

## TECHNICAL REPORT

*Microbiologic Properties of Nitrofurantoin 25 mg Capsules (3 capsules) mixed with BASSA-GEL™ against selected pathogens was assessed and the results are conveyed here.*

**Executive Summary:** Nitrofurantoin 25 mg 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.** BASSA-GEL™ is an over-the-counter cosmetic water-washable gel commonly used for skin hydration. Usage of BASSA-GEL™, a cosmetic moisturizer product, in conjunction with an actual DRUG can be useful as the water-washable gel can be washed off solely utilizing water without any physical debriding activity generally being required (while also keeping a DRUG in contact with the targeted area).

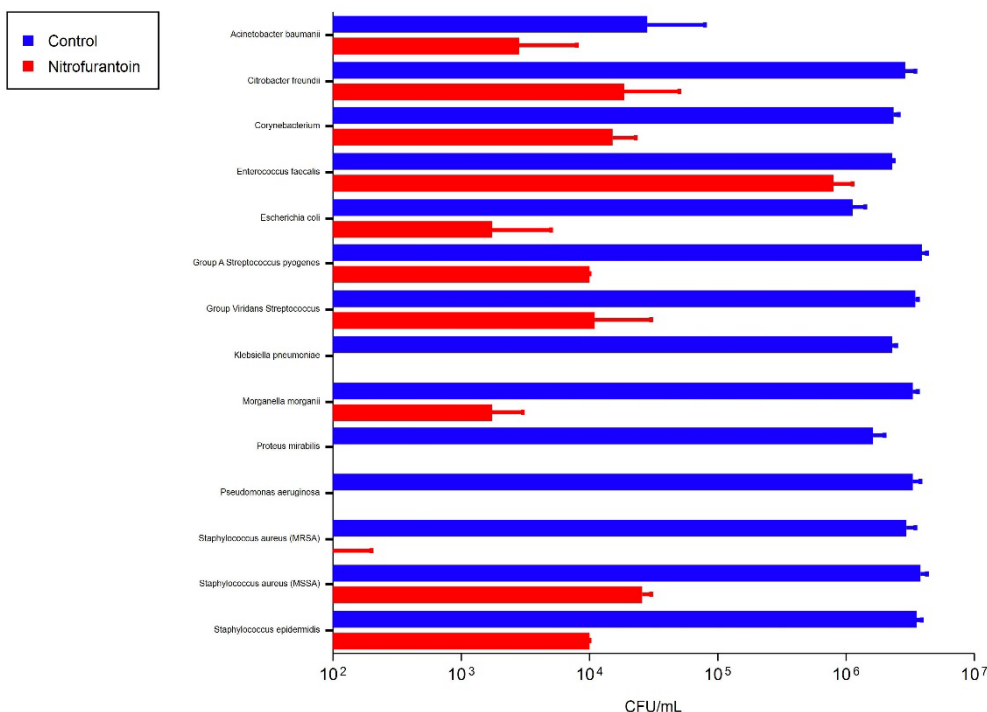
**Methods overview:** Methods for this laboratory study were adapted from Bearden *et al* and from FDA Docket No. FDA-1975-N-0012.<sup>1,2</sup> All experiments were performed using the commercially available formulations. Reductions in bacterial counts between agents were determined.

### Methods and Results:

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

**Antimicrobial agents:** Nitrofurantoin 25 mg capsule ( $n=3$ ; NDC 47781-0306-01) – 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  $\pm$  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:** Nitrofurantoin with BASSA-GEL™ was tested in a model mimicking a bandaged wound. The experiment demonstrated significant reductions in most gram-negative and gram-positive bacterial species tested.

**Table 1. Organisms Included in Testing**

<b>Organism</b>	<b>ATCC number</b>
<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.



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