University of Houston Microbiology Research Labs
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**TECHNICAL REPORT**

*Microbiologic Properties of* Cefixime 400mg Capsule and Cefadroxil 500mg Capsule *mixed with BASSA-GEL™ against selected pathogens was assessed and the results are conveyed here.*

**Executive Summary:** One capsule each of Cefixime 400mg and Cefadroxil 500mg (Collectively Referenced as "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).

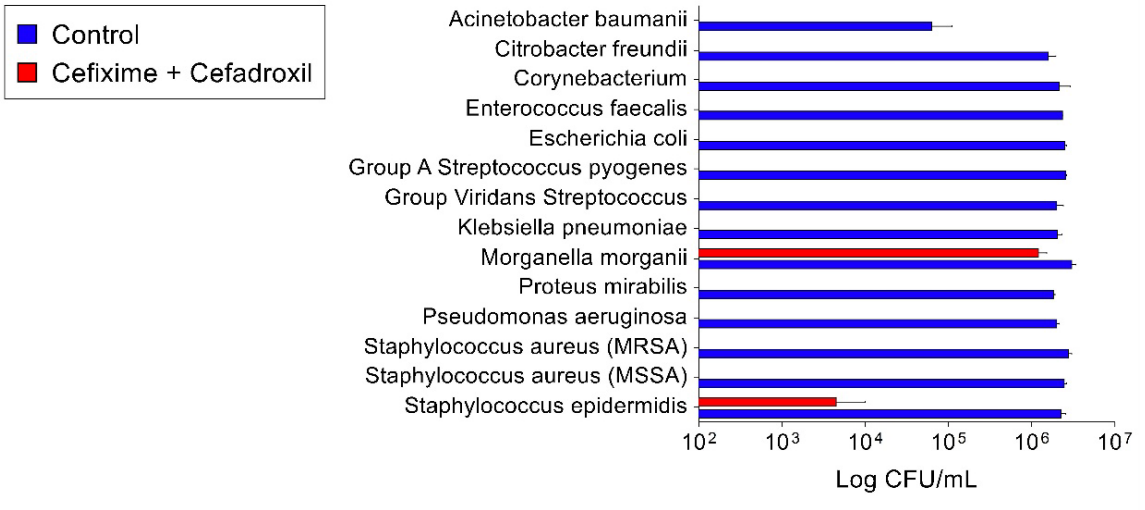
**Methods overview**: Methods for this laboratory study were adapted from Bearden *et al* and from FDA Docket No. FDA-1975-N-0012.[1,2] All experiments were performed using the commercially available formulations. Reductions in bacterial counts between agents were determined.

**Methods and Results:**

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

*Antimicrobial agents*: Cefixime 400mg (NDC 67877-0584-50) and Cefadroxil 500mg (NDC 68190-0180-01) 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:* Cefixime and Cefadroxil mixed 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.

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**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.

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