



Compounding Pharmacy Assessment Questionnaire (CPAQ™)

The International Academy of Compounding Pharmacists represents more than 2,700 pharmacists and other professionals who specialize in the provision of customized medication solutions for patients who have unique therapeutic or health needs. IACP developed this **Compounding Pharmacy Assessment Questionnaire (CPAQ™)** to facilitate discussions and the establishment of collaborative and referral relationships between prescribers, clinics, hospitals, other pharmacies and its members.

IACP provides a free Pharmacy Locator Service to assist consumers and health professionals in identifying local compounders. Visit IACP's website at www.iacprx.org or call (800) 927-4227.

LICENSES - PERMITS

CRITERIA	YES	NO	N/A	COMMENT
1. Is the pharmacy licensed and in good-standing with the state board of pharmacy? 2. Has the pharmacy ever been disciplined for any infractions related to its compounding services?	1.____ 2.____	1.____ 2.____	1.____ 2.____	
1. If the pharmacy is in a different state than the purchasing institution, is the pharmacy licensed to dispense/distribute/provide medications in this state as well? 2. What is the license number? 3. Is the permit in good standing? 4. Will the pharmacy become licensed? 5. Has the pharmacy ever been disciplined for any infractions related to its compounding services in those states in which it currently or formerly had a license/permit?	1.____ 2.____ 3.____ 4.____ 5.____	1.____ 2.____ 3.____ 4.____ 5.____	1.____ 2.____ 3.____ 4.____ 5.____	
1. If the pharmacy is in a different state than the purchasing institution, is the <u>pharmacist-in-charge</u> or another full-time pharmacist licensed in the state as well? 2. What is the license number(s)? 3. If not, will the pharmacy agree to have one of its staff pharmacists become licensed? 4. Has the pharmacist ever been disciplined for any infractions related to his/her compounding services?	1.____ 2.____ 3.____ 4.____	1.____ 2.____ 3.____ 4.____	1.____ 2.____ 3.____ 4.____	

1. Has the pharmacy demonstrated it meets national quality standards by earning accreditation by the Pharmacy Compounding Accreditation Board (PCAB)? Current accreditation can be verified at http://www.pcab.org . 2. Is the pharmacy accredited by any other accrediting bodies? If so, which ones?	1.____ 2.____	1.____ 2.____	1.____ 2.____	
1. Are the pharmacist(s) and/or its staff members of the International Academy of Compounding Pharmacists (IACP)? 2. Of the American Society of Health-System Pharmacists?	1.____ 2.____	1.____ 2.____	1.____ 2.____	
COMPOUNDING SERVICES PROVIDED				
1. What types of dosage forms does the pharmacy prepare (e.g., injectables, capsules, troches, oral liquids, suppositories, topicals, ophthalmics, inhalations)? 2. How long has the pharmacy compounded these various dosage forms?	1.____ 2.____	1.____ 2.____	1.____ 2.____	
1. Does the pharmacy provide sterile compounding services? 2. If so, what level of complexity?	1.____ 2.____	1.____ 2.____	1.____ 2.____	
INTERNAL CONTROLS AND QUALITY ASSURANCE				
Does the pharmacy have written and active Standard Operating Procedures (SOPs) in place for all compounding activities?				
1. Does the pharmacy obtain its pharmaceutical ingredients from an FDA- and DEA-registered Pharmaceutical Ingredients supplier? 2. How is that documented? 3. Are SOPs in place to demonstrate verification of supplier registration status?	1.____ 2.____ 3.____	1.____ 2.____ 3.____	1.____ 2.____ 3.____	
1. Does the pharmacy obtain Certificates of Analysis (CoA) for all formula ingredients from its suppliers? 2. Are those available for verification?	1.____ 2.____	1.____ 2.____	1.____ 2.____	

