

Because of the new, strict USP 797-guidelines for sterile compounding, it's more important than ever for doctors to choose a compounding pharmacy they can trust with their reputations. When you are choosing a compounding pharmacy to work with you, be sure to ask questions like those we've listed here.

### **Doctor's Due Diligence Check List for Compounding Pharmacy Quality and Sterility**

**The Apothecary Shoppe  
Pharmacies**

**Other  
Compounding  
Pharmacy**

**QUESTION**

Are you committed to compliance with the new USP-797-guidelines for sterile compounding? Where are you in the implementation?	<b>YES</b>	?
Do you filter (0.2 micron) in a Class 100 laminar airflow hood contained in a class 1000 cleanroom, or autoclave where appropriate, to achieve sterility?	<b>YES</b>	?
Do you obtain independent, semi-annual certification of your cleanrooms and laminar airflow hoods?	<b>YES</b>	?
Do you perform sterility testing on every product batch?	<b>YES</b>	?
Do you perform post-filtration filter-integrity testing?	<b>YES</b>	?
Do you conduct monthly independent lab tests of air and surface samples in the cleanrooms?	<b>YES</b>	?
Is the air quality in your general compounding lab engineered for HEPA filtration to reduce particulates?	<b>YES</b>	?
Are your pharmacists, technical and customer service staff dedicated exclusively to compounding?	<b>YES</b>	?
Are you active members of the American College of Apothecaries, the American College of Veterinary Pharmacy and the International Academy of Compounding Pharmacists?	<b>YES</b>	?
Is your staff trained and validated in proper gowning And aseptic techniques, cleanroom regulations and USP Guidelines?	<b>YES</b>	?
Do you purchase pharmaceutical-grade chemicals (USP, NF equivalent) from FDA-registered suppliers?	<b>YES</b>	?
Do you perform pH testing on injections, ophthalmic preparations and other compounds?	<b>YES</b>	?
Do you verify the potency of finished compounds through weight, volume, and yield checks? Do you perform HPLC validation on selected formulations?	<b>YES</b>	?
Is every step of the compounding process from prescribing to compounding and labeling through dispensing reviewed and authorized by a licensed pharmacist?	<b>YES</b>	?
Do you maintain both master formulas and lot-specific worksheets for all compounds? (Do they include the manufacturer and lot number of each ingredient and quality-control test result?)	<b>YES</b>	?

Can you trace the prescription back to the original formula log sheet and the source of ingredients?	YES	?
Does the pharmacy have adequate liability insurance?	YES	?

The Apothecary Shoppe Pharmacies Corporate Office,

Long-Term Care and Compounding Center

304 West Wackerly • Midland Michigan 48640

Phone: (989)837-3636 • Fax: (989) 835-4610

[www.apothecaryshopperx.com](http://www.apothecaryshopperx.com)