

## TECHNICAL REPORT

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

**Executive Summary:** Tetracycline 500mg Capsule (“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).

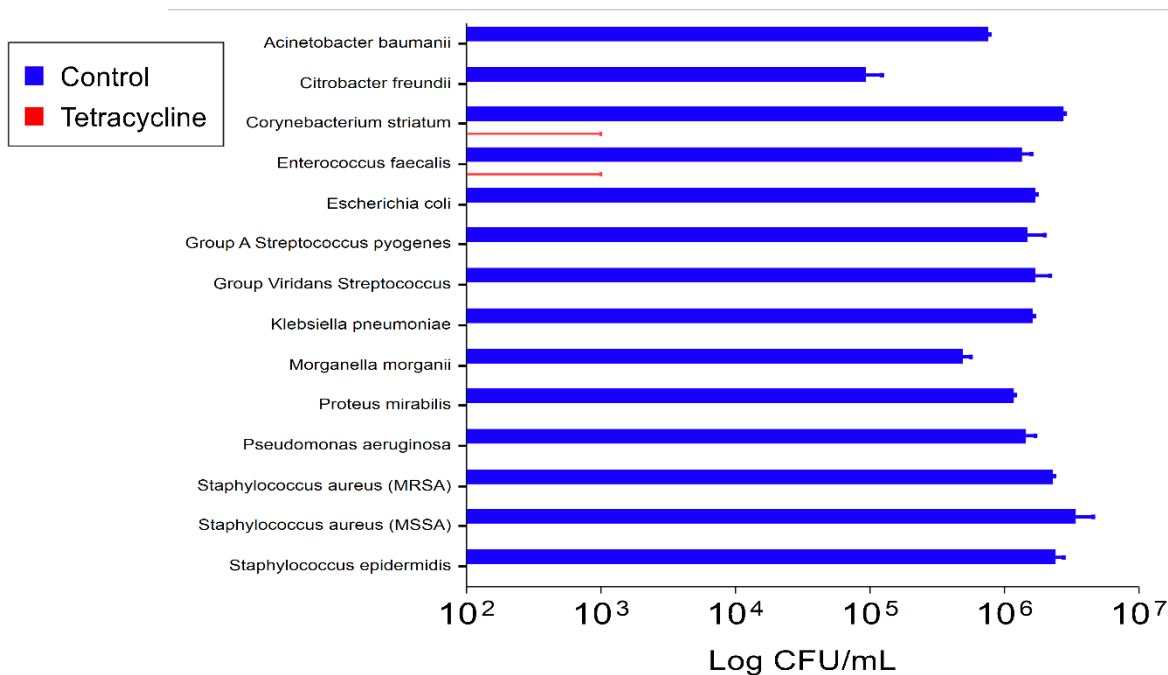
**Methods overview:** Methods for this laboratory study were adapted from Bearden *et al* and from FDA Docket No. FDA-1975-N-0012.<sup>1,2</sup> All experiments were performed using the commercially available formulations. Reductions in bacterial counts between agents were determined.

### Methods and Results:

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

**Antimicrobial agents:** Tetracycline 500mg capsule (NDC 51991-0907-01) – 1 capsule 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:** Tetracycline with BASSA-GEL™ was tested in a model mimicking a bandaged wound. The experiment demonstrated significant reductions in all gram-negative and most 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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