

Fact sheet

10 Tips for Compounding

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1. Understand legal and regulatory requirements

It is crucial for compounding pharmacists to ensure compliance, safeguard patient safety, and maintain high standards of practice. By adhering to regulations, laws and guidelines on how compounded medications should be prepared, labelled, stored, dispensed, and monitored, compounding pharmacists can ensure they meet the highest standards for safety, efficacy, and quality.

By adhering to the guidelines and ensuring proper clinical oversight, compounding can be a valuable tool for providing personalised care for patients in situations where commercial medications are insufficient or inappropriate.

- **Australian Therapeutic Goods Administration (TGA):** The TGA regulates pharmaceutical compounding and ensures that compounded medications meet safety standards. Pharmacists must be aware of TGA guidelines on the manufacturing and labelling of compounded medicines.
- **Pharmacy Board of Australia (PBA):** The PBA ensures compliance with professional standards set by the Pharmacy Board, which includes ethical practices, patient safety, and confidentiality.
- **Australian Pharmaceutical Formulary and Handbook (APF):** The APF provides specific instructions for creating compounded medications safely and effectively. Refer to the APF for standardised formulations and compounding guidelines.

2. Clinical justification

There must be a valid clinical reason for compounding the product. Compounding is typically performed in specific situations when a commercially available medication is unsuitable or unavailable for a patient's needs. Medicines should not be compounded if there is a suitable commercial product that has a similar therapeutic effect and can be safely used for the intended purpose, and that can be accessed within a suitable timeframe.

Some of the key scenarios in which compounding a pharmaceutical product is appropriate include:

- **When a commercial product is unavailable or out of stock**
 - Shortages: If a medication is in short supply or discontinued, compounding can be a solution to meet patient needs when no alternative commercial product is available.
 - Formulation issues: If a commercially available product doesn't come in the required dosage form (e.g., liquid instead of tablet), compounding can offer a tailored solution.
- **When a patient has an allergy or sensitivity**
 - Allergens or ingredients: Some patients may have allergies or sensitivities to certain ingredients in commercially available products (e.g., lactose, gluten, or dyes). Compounding allows the pharmacist to create a medication without those allergens.
 - Sensitive ingredients: For patients who cannot tolerate certain excipients (e.g., preservatives, colorants), a compounded product can be formulated with appropriate alternatives.
- **When the dosage strength needs to be adjusted**
 - Customised dosage: If a patient requires a dosage strength that is not commercially available (e.g., a lower or higher dose), compounding allows for precise tailoring to the required strength.

- Paediatric or geriatric doses: Children or elderly patients often need specific dosing adjustments, such as a liquid form or a smaller dosage than what's commercially available.
- **For specialised dosage forms**
 - Non-standard forms: Some patients may require medications in specialised forms, such as creams, gels, suppositories, lozenges, or transdermal patches, which may not be commercially available for every drug.
 - Custom delivery methods: If a medication needs to be delivered in a specific form that isn't available in the market (e.g., topical preparations for localized conditions), compounding can address this need.
- **When a patient requires a combination of medications**
 - Polypill or combination therapy: Sometimes, patients need a combination of medications in a single dosage form, such as combining two or more drugs into one tablet or capsule for easier administration.
 - Chronic disease management: Compounding can help manage chronic conditions by combining multiple medications into a single, more convenient formulation.
- **When a medication requires modification due to special needs**
 - Swallowing difficulties: Some patients, especially elderly individuals or children, may have difficulty swallowing tablets or capsules. Compounding can provide liquid or flavoured formulations that are easier to ingest.
 - Patient preference: Some patients may prefer specific forms of medication (e.g., a flavoured oral suspension rather than a pill) to improve compliance and ease of use.
- **Hospice and palliative care**
 - End-of-life care: Compounding is often used in hospice or palliative care settings to create formulations that manage symptoms (e.g., pain relief) in a way that is more comfortable for patients, especially those who have difficulty swallowing or require a special route of administration.
- **Veterinary compounding**
 - Animal medications: Compounding is also common in veterinary care to provide the appropriate formulation and dosage for animals, especially when there are no commercial products available for certain species or conditions.
- **Clinical trials and research**
 - Trial preparations: In some research settings, compounded medications may be needed for clinical trials or investigational drugs. These medications may not yet be commercially available, but compounding ensures that participants receive the correct dosage and form.
- **Patient-specific requests**
 - Unique therapeutic needs: In some cases, a healthcare provider may request a compounded medication for a specific patient based on their individual medical needs, therapeutic goals, or circumstances that cannot be addressed with a standard product.