1. Does the pharmacy have an SOP in place in case of a recall? 2. Has the pharmacy had a recall in the last 24 months?	1.____ 2.____	1.____ 2.____	1.____ 2.____	
Does the pharmacy have an SOP on how a customer can report problems to the pharmacy?				
1. Has the pharmacy staff been trained and evaluated in proper aseptic technique, gowning and cleanroom procedures? 2. What SOPs exist that show performance compliance with those procedures?	1.____ 2.____	1.____ 2.____	1.____ 2.____	
1. Does the pharmacy compound sterile preparations? 2. What level of sterile compounding is performed by the pharmacy using the commonly named "low-risk, medium-risk, and/or high-risk" categories?	1.____ 2.____	1.____ 2.____	1.____ 2.____	
1. Does the pharmacy comply with current <i>USP <797></i> standards for sterile compounding? 2. How is that compliance documented through SOPs?	1.____ 2.____	1.____ 2.____	1.____ 2.____	
1. Does the pharmacy compound non-sterile preparations? 2. Are the preparations simple, medium and/or complex?	1.____ 2.____	1.____ 2.____	1.____ 2.____	
1. Does the pharmacy comply with the current <i>USP <795></i> standards for non-sterile compounding? 2. How is that compliance documented through SOPs?	1.____ 2.____	1.____ 2.____	1.____ 2.____	
TESTING & VERIFICATION				
1. Does the pharmacy use published information or stability studies to establish the preparations' beyond-use dating? 2. What sources are used?	1.____ 2.____	1.____ 2.____	1.____ 2.____	
1. Does the pharmacy have in place quality-assurance and continuous quality-improvement programs? 2. Give an example.	1.____ 2.____	1.____ 2.____	1.____ 2.____	

Does the pharmacy staff participate in ongoing training and continuing education that is specific to compounding pharmacy practice?				
1. Does the pharmacy have its compounded preparations regularly tested for potency to ensure the concentration on the container is what is stated on the label? 2. Which laboratories does the pharmacy use for potency assessments? 3. How frequently are batches tested for potency? 4. What SOPs are in place governing the frequency of testing?	1.____ 2.____ 3.____ 4.____	1.____ 2.____ 3.____ 4.____	1.____ 2.____ 3.____ 4.____	
1. Do the pharmacy's preparations meet the +- 10% of stated concentration that is required from USP? 2. How is that documented?	1.____ 2.____	1.____ 2.____	1.____ 2.____	
Will the pharmacy provide written documentation of all testing results to the purchasing institution?				
1. Has the air quality in the pharmacy's designated compounding areas been independently tested and/or certified? 2. Please provide details.	1.____ 2.____	1.____ 2.____	1.____ 2.____	
1. Does the pharmacy perform or contract with an analytical lab to perform sterility testing according to <i>USP</i> <71> Sterility Tests and <i>USP</i> <85> Bacterial Endotoxin (Pyrogen) Tests? 2. Which laboratories does the pharmacy use for sterility assessments? 3. How frequently are batches tested for sterility? 4. What SOPs are in place governing the frequency of testing?	1.____ 2.____ 3.____ 4.____	1.____ 2.____ 3.____ 4.____	1.____ 2.____ 3.____ 4.____	
1. How are the compounded preparations delivered or shipped? 2. Does the pharmacy assure proper storage conditions are maintained through delivery?	1.____ 2.____	1.____ 2.____	1.____ 2.____	
What is the turn-around time for delivery once the order has been placed?				

1. What information is on the labeling of the preparation? 2. How does the labeling look? 3. Does the pharmacy color code labels?	1.____ 2.____ 3.____	1.____ 2.____ 3.____	1.____ 2.____ 3.____	
How are the preparations packaged? 1. Unit-dose or multiple-dose? 2. Tamper-evident? 3. Protected from light? 4. Overwrapped?	1.____ 2.____ 3.____ 4.____	1.____ 2.____ 3.____ 4.____	1.____ 2.____ 3.____ 4.____	
1. Does the pharmacy accept site visits? 2. How can a site visit be arranged?	1.____ 2.____	1.____ 2.____	1.____ 2.____	

Date of Interview or Visit _____ **Conducted By** _____

Additional Info: _____

Pharmacy Approval (circle one) **YES NO Comment:** _____

The International Academy of Compounding Pharmacists (IACP) invites comments, questions, and suggestions for improving our *Compounding Pharmacy Assessment Questionnaire (CPAQ™)*. Contact IACP at (281) 933-8400 or visit our website at www.iacprx.org. The information contained in this *Compounding Pharmacy Assessment Questionnaire* is constantly evolving because of ongoing research and improvements in technology and is subject to the professional judgment and interpretation of the involved healthcare professionals. The International Academy of Compounding Pharmacists and its committee members have made reasonable efforts to ensure the accuracy and appropriateness of the information presented. However, any reader of this information is advised that the International Academy of Compounding Pharmacists, its advisory panel, and its committee members are not responsible for the continued currency of the information, for any errors or omissions and/or for any consequences arising from the use of the information in the *Compounding Pharmacy Assessment Questionnaire* in any and all practice settings. Any reader of this document is cautioned that the International Academy of Compounding Pharmacists makes no representation, guarantee or warranty, express or implied, as to the accuracy and appropriateness of the information contained in this *Compounding Pharmacy Assessment Questionnaire* and will bear no responsibility or liability for the results or consequences of its use.