University of Houston Microbiology Research Labs
Kevin W. Garey, PharmD, MS, FASHP
Professor and Chair

TECHNICAL REPORT **August 21, 2019**

Microbiologic Properties of Erythromycin Topical Solution 2% 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: Erythromycin Topical Solution 2% ("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 using analysis of variance.

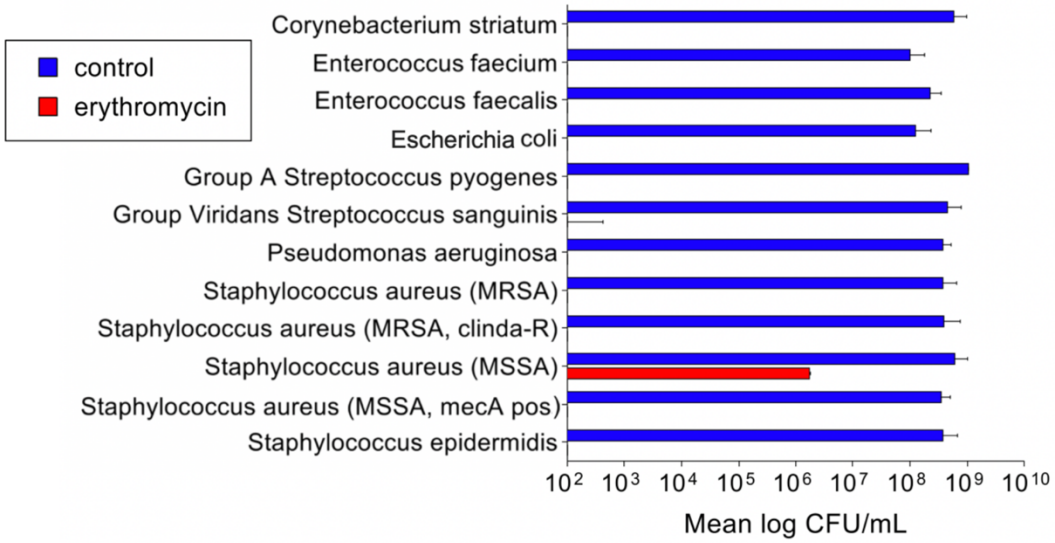
Methods and Results

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

Antimicrobial agents: Erythromycin Topical Solution 2% (NDC 60432-0671-60)

Experiment: Pre-sterilized gauze was inoculated with 1 x$10^{7\text{-}8}$ 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 DRUG was so effective against the pathogen that the detection limit was below the assay of the experiment.

Figure 1. Erythromycin was effective against multiple strains of Gram-positive and Gram-negative bacteria including *Staphylococcus*, *Streptococcus*, *Escherichia*, and *Pseudomonas* species



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

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Table 1. Organisms Included in Testing

Organism	ATCC number
Staphylococcus aureus (MSSA)	29213
Staphylococcus aureus (MSSA, mecA positive)	BAA-2419
Staphylococcus aureus (MRSA)	BAA-41
Staphylococcus aureus (MRSA, clindamycin-resistant)	BAA-44
Staphylococcus epidermidis	12228
Corynebacterium striatrum	BAA-1293
Streptococcus pyogenes	19615
Streptococcus sanguinis	10556
Enterococcus faecalis	BAA-29212
Enterococcus faecium	BAA-2127
Escherichia coli	25922
Pseudomonas aeruginosa	CDC AR #0447

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.