Compounded Medications in Veterinary Practice: The Importance of 503B Outsourcing Facilities

Modern compounding pharmacies fill custom patient-specific prescriptions issued by health care licensees. They are classified by federal and state law as 503A facilities and follow compounding standards set forth by the United States Pharmacopeia (USP) in its chapters <795> and <797> on non-sterile and sterile compounding, respectively.

While it is lawful for 503A pharmacies to provide compounded medications to veterinary practices for in-house use (administration) and secondary distribution (dispensation) to clients, the California Board of Pharmacy (BOP) has taken both regulatory and enforcement actions in recent years to curb this practice. The CVMA is working to represent the needs of the veterinary profession at both the BOP and state legislature levels, but overall, obtaining compounded medications for veterinary practice use has become increasingly difficult in recent years due to concerns about 503A facilities testing requirements for potency, sterility, and endotoxin in injections.

	503A	503B
Type of Facility	Traditional compounding pharmacy	Outsourcing facility
Method of Distribution	Singular, patient-specific prescriptions	Distribution to veterinarians only, for medication use in-house
Quality Assurance Standards	United States Pharmacopoeia chapters <795>, <797>, and <800>	FDA Current Good Manufacturing Practices (cGMPs)
FDA Inspections	For cause	Regularly
Required Stability Testing	No	Yes
Required Sterility Testing	Limited, based on batch size	Yes, always
Required Finished Product Testing (Potency, Endotoxin)	No	Yes
Required Particle Monitoring	No	Yes
Required Viable Monitoring	Air: two times per year. Surface: routinely. Personnel: initially and one-to-two times per year.	Daily (Air, Surface and Personnel) and with every batch.

Another type of facility, called a 503B "outsourcing facility," manufactures medications for sale directly to health care professionals and are not permitted in California to fill patient-specific prescriptions. The table provides a comparison of 503A vs. 503B facilities, but in summary, 503B facilities follow current Good Manufacturing Practices (cGMPs) defined by the Food and Drug Administration (FDA), which are more stringent than the practices defined in USP chapters <795> and <797>. Testing for potency, sterility, and the presence of endotoxin are also different for 503B outsourcers than they are for 503A patient-specific compounders. These 503B facilities are of significant importance to California veterinarians, because they do—and will at an increasing frequency—provide vital cGMP medications which veterinarians may administer in-house and dispense to clients. There are only a handful of 503B outsourcing facilities licensed in California.

Of the small number of outsourcing facilities currently licensed in California, only a few offer veterinary products. Of those, only two currently offer substantial product lines for sterile injectables, oral liquids, tablets, ophthalmic medications, and chemotherapy drugs. More information about these facilities and outsourcing facilities in general may be accessed at: https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities. ■