

TECHNICAL REPORT

November 13, 2019

Microbiologic Properties of Nitrofurantoin 25mg Capsules against selected pathogens was assessed and the results are conveyed here.

Disclosure: This study was funded by Richie's Specialty Pharmacy ("RSP") pursuant to its research agreement with the UH College of Pharmacy ("UHCOP"). RSP is owned solely by Richie Ray, R.Ph. and he serves as its Pharmacist-In-Charge. He is a 1996 graduate of the UHCOP and RSP has had a research agreement with UHCOP since May 2012. RSP promotes appropriate pharmacy practices and is an advocate for infection treatments based upon supporting clinical data such as that provided by this report.

Executive Summary: Nitrofurantoin 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.

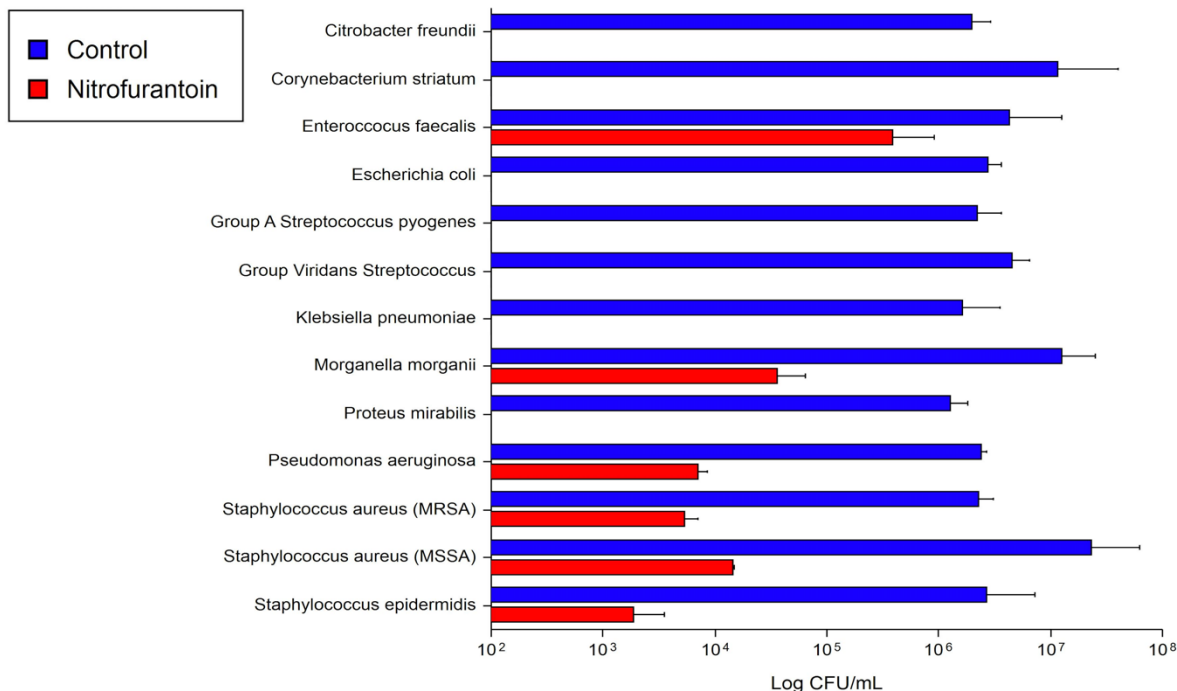
Methods overview: Methods for this laboratory study were adapted from Bearden *et al* and from FDA Docket No. FDA-1975-N-0012.^{1,2} All experiments were performed using the commercially available formulations. Reductions in bacterial counts between agents were determined using analysis of variance.

Methods and Results

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

Antimicrobial agents: Nitrofurantoin 25mg Capsules (NDC 47781-0306-01)

Experiment: Pre-sterilized gauze was inoculated with $1 \times 10^{7-8}$ CFU/mL of bacterial culture, allowed to incubate for 24 hours to mimic *ex vivo* infection, exposed to drug or negative control (phosphate buffer saline, PBS), and then incubated aerobically at 37°C for 48 hours. After this time, samples were cultured onto blood agar plates for colony forming unit (CFU/gauze) counts using serial dilution spread plate technique. The results are reported below. As stated above in the executive summary, should there be only a "blue-line" reported that means the nitrofurantoin was so effective against the pathogen that the detection limit was below the assay of the experiment.



Interpretation: Nitrofurantoin was tested in a model mimicking a bandaged wound. The experiment demonstrated significant reductions in select Gram-positive and Gram-negative bacterial species.

Table 1. Organisms Included in Testing

| Organism | ATCC number |
|---|-------------|
| <i>Citrobacter freundii</i> | 8090 |
| <i>Corynebacterium striatum</i> | BAA-1293 |
| <i>Enterococcus faecalis</i> | BAA-29212 |
| <i>Escherichia coli</i> | 25922 |
| <i>Streptococcus pyogenes</i> | 19615 |
| <i>Streptococcus sanguinis</i> (Viridans Group) | 10556 |
| <i>Klebsiella pneumoniae</i> | BAA-2524 |
| <i>Morganella morganii</i> | 25830 |
| <i>Proteus mirabilis</i> | CDC AR-29 |
| <i>Pseudomonas aeruginosa</i> | 27853 |
| <i>Staphylococcus aureus</i> (MSSA) | 29213 |
| <i>Staphylococcus aureus</i> (MRSA) | 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. Enterotoxigenic *Escherichia coli*: an emerging enteric pathogen. *Am J Gastroenterol* 2004;99:383-9.