

TECHNICAL REPORT

Microbiologic Properties of Compounded Streptomycin 150mg/Vancomycin 60mg/Flucytosine 250mg Capsules ("SVF") mixed with BASSA-GEL™ against selected pathogens was assessed and the results are conveyed here.

Executive Summary: SVF (3 capsules) ("DRUG") mixed with BASSA-GEL™ ("DRUG") 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.

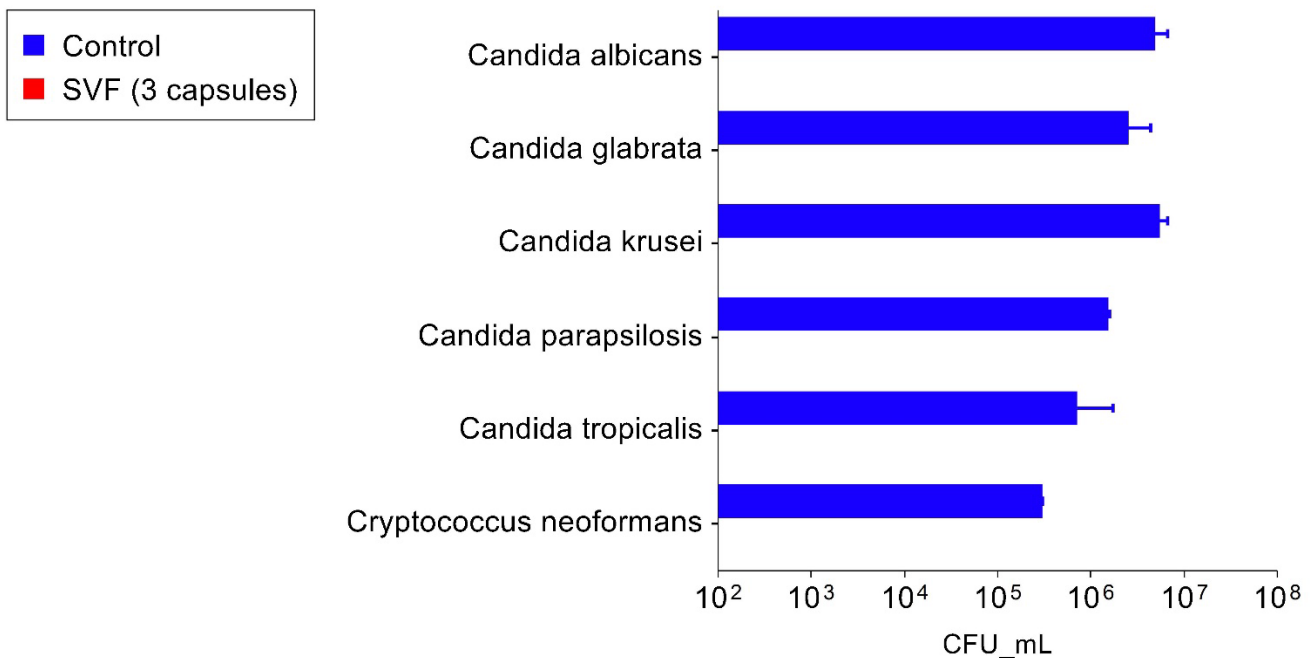
Methods overview: Methods for this laboratory study were adapted from Bearden *et al* and from FDA Docket No. FDA-1975-N-0012.^{1,2} All experiments were performed using the commercially available formulations. Reductions in fungal counts between agents were determined.

Methods and Results:

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

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

Experiment: Pre-sterilized discs were saturated with $1 \times 10^{7-8}$ 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 \pm 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: SVF (3 capsules) with BASSA-GEL™ was tested in a model mimicking a bandaged wound. The experiment demonstrated significant reductions in yeast species tested.

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	ATCC 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.