Stokes Pharmacy®

Precision Compounding - Nationwide.

Stokes Pharmacy Response:

Poor Accuracy, Precision and Consistency of Compounded Famciclovir Formulated For Management of Feline Herpesvirus-1 in Cats

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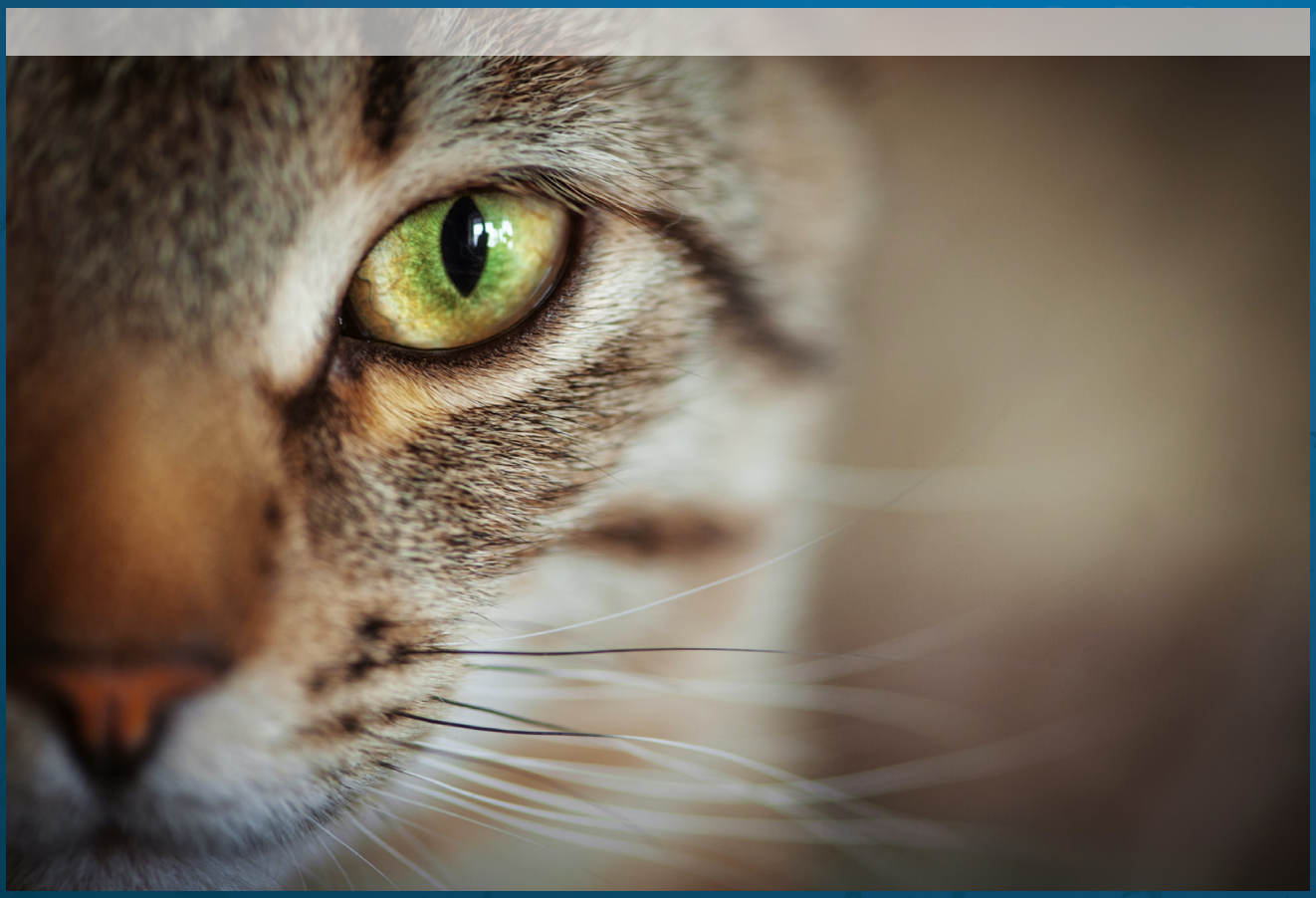

By Megan Chase, PharmD, Director of Pharmacy Compounding
November 9, 2020

Is the compounded preparation that you are about to administer to your patient accurate, precise, and consistent with United States Pharmacopeia (USP) standards? That is a very popular question amongst veterinarians. It was questions like this that led the staff at Iowa State University College of Veterinary Medicine to evaluate compounded famciclovir oral suspension for the treatment of Herpesvirus-1 in feline patients. They concluded that the compounded formulations that they received from nine different compounding pharmacies were inaccurate, imprecise, and inconsistent compared to commercially available tablets. These results reinforce two facts as to why Stokes Pharmacy has been adamant about educating veterinary professionals. First, compounding pharmacies do not have equal quality standards under which they operate. Second, we need to continue to educate veterinarians about what standards they need to look for in a compounding pharmacy. Education disseminated to veterinarians aids them in ensuring their patients receive high-quality preparations.

