STUDY TITLE
Non-GLP Suspension Time-Kill ASTM E2315

Product Identity
Femiclear 1 Day (New Formula)
Femiclear 2 Day (New Formula)

Test Microorganism(s)
C. albicans ATCC 10231
C. glabrata ATCC 90876
C. parapsilosis ATCC 22019

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RESULTS

Table 1: *C. albicans* Percent Reduction and Log_{10} Reduction Compared to Time Zero Average

Test Microorganism	Contact Time	Test Substance	Replicate	CFU/ml	Average CFU/ml	Percent Reduction compared to Time Zero	Log Reduction Compared to Time Zero
C. albicans ATCC 10231	Time Zero		1	1.37E+05	1.32E+05	N/A	
			2	1.26E+05			
	4 hours	Femiclear 1 Day (new)	1	<1.00E+01*	<1.00E+01*	>99.99%	>4.12
			2	<1.00E+01*			
		Femiclear 2 Day (new)	1	<1.00E+01*	<1.00E+01*	>99.99%	>4.12
			2	<1.00E+01*			

*Limit of detection. Values below limit of detection <1.00E+01

Table 2: *C. glabrata* Percent Reduction and Log_{10} Reduction Compared to Time Zero Average

Test Microorganism	Contact Time	Test Substance	Replicate	CFU/ml	Average CFU/ml	Percent Reduction compared to Time Zero	Log Reduction Compared to Time Zero
C. glabrata ATCC 90876	Time Zero		1	4.11E+05	3.75E+05	N/A	
			2	3.39E+05			
	4 hours	Femiclear 1 Day (new)	1	<1.00E+03*	<1.00E+03	>99.73%	>2.57
			2	<1.00E+03*			
		Femiclear 2 Day (new)	1	<1.00E+03*	<1.00E+03	>99.73%	>2.57
			2	<1.00E+03*			

*Limit of detection. Values below limit of detection <1.00E+03

Table 3: *C. parapsilosis* Percent Reduction and Log_{10} Reduction Compared to Time Zero Average

Test Microorganism	Contact Time	Test Substance	Replicate	CFU/ml	Average CFU/ml	Percent Reduction compared to Time Zero	Log Reduction Compared to Time Zero
C. parapsilosis ATCC 22019	Time Zero		1	1.04E+05	1.09E+05	N/A	
			2	1.13E+05			
	4 hours	Femiclear 1 Day (new)	1	<1.00E+03*	<1.00E+03*	>99.08%	>2.04
			2	<1.00E+03*			
		Femiclear 2 Day (new)	1	<1.00E+03*	<1.00E+03*	>99.08%	>2.04
			2	<1.00E+03*			

*Limit of detection. Values below limit of detection <1.00E+03

Table 4: *C. albicans* Neutralization Verification

Test Microorganism	Test Substance	Test	Replicate	Neutralization Validation plate counts (CFU)		Average CFU	Neutralization verified
C. albicans ATCC 10231*	N/A	Test C	1	5.00E+00	4.00E+00	4.75E+00	N/A
			2	5.00E+00	5.00E+00		
	N/A	Test B	1	1.00E+01	4.00E+00	6.25E+00	131.58%
			2	6.00E+00	5.00E+00		
	Femiclear 1 Day (new)	Test A	1	6.00E+00	5.00E+00	4.50E+00	94.74%
			2	3.00E+00	4.00E+00		
	Femiclear 2 Day (new)	Test A	1	8.00E+00	4.00E+00	6.50E+00	136.84%
			2	7.00E+00	7.00E+00		

* Neutralization verification was only performed using *C. albicans* ,it is representative of all candida species used in testing.

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RESULTS (cont.)

Table 5: Average Percent Reduction for all Three Test Microorganisms

Test Microorganism	Test Substance	Average % Reduction of all 3 Test Microorganisms
C. albicans ATCC 10231 C. glabrata ATCC 90876 C. parapsilosis ATCC 22019	Femiclear 1 Day (new)	>99.60%
	Femiclear 2 Day (new)	>99.60%

Table 6: Media Sterility and Purity Controls

Control	Result
C. albicans ATCC 10231 Purity	Pure Growth
C. glabrata ATCC 90876	Pure Growth
C. parapsilosis ATCC 22019	Pure Growth
Phosphate Buffer Saline Culture Diluent Sterility	No Growth
Phosphate Buffer Saline Dilution Sterility	No Growth
Dey-Engley Neutralizing Broth (D/E Broth)	No Growth
Potato Dextrose Agar Sterility	No Growth

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REFERENCES

ASTM E2315. Standard Guide for Assessment of Activity Using a Time-Kill Procedure. West Conshohocken, PA. American Society for Testing and Materials.

Microchem Laboratory's SOP General Laboratory Safety, Organization and Personnel 008, current revision.

Microchem Laboratory's SOP Dilution, Plating, Counting, and Calculations, Testing Facility Operation 017, current revision.

Microchem Laboratory's SOP Test and Control Article/Substance Preparation, Test, Control and Reference Substances 003, current revision.

STUDY RECORD AND TEST SUBSTANCE RETENTION

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