

Koshland Pharm

Custom Compounding Pharmacy

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How to Evaluate a Compounding Pharmacy



Compounding pharmacies, through the dispensing of customized medications, provide important treatments that can have a dramatic impact on a patient's health and well-being. Selecting the right pharmacy may mean the difference between getting the right or wrong medication.

Compounding pharmacies are not regulated by the FDA. Instead, they are regulated by individual state boards of pharmacy with federal guidelines set by the United States Pharmacopeia (USP).

Pharmacies that have good policies and procedures, top-of-the-line equipment, and continual quality control can make a compounded medication that rivals a mass produced pharmaceutical in its potency and purity. However, not all pharmacies that compound have the same commitment to quality. Therefore, it is important to critically evaluate the compounding pharmacy that is going to make your patients' medications.

Here are some good questions to ask a compounding pharmacy when deciding whether to use their services:

1. *Where does the pharmacy source their chemicals?*

A good compounding pharmacy should be committed to sourcing the highest quality chemicals from reputable FDA approved suppliers. A certificate of analysis of any chemical used in a compounded prescription should be readily retrievable and available to the prescriber if there are any questions or concerns about a medication.

2. *What kind of equipment is used?*

Using the right equipment can mean the difference between getting a compounded medication that works and one that doesn't. If a topical dosage form is being prescribed, i.e. a cream, ointment or gel, the pharmacy should be using specialized machines like an ointment mill and homogenizer (or electric mortar and pestle) to ensure small particle size of

the active ingredient and a homogenous mixture. All compounded topical dosage forms that use powders as the active ingredient must be run through these two pieces of equipment to be considered high quality.

3. *What kind of in-house procedures does the pharmacy have to ensure quality?*

Compounding pharmacies can do many things on a daily basis to ensure quality. These include error calculations on all capsule batches, bar coding chemicals and integrating weight capturing from the balances to the computer. Pharmacies should also have a rigorous *Continuing Quality Improvement (CQI)* program where frequent staff meetings are held to discuss ways of improving quality in the pharmacy.

4. *What kind of outside testing does the pharmacy do to ensure quality?*

Pharmacies committed to quality need to test the final preparations of their products to ensure appropriate potency. Because compounded medications are made to order for a unique patient's needs, it would be impossible for a pharmacy to test every batch it makes. To address this problem, pharmacies use a method called "skip lot testing." This method assigns random finished products to be tested on a monthly basis based on the type of compounds a pharmacy does. The number of samples a pharmacy tests should be based on the volume of prescriptions the pharmacy does (roughly 10% of a pharmacy's daily volume per month).

5. *How is the pharmacy accountable to the prescriber and the patient?*

For optimal patient outcomes, the compounding pharmacy should be committed to close communications with both the prescriber and the patient. Because of the customized nature of compounded medications, the pharmacist needs to be readily available to the prescriber to be a resource for possible therapies and to make sure a compound will be formulated in the best possible way. The pharmacist should also be readily available to the patient to help answer any questions and forward questions to the prescriber when appropriate.

6. *Is the pharmacy PCAB accredited?*

The Pharmacy Compounding Accreditation Board (PCAB) is an independent, national organization that evaluates compounding pharmacies and grants accreditation once they have met strict standards and undergone a thorough on-site inspection. Requirements for accreditation include having documented and thoroughly reviewed policies and procedures, ongoing training and education program for all pharmacy staff, and multiple quality assurance procedures including a well-documented *Continuous Quality Improvement (CQI)* program.