



PRE-KLENZ™ USP PRESERVATIVE EFFECTIVENESS TESTING

PURPOSE

The purpose of this test was to evaluate the preservative efficacy of PRE-Klenz. This was done using the United States Pharmacopeia XXIV (USP) <51> Antimicrobial Preservatives Effectiveness Test.

METHODS

In this study, 0.1 mL of a suspension of test organism was added to a 20 mL aliquot of PRE-Klenz in a sterile jar and mixed thoroughly. Immediately after inoculation and at 7, 14, and 28 days after inoculation, a sample of product was removed and the number of viable organisms remaining per mL were determined by the plate count method.

RESULTS

The USP preservative effectiveness protocol requires that the concentrations of viable bacteria are reduced to not more than 2.0 log reduction of the initial concentrations at the fourteenth day. It is also required that the concentrations of viable yeasts and molds remain at or below the initial concentrations during the first 14 days and the concentration of each test organism remains at or below these designated levels during the remainder of the 28-day test period.

**TABLE I:
PRE-KLENZ PRESERVATIVE EFFECTIVENESS TESTING RESULTS***

Organism	ATCC#	Inoculum CFU/mL	CFU/mL at:		
			Day 7	Day 14	Day 28
<i>Aspergillus niger</i>	16404	1.5×10^5	< 100	<100	<100
<i>Candida albicans</i>	10231	4.1×10^5	<10	<10	<10
<i>Escherichia coli</i>	8739	6.4×10^5	<10	<10	<10
<i>Pseudomonas aeruginosa</i>	9027	3.4×10^5	<10	<10	<10
<i>Staphylococcus aureus</i>	6538	6.7×10^5	<10	<10	<10

CONCLUSION

The results of the preservative effectiveness testing of PRE-Klenz show that it is an adequately preserved product as defined by this standard assay. The counts of *Candida albicans*, *Escherichia coli*, *Pseudomonas aeruginosa*, and *Staphylococcus aureus* were <10 by Day 7 of the test and remained at <10 for the remainder of the test period. The counts of *Aspergillus niger* were well below the initial levels by Day 7 and remained below initial levels by Day 28. These levels are well below the allowable levels for the test, confirming the preservative effectiveness of PRE-Klenz.

For further information, please contact:



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