University of Houston Microbiology Research Labs
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TECHNICAL REPORT

Microbiologic Properties of Compounded Streptomycin 215mg/Flucytosine 250mg Capsules ("SF") *mixed with BASSA-GEL™ against selected pathogens was assessed and the results are conveyed here.*

Executive Summary: SF (3 capsules) ("DRUG") mixed with BASSA-GEL™ was tested against the identified pathogens and the results of these tests are reported as follows. Should there be only a "blue-line" reported that means the DRUG was so effective against the pathogen that the detection limit was below the assay of the experiment.

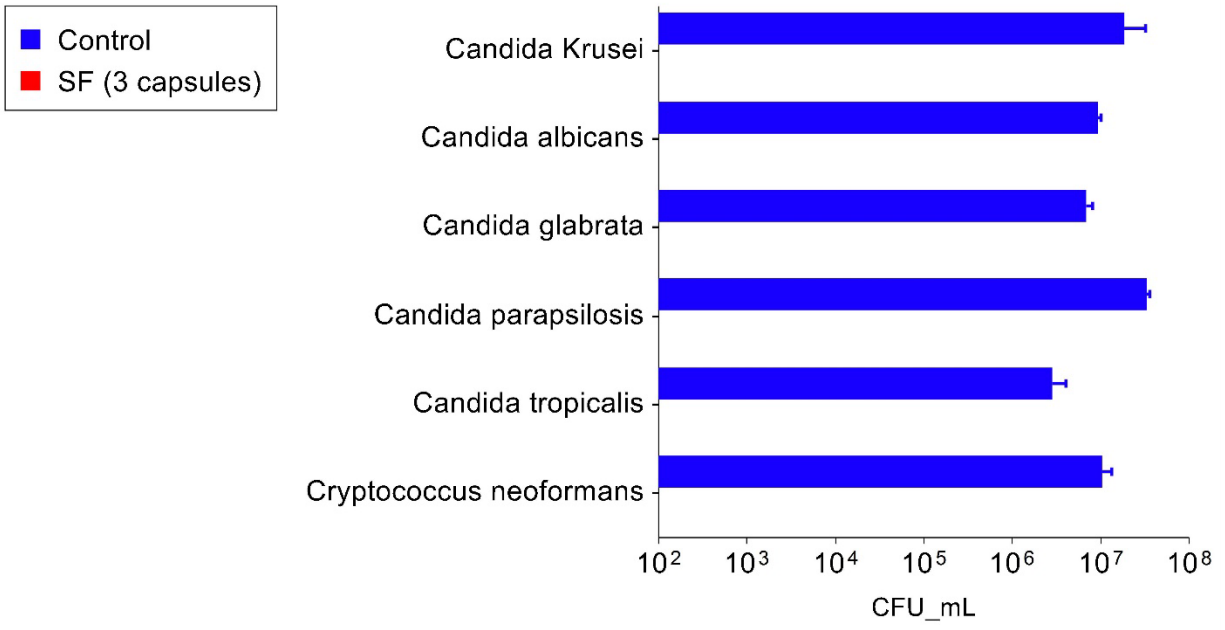
Methods overview: Methods for this laboratory study were adapted from Bearden *et al* and from FDA Docket No. FDA-1975-N-0012.[1,2] All experiments were performed using the commercially available formulations. Reductions in fungal counts between agents were determined.

Methods and Results:

Fungal strains: Pathogens selected are defined in ATCC or CDC AR strains (Table 1, page 2).

Antimicrobial agents: SF (3 capsules) mixed with BASSA-GEL™

Experiment: Pre-sterilized discs were saturated with 1 x$10^{7\text{-}8}$ CFU/mL of fungal culture, allowed to incubate for 24 hours to mimic *ex vivo* wound infection, exposed to the gel/drug solution or positive control (phosphate buffer saline, PBS), and then incubated aerobically at 37°C for 24 hours. After this time, disks were washed, diluted, and then cultured onto blood agar plates for colony forming unit (CFU/mL) counts using serial dilution spread plate technique. The results are reported below (mean log CFU/mL ± standard error). As stated above in the executive summary, should there be only a "blue-line" reported that means the DRUG was so effective against the pathogen that the detection limit was below the assay of the experiment.



Interpretation: SF (3 capsules) with BASSA-GEL™ was tested in a model mimicking a bandaged wound. The experiment demonstrated significant reductions in yeast species tested.

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Table 1. Organisms Included in Testing

Organism	**ATCC/CDC #**
Candida albicans	ATCC 90028
Candida glabrata	ATCC 2001
Candida krusei	ATCC 2159
Candida parapsilosis	ATCC 22019
Candida tropicalis	AR 0345
Cryptococcus neoformans	A*TCC 14116*

References

1. Bearden DT, Allen GP, Christensen JM. Comparative in vitro activities of topical wound care products against community-associated methicillin-resistant Staphylococcus aureus. *J Antimicrob Chemother* 2008;62:769-72.
2. Huang DB, Okhuysen PC, Jiang ZD, DuPont HL. Enteroaggregative Escherichia coli: an emerging enteric pathogen. *Am J Gastroenterol* 2004;99:383-9.