

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 vials (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.

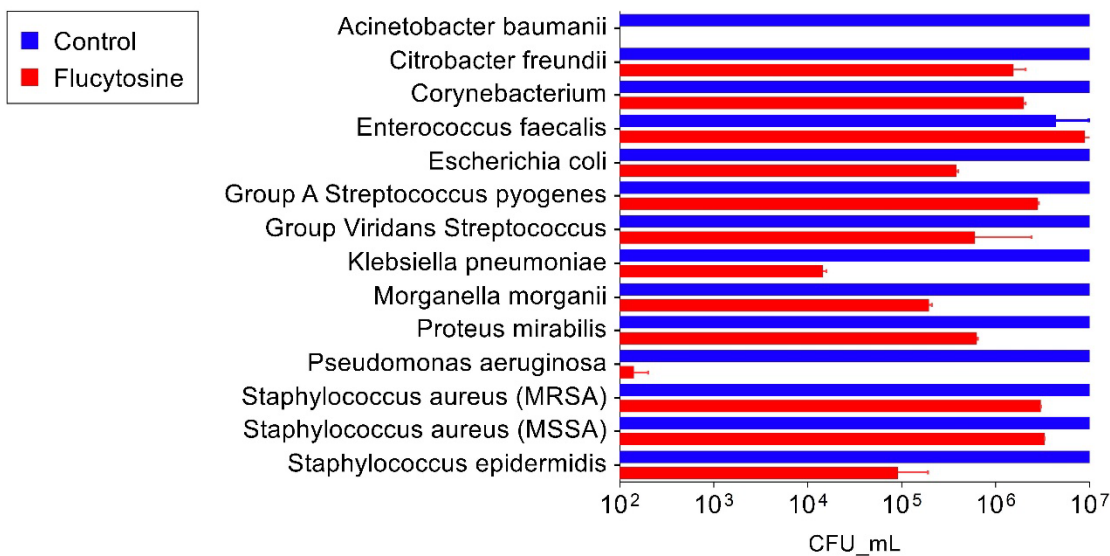
Methods overview: Methods for this laboratory study were adapted from Bearden *et al* and from FDA Docket No. FDA-1975-N-0012.^{1,2} All experiments were performed using the commercially available formulations. Reductions in bacterial counts between agents were determined.

Methods and Results:

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

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

Experiment: Pre-sterilized discs were saturated with $1 \times 10^{7-8}$ 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.

Table 1. Organisms Included in Testing

Organism	ATCC number
<i>Acinetobacter baumannii</i>	BAA747
<i>Citrobacter freundii</i>	8090
<i>Corynebacterium striatum</i>	BAA-1293
<i>Enterococcus faecalis</i>	BAA-29212
<i>Escherichia coli</i>	25922
<i>Klebsiella pneumoniae</i>	BAA-2524
<i>Streptococcus pyogenes</i>	19615
<i>Morganella morganii</i>	25830
<i>Proteus mirabilis</i>	CDC AR-29
<i>Pseudomonas aeruginosa</i>	27853
<i>Staphylococcus aureus (MSSA)</i>	29213
<i>Staphylococcus aureus (MRSA)</i>	BAA-41
<i>Staphylococcus epidermidis</i>	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.