Stokes Pharmacy compounds many strengths of famciclovir suspension in an oil base, similar to the compounding pharmacies used in the study. However, drastically different than the compounding pharmacies used in the study, the max concentration that we will compound is 250 mg/ml. Based on observational data, we discovered that any strength above 250 mg/ml resulted in the suspension becoming very viscous. As a result, the client was unable to shake or withdraw the suspension from the bottle. If the suspension was able to be withdrawn, the drug was not evenly dispersed, resulting in either an under or over potent preparation. In the case listed in the article, the preparations were under potent. The solidifying reaction of famciclovir is not seen immediately after compounding. In fact, this reaction may occur hours or days after the preparation is made. Unless the compounding pharmacy is holding their compounded preparations for observation or tracking data about events reported by clients, this compounding mistake is made repeatedly. In order to constantly improve our line of preparations, Stokes Pharmacy performs observational evaluations of preparations, as well as records and tracks data reported by patients of any abnormal event pertaining to a preparation.

How do you know that the compounding pharmacy you are contacting will provide a high-quality preparation? There are many facets to how quality can be measured. Preparation inspection, labeling, and potency testing are important quality factors to consider when questioning a potential compounding pharmacy. Preparation inspection is critical to a quality preparation. Both a pharmacist and a quality technician are involved in the preparation inspection process at Stokes. They note any irregularity in the preparation, and the pharmacist determines if the preparation meets quality standards set forth in the standard description of the preparation. If an inspection is not performed, issues of preparations not being uniform will be missed, leading to an over or under potent product. This could have been the case with the preparations used in the study.

The labeling of the preparation by the compounding pharmacy is another important quality factor to consider. Ambiguous labeling will lead to incorrect usage and storage by the patient or care giver. Stokes Pharmacy clearly states the storage conditions on the label that are required for the preparation. In the case of famciclovir suspensions in an oil base, the correct storage conditions are at room temperature. If an oil base preparation is stored in the refrigerator the preparation will solidify and not be evenly dispersed when it is withdrawn from the bottle. This will again lead to an over or under potent preparation. The study did not state the storage conditions of the preparations or if a storage recommendation was stated on the label, which could lead to variability in results.

The study performed by Iowa State used potency testing of the preparations to dismiss the use of compounded famciclovir suspensions for the treatment of Herpesvirus-1 in feline patients. Potency is affected by many of the factors that were discussed, including preparation strength, uniformity of the suspension, and storage conditions. Some of these factors were unknown in this study, leading one to question the validity of the potency. At Stokes Pharmacy, these factors are always known for the preparations that are being tested for potency. While potency testing is not required to be performed by compounders, Stokes chooses to have preparations sent out for potency testing to ensure the highest quality compounded preparations are provided. We feel potency tests provide data points that are critical for a quality preparation. These data points ensure patients are receiving the correct dose and validates the compounding method used in making the preparation. Based on Exhibit A, the enclosed certificate of analysis (C of A) for famciclovir 250 mg/ml compounded at Stokes Pharmacy, it proves to be a quality preparation. With a potency result of 99.1%, we are confident that this is an acceptable alternative to famciclovir tablets for treating Herpesvirus-1 in feline patients. Continued potency testing of famciclovir 250 mg/ml allows us to collect data points over time. The data points will ensure the potency stays within acceptable USP standards and patients continue to receive a quality preparation.

The use of specialty compounded medications provides numerous benefits to patients including ease of administration, increase in palatability, and increased variety of dosage forms. Patients at Stokes Pharmacy receive the benefits of specialty compounded medications because we strive to provide a quality preparation. Our efforts always put the patient's health and safety first!

Exhibit A

Certificate of Analysis

CLIENT : Stokes Pharmacy
DESCRIPTION : STOCK FAMCICLOVIR COSG 250 MG/ML SUSPENSION
LOT # : 10232020@12
ARL # : 717016 **DATE RECEIVED :** 10/27/2020
FORMULATION ID : 99002 **STORAGE :** 20°C to 25°C

Test	Method	Specifications	Results	Date Tested
Assay - Famciclovir	HPLC	90.0% - 110.0%	99.1% (247.8572mg / 1.00mL)	10/30/2020

Notes

The potency method(s) used for testing passed system suitability requirements per ARL SOP AMP-012 for non-cGMP analysis. Product specific method validation is not available for this sample and specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.

Katie Coats - Chemist II

10/30/2020

Date