3. Follow good compounding practice (GCP)

Good compounding practice (GCP) is essential to ensure that compounded medications are prepared safely, accurately, and effectively for patient use. It includes following established guidelines, maintaining high standards of hygiene, and utilizing appropriate techniques and equipment to deliver quality compounded products. GCP is key to minimizing errors, preventing contamination, and ensuring the safety and well-being of patients.

Good compounding practice includes:

- **Quality assurance**: Follow Good Manufacturing Practice (GMP) or Good Compounding Practice (GxP) standards to ensure consistency and quality. This includes maintaining clean environments, calibrated equipment, and proper documentation.
- **Personal protective equipment (PPE)**: Wear appropriate PPE (e.g., gloves, lab coats, face shields) to avoid contamination and ensure the safety of both the compounder and patient.
- **Storage conditions**: Ensure proper storage conditions for both raw ingredients and compounded medications, which may involve temperature-controlled storage or protection from light.

4. Appropriate equipment and procedures

Compounding pharmaceutical products requires a variety of equipment to ensure that medications are accurately prepared, mixed, and packaged. By using the right equipment and following proper procedures, pharmacists can ensure that compounded pharmaceuticals are produced to the highest standards of quality, safety, and efficacy.

Consideration should be given to:

- **Clean environment:** Ensure that the compounding area is clean and free from contaminants, especially when preparing sterile formulations.
- **Equipment maintenance and calibration:** Regular calibration of weighing and measuring equipment ensures that the final product is accurate and consistent.
- **Standard operating procedures (SOPs):** Always adhere to SOPs for each compounding step to ensure that medications are compounded safely and effectively.

5. Accurate formulation and documentation

Accurate formulation and documentation are critical elements in the compounding process to ensure the safety, quality, and efficacy of the compounded medications. Proper formulation involves using the correct ingredients, quantities, and methods to prepare medications that are safe for patients. Comprehensive documentation serves as a record of the entire compounding process and ensures compliance with regulatory and professional standards.

Accurate formulation and documentation includes:

- **Precise measurements:** Use precise and calibrated equipment when measuring raw ingredients to ensure accurate dosing and effectiveness.
- **Record keeping:** Keep detailed records of each compounded prescription, including the patient's details, formula used, batch numbers, and any special instructions. This documentation is crucial for patient safety and legal compliance.
- **Labelling:** Properly label compounded medications with information such as the patient's name, dosage instructions, and storage conditions. This helps ensure safe and effective use.

6. Patient-centred approach

A patient-centred approach in compounding focuses on tailoring medications to the individual needs of each patient, to ensure that their health outcomes are optimised. When compounding, this approach means prioritising the patient's specific medical conditions, preferences, and circumstances when creating a custom formulation.

A patient-centred approach considers:

- **Personalised compounding:** Ensure that the compounded medication meets the unique needs of the patient. This may include adjusting strength, dosage form (e.g., cream, oral liquid, or suppository), or excluding allergens.
- **Consultation:** Offer thorough consultation with patients or healthcare providers to understand the requirements for compounding and clarify any questions regarding use, side effects, or dosage adjustments.
- **Patient safety monitoring:** Monitor for adverse reactions or effectiveness when using compounded medications and maintain communication with the patient or healthcare provider for any adjustments.
- **Patient consent:** Before compounding, it is essential to obtain proper consent from the patient or their caregiver, especially when making changes to their medication regimen.

7. Use of quality ingredients

To help maintain the integrity of the final product and minimise the risks associated with contamination, impurities, or ineffective formulations, the use of quality ingredients is essential. Inappropriate or poor-quality ingredients can lead to ineffective treatments, adverse effects, or even harm to patients. Using quality ingredients is fundamental to ensuring the safety, efficacy, and stability of compounded medications.

From sourcing reputable suppliers to properly storing and inspecting ingredients, the quality of the ingredients used in compounding directly impacts the final product and patient outcomes.

