Comparison of Pharmaceutical Equivalence for Commercially Available Preparations of Omeprazole

Scott D. Stanley, PhD*; and Heather K. Knych, DVM, MS, PhD

Analysis of the potency of compounded formulations demonstrated a wide variation in omeprazole concentrations, both relative to the labeled potency as well as with respect to time. Authors’ address: K. L. Maddy Equine Analytical Chemistry Laboratory, School of Veterinary Medicine, University of California, Davis, CA 95616; e-mail: sstanley@cahfs.ucdavis.edu. *Corresponding author. © 2011 AAEP.

1. Introduction
Omeprazole is a potent proton pump inhibitor with demonstrated efficacy in the prevention as well as treatment of gastric ulcers in horses. There is currently only one omeprazole product labeled for prevention and one for treatment of gastric ulcers in horses. However, even though their use is not permitted, a multitude of compounded products are readily available from veterinary compounding pharmacies. The goal of the current study was to compare the potency of these compounded products with the labeled concentration as well as to describe the change in concentration of omeprazole with respect to time (i.e., storage stability).

2. Materials and Methods
The propriety omeprazole formulation (0.22 mg/mL) as well as 5 compounded omeprazole paste formulations (0.133–0.308 mg/mL) were purchased. Liquid chromatography-mass spectrometry methods were used to determine the initial concentration of omeprazole in all formulations as well as concentrations at days 30 and 60 after purchase.

3. Results and Discussion
The propriety omeprazole formulation contained 99% of the labeled concentration of omeprazole on day 0, whereas concentrations of the compounded formulations varied from more than 100% to approximately 63% of the labeled concentration. Omeprazole concentrations in propriety omeprazole formulation were greater than 97% of the labeled concentration on day 30, whereas concentrations in the compounded formulations varied from approximately 88% to less than 45% on day 30 and from 82% to less than 17% on day 60.

Footnotes
aUlcerGard, Merial, Ltd., Duluth, GA 30096.
bGastroGard, Merial, Ltd., Duluth, GA 30096.