

Compounded Fluconazole Pitfalls

JD Foster, VMD, DACVIM

*Friendship Hospital for Animals
Washington, DC*

In the Literature

Laporte CM, Cruz-Espindola C, Thungrat K, et al. Quality assessment of fluconazole capsules and oral suspensions compounded by pharmacies located in the United States. *Am J Vet Res.* 2017;78(4):421-432.

FROM THE PAGE ...

Fluconazole is a commonly prescribed antifungal drug in small animal practice. Although there is no FDA-approved formulation for veterinary use, both the pioneer and generic formulations are FDA approved for human administration.

Despite available dosing options, compounding may be required to obtain a dose that is safe for the body size of some veterinary patients. Whereas generic drugs must undergo FDA evaluation and approval, compounded drugs are regulated by state pharmacy boards. Because compounded drugs are not subject to the same quality control as are FDA-approved products, the strength and precision of compounded products may potentially differ from what was prescribed.

This study evaluated compounded fluconazole in both capsule and liquid suspension formulations from 4 veterinary compounding pharmacies. Products were analyzed for concentration (ie, strength), precision (ie, repeatability of concentration between batches), labeling, bacterial contamination, and physical defects (eg, leaking capsules, uneven suspension).

No bacterial contamination was present in any sample. Physical defects were detected in capsules from all 4 pharmacies. The accuracy and precision of tablet strengths were in acceptable limits for 3 pharmacies, as were all but one capsule formulation from the last. However, the accuracy and precision of nearly every liquid suspension was outside acceptable limits. In addition, the actual fluconazole concen-

tration in all compounded suspensions was less than prescribed.

The results of this study suggested that clinicians should use FDA-approved formulations of fluconazole for small animals when possible. However, if compounding is required, better dosing accuracy is obtained when fluconazole is formulated into capsules rather than a suspension. Inappropriate dosing, particularly underdosing, should be recognized as a possible cause of treatment failure when using compounded liquid formulations to treat fungal infections. In such cases, switching to a compounded capsule or the FDA-approved drug for humans may improve results.

... TO YOUR PATIENTS

Key pearls to put into practice:

- 1** Unlike generic drug formulations, compounded drugs are not FDA-regulated.
- 2** Because of the potential for variation when using compounded fluconazole, clinicians should use FDA-approved human formulations when possible.
- 3** If compounded fluconazole must be used, using the drug in capsule form will improve dosing accuracy as compared with suspension.