

Compounding Pharmacy Safety Checklist

Because of the strict USP guidelines for compounding, it's more important than ever for prescribers to choose a compounding pharmacy they can trust. When you are choosing a compounding pharmacy to work with you, be sure to ask questions like those listed below. ApothéCure is known for providing its clients with the safest products on the market.

✓	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 the weight, volume and yield checks?
✓	Do you perform pH testing on injections and other compounds?
✓	Do you perform 3rd party HPLC verification on certain formulations?
✓	Are you committed to compliance with the USP <797> guidelines for sterile compounding? Have you completed a <797> gap analysis?
✓	Based on your assessment of <797>, are you compounding preparations at the lowest risk to your doctors and patients?
✓	If you are compounding sterile preparations, do you conduct weekly and monthly independent lab tests of air and surface samples in your clean-room and other controlled environments?
✓	Is the air quality in your general 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?
✓	Is your staff properly trained and evaluated in aseptic manipulation skills, gowning technique and clean-room use?
✓	Do you have systems in place for handling complaints and investigating sterility 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 filter (0.2 micron) in a Class 100 (ISO 5) laminar airflow hood contained in a Class 1000 (ISO 6) clean-room, or autoclave where appropriate, to achieve sterility?
✓	Do you perform sterility testing on every preparation batch?
✓	Do you perform sterility testing according to USP <71> — Sterility Tests and USP <85> — Bacterial Endotoxin (Pyrogen) Test?
✓	Do you purchase USP pharmaceutical-grade chemicals?
✓	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?
✓	Are your pharmacists, technical and customer-service staff dedicated exclusively to compounding?
✓	Does the pharmacy have adequate liability insurance?
✓	Do you belong to professional organizations? ApothéCure is a member of IACP, The International Association of Compounding Pharmacies and the IAACN, The International Academy of Clinical Nutritionists.