

Results

Validation of test parameters: validation of drug neutralization by D/E broth and dilution.

A dilution factor of 1:25 appears to be sufficient to neutralize the active and preservative ingredients in the Finipil antiseptic drug product that may be carried over onto the agar plate. In no instance was there a greater than $\pm 10\%$ difference in recovered counts of *S. aureus* ATCC # 6538, *E. coli* ATCC # 8739 and *P. aeruginosa* ATCC 9027 between the control and test groups.

Modified ASTM method E2315-03 in vitro 15 second time kill assays:

Table 1. Results expressed as % reduction of microbes in the test group versus the control group after a 15 second exposure.

Challenge Organism	Control	Finipil OTC	
	cfu/ml	cfu/ml	% reduction
<i>S. aureus</i> ATCC 6538	1.9×10^7	1.9×10^3	99.99
<i>S. aureus</i> ATCC 33592	2.5×10^7	2.6×10^4	99.9
<i>P. aeruginosa</i> ATCC 9027	1.3×10^8	<49	>99.99996
<i>E. coli</i> ATCC 8739	7.8×10^8	<49	>99.99999
<i>C. albicans</i> ATCC 10231	6.0×10^6	1.3×10^2	99.998

Table 2. Results expressed as Log 10 reduction in microbial counts in the test groups compared to those in the control group after a 15 second exposure.

Challenge Organism	Control	Finipil OTC	
	Log 10 CFU/sample	Log 10 CFU/sample	Log 10 Reduction
<i>S. aureus</i> ATCC 6538	7.3	3.3	4.0
<i>S. aureus</i> ATCC 33592	7.4	4.4	3.0
<i>P. aeruginosa</i> ATCC 9027	8.1	<1.7	>6.4
<i>E. coli</i> ATCC 8739	8.9	<1.7	>7.2
<i>C. albicans</i> ATCC 10231	6.8	2.1	4.7

The time kill results show that the *Finipil*[®] OTC formulation evaluated in this *in vitro* study meets and exceeds the FDA criteria for antimicrobial efficacy, i.e. a greater than 99.9% or 3 Log 10 reduction of a broad spectrum of organism in 15 seconds.

Discussion and Conclusions

One of the major concerns of product manufacturers and end users of beauty products such as salons is the risk of microbial contamination and, indeed, outbreaks of infections have been documented.^{5,6} In order to minimize this risk, the industry uses various

strategies including preservatives, single use products and cleaning/sanitization procedures. To further increase the safety of the client undergoing a delapitory procedure in a salon setting, Finipil[®] OTC, a new antiseptic cream containing 0.2% benzethonium chloride (BZT) as the active ingredient formulated in a novel base, has been developed for use after hair removal.

This study is designed to determine the rapid sanitizing efficacy of this new topical agent against a broad spectrum of pathogens. The *in vitro* time kill studies were carried out in accordance with the US FDA's Tentative Final Monograph for Health-Care Antiseptic Drug Products; Proposed Rule.²

Using an antiseptic drug product as opposed to a non-sanitizing cosmetic on skin that is mildly traumatized due to hair removal procedures may reduce the number of germs thus lowering the risk of folliculitis¹.

In conclusion, the tests carried out in this study of Finipil[®] OTC demonstrate that the product has rapid and broad spectrum activity against pathogens. In addition, this product is self-preserving and retains the same properties, i.e., soothing, cooling, moisturizing and other characteristics of the first generation version and is non-irritating even when used continuously over several weeks (data available on request from Equibal Labs).

References

1. <https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001826/>
2. Federal Register of Friday June 17, 1994: Volume 59, No. 116; 21 CFR Parts 333 and 369. "Tentative Final Monograph for Health-Care Antiseptic Drug Products; Proposed Rule."
3. ASTM E2315 - 03(2008) Standard Guide for Assessment of Antimicrobial Activity Using a Time-Kill Procedure. 100 Barr Harbor Drive, West Conshohocken, Pennsylvania, USA. <http://www.astm.org/Standards/E2315.htm>
4. National Committee for Clinical Laboratory Standards, Standard M7-A5: Methods for dilution antimicrobial susceptibility tests for bacteria that grow aerobically. Fifth Edition, National Committee for Clinical Laboratory Standards, Wayne, PA, 1997.
5. Winthrop KL, Abrams M, Yakrus M, et. al. An outbreak of mycobacterial furunculosis associated with footbaths at a nail salon. *New England Journal of Medicine*. 2002;326(18):1366-1371.
6. http://wwwnc.cdc.gov/eid/article/14/11/07-1297_article.htm

