University of Houston Microbiology Research Labs
Kevin W. Garey, PharmD, MS, FASHP, FIDSA
Professor and Chair

TECHNICAL REPORT

Antifungal Properties of a Combination of the Following – (a) Compounded Clotrimazole 20mg in Loxasperse® (www.loxasperse.info) Capsule, (b) Commercially Available Flucytosine 500mg Capsule and (c) Commercially Available Diclofenac 1.5% in 45.5% DMSO Solution referred to hereafter as "CFD" applied with BASSA-GEL™ was assessed against selected fungi and the results are conveyed here.

Executive Summary: CFD ("DRUG") applied with BASSA-GEL™ and 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.

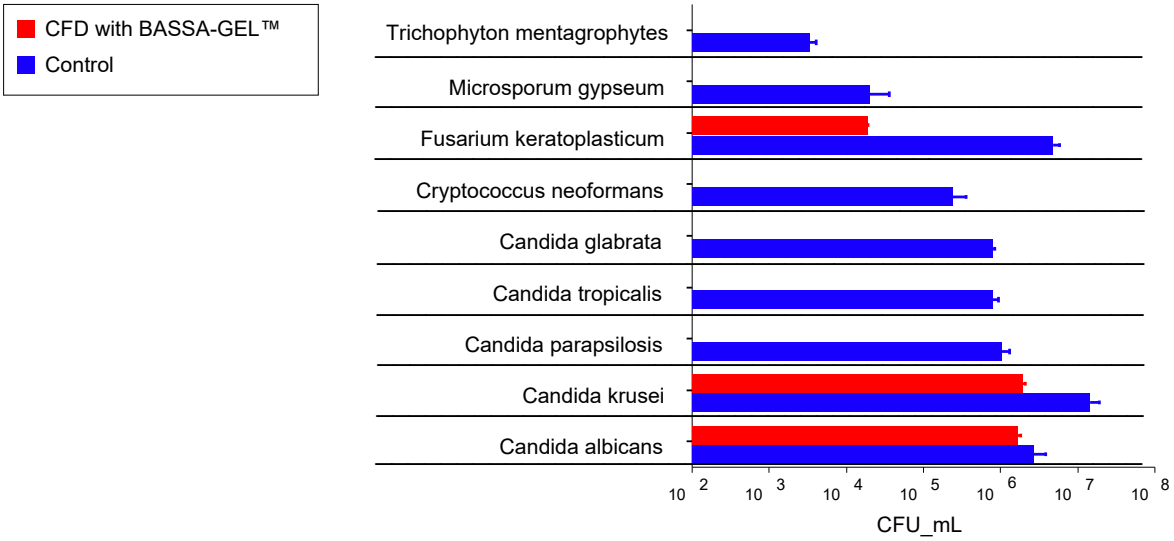
Methods overview: Methods for this laboratory study were adapted from Bearden *et al* and from FDA Docket No. FDA-1975-N-0012.[1,2] All experiments were performed using the medications listed above – both commercially available and compounded as identified above. Reductions in fungal counts between agents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

Methods and Results:

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

Antifungal agents: CFD applied with BASSA-GEL™

Experiment: Pre-sterilized discs were saturated with 1 x10^{7-8} CFU/mL of microbial 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: CFD with BASSA-GEL™ was tested in a model mimicking a bandaged wound. The experiment demonstrated significant reductions in fungal species tested.

UNIVERSITY of HOUSTON COLLEGE OF PHARMACY
University of Houston Microbiology Research Labs
Kevin W. Garey, PharmD, MS, FASHP, FIDSA
Professor and Chair

Table 1. Organisms Included in Testing

Organism	***ATCC/CDC #***
Trichophyton mentagrophytes	ATCC 18748
Microsporum gypseum	ATCC 24102
Fusarium keratoplasticum	ATCC 36031
Cryptococcus neoformans	ATCC 14116
Candida albicans	ATCC 90028
Candida glabrata	ATCC 2001
Candida krusei	ATCC 2159
Candida parapsilosis	ATCC 22019
Candida tropicalis	AR 0345

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.

Information on Bassa-Gel™ being used with various anti-infective medications can be found by scanning this QR-Code or going to www.bassagel.com.

Information on Loxasperse® being used in dry powder capsules can be found by scanning this QR-Code or going to www.loxasperse.info.