 ⁷	-83	-0.26
	Test Article			<2.0 x 10 ²	>99.9972	>4.56

Neutralization:

Organism	Average Test Article Counts (CFU)	Average Control Counts (CFU)	Percent Neutralization (%)
MRSA	153	126	121
<i>S. aureus</i>	43	41	105
<i>P. aeruginosa</i>	64	54	119
<i>E. coli</i>	36	40	90
<i>E. faecalis</i>	69	55	125
<i>C. albicans</i>	39	45	87