

Koshland Pharm

Custom Compounding Pharmacy

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How to Evaluate A Compounding Pharmacy



(Negative Pressure Room, Koshland Pharm 2018)

Not all compounding pharmacies are the same. Quality differences among compounding pharmacies can come as a surprise to consumers. For a commercially available product, the drug is the same regardless of which pharmacy it comes from. This is not the case with a compounded medication, whose quality depends on the specific procedures used by the compounding pharmacy where it is made. It is important to ask a compounding pharmacy **6 questions to assess its commitment to quality.**

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

A compounding pharmacy should source the highest quality chemicals from reputable FDA-approved suppliers. **Koshland Pharm sources its active ingredients only from vendors who test and verify every chemical. Every chemical's certificate of analysis is reviewed by a pharmacist before being used and is readily retrievable and available.**

2. **What kind of equipment is used?**

Not all pharmacies use the same equipment. If a topical dosage form is being made, the pharmacy should use specialized machines, such as ointment mills and electric mortar and pestles (homogenizers). An ointment mill pulverizes the active ingredients, making them micro-sized and thereby improving penetration through the skin. A homogenizer mixes the cream at a high speed so that each teaspoonful has the same amount of active ingredient. **Koshland Pharm uses the most advanced technology in the compounding industry, such as ointment mills and homogenizers for creams and acoustic resonant mixers for the dry ingredients that fill capsules.**

3. **What in-house procedures does the pharmacy follow to ensure quality?**

Compounding pharmacies must have numerous procedures in place to ensure quality. 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. **At Koshland Pharm, error calculations are performed on all capsule batches; all chemicals are bar-coded; and weight captures are integrated from balances to computers. Additionally, Koshland Pharm tracks and trends over six criteria as they relate to quality assurance, including internal errors, patient complaints, and formula accuracy. The results of this tracking are used to continuously improve quality assurance procedures at the pharmacy.**

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

Pharmacies committed to quality need to test the final preparations of their products to ensure quality, safety, and potency. **Koshland Pharm performs in-house sterility and endotoxin testing on every sterile medication, and validates sterile formulas for potency over time. Koshland Pharm sends at least 10 percent of its daily volume of prescriptions, both sterile and non-sterile, to an outside lab each month to ensure appropriate potency. Certificates of analysis, sterility test results, and endotoxin test results are available for doctors and patients to review upon request at any time.**

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

For optimal patient outcomes, a compounding pharmacy needs to communicate closely with both the prescriber and the patient. **At Koshland Pharm, pharmacists are available to prescribers by phone and email as a resource for possible therapies and to make sure a compound is formulated in the best possible way. They welcome in-person tours of the pharmacy. Pharmacists are also available to the patient to help answer questions or forward questions to the prescriber when appropriate.**

6. Is the pharmacy licensed by the California State Board of Pharmacy and is it PCAB accredited?

A compounding pharmacy that prepares sterile medications for California residents must pass a yearly on-site inspection by the State Board of Pharmacy. A compounding pharmacy that makes non-sterile medications is required by the State Board to have a negative pressure room for the making of certain compounded medications, such as hormone replacement therapy. A pharmacy's current California state license can be checked at www.pharmacy.ca.gov. In addition to maintaining its California pharmacy license, a compounding pharmacy can demonstrate an even higher level of accountability by choosing to apply for accreditation with the Pharmacy Compounding Accreditation Board (PCAB). This outside organization assesses pharmacies based on a rigorous set of standards that concentrate on the quality and consistency of the medications produced. A pharmacy's PCAB status can be searched at www.pcab.org. **Koshland Pharm has a California state license for sterile and non-sterile compounding and has been PCAB accredited since its first year of operation in 2010.**