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

TECHNICAL REPORT

Microbiologic Properties of Flucytosine 500 mg two capsules mixed with BASSA-GEL™ against selected pathogens was assessed and the results are conveyed here.

Executive Summary: Flucytosine 500 mg capsules (2 capsules) 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.

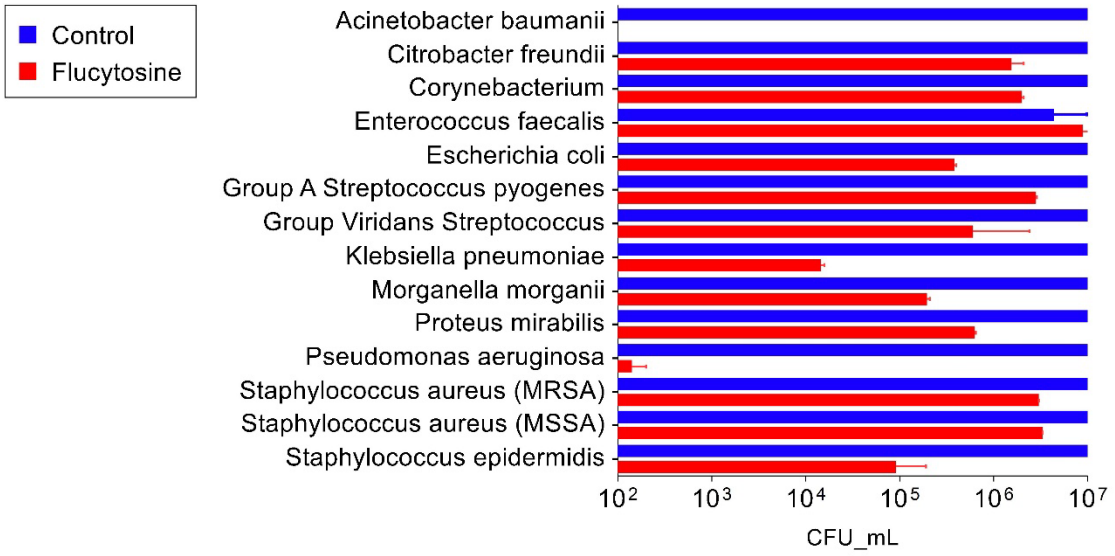
Methods overview: Methods for this laboratory study were adapted from Bearden *et al* and from FDA Docket No. FDA-1975-N-0012.[1,2] All experiments were performed using the commercially available formulations. Reductions in bacterial counts between agents were determined.

Methods and Results:

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

Antimicrobial agents: Flucytosine 500 mg capsules (NDC 42494-0340-01) – 2 capsules mixed with BASSA-GEL™

Experiment: Pre-sterilized discs were saturated with 1 x$10^{7\text{-}8}$ CFU/mL of bacterial 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: Flucytosine with BASSA-GEL™ was tested in a model mimicking a bandaged wound. The experiment demonstrated significant reductions in some of the bacterial species tested.

https://pubmed.ncbi.nlm.nih.gov/30915278/ https://pubmed.ncbi.nlm.nih.gov/30455950/

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 number
Acinetobacter baumanii	BAA747
Citrobacter freundii	8090
Corynebacterium striatrum	BAA-1293
Enterococcus faecalis	BAA-29212
Escherichia coli	25922
Klebsiella pneumoniae	BAA-2524
Streptococcus pyogenes	19615
Morganella morganii	25830
Proteus mirabilis	CDC AR-29
Pseudomonas aeruginosa	27853
Staphylococcus aureus (MSSA)	29213
Staphylococcus aureus (MRSA)	BAA-41
Staphylococcus epidermidis	12228

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.