The use of quality ingredients includes consideration of:

- **Pharmacopoeia-approved substances:** Always use quality, pharmaceutical-grade ingredients sourced from reputable suppliers. Raw materials should comply with the United States Pharmacopeia (USP) or European Pharmacopoeia (EP) standards, where applicable.
- **Shelf life and expiry:** Be mindful of the shelf life of each ingredient and the final compounded product. Make sure to mark expiry dates clearly and educate patients on proper use within the recommended time frame.
- **Records:** Ensure that all products are accurately records for each item, including recording expiration dates and batch numbers for each ingredient used. Regular audits should be undertaken to ensure stock is within expiration date.

8. Risk assessment and error prevention

A crucial component to ensuring the safety, efficacy, and quality of compounded medications is risk assessment and error prevention. Compounding pharmacies face numerous challenges, including the possibility of human error, contamination, and equipment failure. By identifying and managing risks, implementing comprehensive error prevention strategies, and fostering a culture of continuous improvement, compounding pharmacies can minimise the likelihood of errors, ensure regulatory compliance, and provide patients with the best possible care.

Compounder must ensure any item they are making is the right drug and right formulation for the right person at the right time.

This includes verifying the following information:

- **Risk assessment:** All prescriptions for compounded medicines should have a risk assessment undertaken to ensure the product is appropriate for the patient at the time of compounding. This should occur regardless of if the compounded product is new, or a repeat prescription.
- **Cross-contamination prevention:** Employ strategies to prevent cross-contamination, especially when dealing with potent or hazardous drugs. This includes dedicated equipment for certain drugs or protocols for cleaning workspaces.
- **Double-check procedures:** Implement systems for double-checking each compounded product, whether it's through peer review or additional safety protocols. Reducing human error is critical for patient safety.

9. Training and education

Training and education are fundamental components of maintaining high standards in compounding. Properly trained personnel ensure the accuracy, safety, and effectiveness of compounded medications, while also ensuring compliance with regulations and industry best practices. Ongoing education is also critical to ensure that pharmacy personnel stay updated on the latest industry practices, regulatory standards, and technological innovations, ultimately contributing to better patient outcomes and compliance with standards.

Proprietors and compounding pharmacists must ensure that all compounding staff have undertaken the following:

- **Personnel certification and training:** Ensure all compounding pharmacists and technicians have appropriate training in pharmaceutical compounding techniques, regulatory compliance, and patient safety.
- **Competency assessment:** Evaluate whether employees are assessed for their skills and knowledge regularly, especially in handling specialised equipment or high-risk medications.
- **Continual education:** Pharmacists and technicians involved in compounding should regularly update their knowledge on compounding practices, new formulations, and regulations. Attending workshops, training sessions, and staying updated with relevant literature helps maintain competency.
- **Accredited programs:** Participate in accredited training programs that focus on pharmaceutical compounding and the specific regulatory and safety standards within Australia.

10. Self-assessment and audits

An essential component of Good Compounding Practice (GCP) is self-assessment and audits. They help ensure that the compounding process adheres to the highest standards of quality, patient safety, and regulatory compliance. Regular reviews, staff training, and adherence to SOPs are vital for maintaining high-quality standards in pharmaceutical compounding.

By regularly conducting these assessments, pharmacies can identify potential risks, improve practices, and ensure that compounded medications meet the needs of their patients while reducing errors and ensuring compliance with relevant standards.

Compounding pharmacist staff must undertake regular assessment and audits to ensure:

- **Improved patient safety:** Regular audits help identify and correct issues before they impact patient health, ensuring compounded medications are safe and effective.
- **Compliance with regulatory requirements:** Staying in compliance with relevant regulations helps avoid fines, penalties, and potential legal issues while ensuring that compounded medications meet legal standards.
- **Improving quality:** Self-assessments allow pharmacies to continuously improve their processes by regularly reviewing their practices and comparing them to best practices, reducing errors and enhancing medication quality.
- **Enhanced quality of practice:** Ongoing assessments allow for continuous improvement in compounding practices, leading to better medication quality and patient outcomes.
- **Increased confidence:** Patients, healthcare providers, and regulatory bodies gain confidence in the pharmacy's ability to produce high-quality, safe compounded medications.

