



How to compare compounding pharmacies.

DUE-DILIGENCE CHECKLIST

For compounding pharmacy quality and sterility

We're meticulous about every custom compound we prepare. Our stringent quality control programs ensure that every dose meets the specifications and highest standards of the pharmacy profession. We're committed to the strict requirements of Chapters <795> and <797> of the U.S. Pharmacopoeia for compounding non-sterile and sterile preparations.

Unique resource and unparalleled support.

When you are choosing a compounding pharmacy to work with you, be sure to ask questions like those we've listed below.

	Wedgewood Pharmacy	Other Compounding Pharmacy
Are you committed to compliance with the USP <797> guidelines for sterile compounding? Have you completed a <797> gap analysis?	✓	
Would you know if you are having a problem with your clean-room or aseptic-compounding environment? (A pharmacy with a clean room should be able to tell you about its environmental monitoring program, which is designed as one means to assure sterility.)	✓	
If you are compounding sterile preparations, do you conduct weekly lab-tests of air and surface samples in your clean room and other controlled environments?	✓	
Is the air quality in your sterile-compounding lab engineered for HEPA filtration to reduce particulates?	✓	
Do you obtain independent, routine certifications of your clean rooms and laminar airflow hoods?	✓	
Do you perform daily monitoring and documentation of your clean-room temperature and humidity?	✓	
Is your staff properly trained and evaluated in aseptic manipulation skills, gowning technique and clean-room use?	✓	
Do you filter (0.2 micron) in a Class 100 (ISO 5) laminar air-flow hood contained in a Class 1000 (ISO 6) clean room, or autoclave where appropriate, to achieve sterility?	✓	
Do you perform post-filtration filter-integrity testing?	✓	
Do you have systems in place for handling complaints and investigating sterility failures and adverse events?	✓	
In the event of a sterility failure, complaint or adverse event, do you have a procedure in place for determining and conducting a recall, if necessary?	✓	
Do you purchase pharmaceutical-grade chemicals (USP, NF equivalent) from FDA-registered suppliers?	✓	
Do you obtain Certificate of Analyses for all formula ingredients?	✓	
Do you maintain both master formulas and lot-specific worksheets for all compounds?	✓	
Can you immediately trace a prescription back to the original formula log sheet and the source of ingredients?	✓	
Is every step of the compounding process from prescribing to compounding and labeling through dispensing reviewed and verified by a licensed pharmacist?	✓	
Do you verify the potency of finished compounds through weight, volume and yield checks?	✓	
Do you perform pH testing on injections, ophthalmic preparations and other compounds?	✓	
Do you perform HPLC verification on selected formulations?	✓	
Are your pharmacists, technical and customer care staff dedicated to compounding?	✓	
Does the pharmacy have adequate liability insurance?	✓	