

Compounding Internationally
International Society of Pharmaceutical Compounding (ISPhC)
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If you will respond to the questions below, we will incorporate your answers in the ISPhC web page section Compounding Internationally, so we will have all the information in a uniform format. You will be listed as an author of the column for your country. Thank you very much for your help.

Is compounding permitted in your country? **Yes**

Who regulates compounding in your country? **State Boards of Pharmacy and the U.S. Food and Drug Administration (FDA).**

Which are the Compounding Pharmacy Regulations or Guidelines in your Country? Please provide a description, a document or link to your country web page to use as a reference. **Each state develops their own regulations, laws or statues. Additionally the United States Congress passed the Drug Quality and Security Act in November of 2013. It contains Section 503A and 503B.**

Section 503A describes conditions that must be satisfied for drug preparations compounded by a licensed pharmacist or licensed physician to be exempt from 3 sections of the Federal Food, Drug and Cosmetic Act. The drug preparation must be for an identified individual patient based on the receipt of a valid prescription. If a pharmacist meets this requirement they would be regulated by their State Boards of Pharmacy.

Section 503B addresses firms that register with the FDA as “outsourcing facilities” and they would be regulated by the FDA. These firms compound sterile preparations where there is not an individual prescription for an individual patient.

List some difficulties you have with regulatory agencies regarding compounding:

Each state has their own laws, rules and regulations so there is no consistency country wide. Keeping up with 50 different regulatory agencies is therefore quite difficult.

It is also difficult to determine who has authority in every situation – the states or federal government.

The FDA allows compounding with Active Pharmaceutical Ingredients (APIs) for humans but the FDA Guidance for animal patients does not. To complicate matters the Guidance for animals is not law – just a guidance which adds to the confusion for compounders.

What are you allowed to compound?

Any nonsterile or sterile preparation, based on a physician’s prescription, for which there is no commercial pharmaceutical product. A pharmacist can compound a commercial pharmaceutical product during periods of drug shortages.

What are you not allowed to compound?

Drugs that have been listed by the FDA as being removed for safety reasons. Preparations that are demonstrably difficult to compound, such as inhalers or transdermal patches. Copies of a manufactured product except during periods of drug shortages.

Describe your compounding pharmacy.

Not applicable. USP is not a dispensing pharmacy. USP is a standard setting organization.

List some unique equipment that you commonly use.

Not applicable

Can you compound or manufacture large quantities to provide to other pharmacies?

Under the new Drug Quality and Security Act a pharmacy registered with the FDA as an outsourcing facility may compound large quantities. The drug will not be sold or transferred by an entity other than the outsourcing facility that compounded the drug. The concept of a “central fill” pharmacy does exist in the United States where one pharmacy does the compounding and transfers the preparation to another pharmacy for patient dispensing.

How do you assign beyond-use dates, or expiration dates to your compounded preparations?

In American compounding practitioners assign beyond-use dates (BUDs) to compounded preparations. Commercial products are assign expiration dates by the pharmaceutical manufacturer.

BUDs are determined based on stability indication assays. In lieu of stability indicating assays USP General Chapter <795> *Pharmaceutical Compounding – Nonsterile Preparations* contains a table of default beyond-use dates. USP General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations* in lieu of stability indicating assays lists storage periods for various risk level Compounded Sterile Preparations (CSPs).

USP has published an article describing the difference between point-in-time potency testing vs determining beyond-use dating based on stability indicating assays. The article is titled: *Strength and Stability Testing for Compounded Preparations* at: <http://www.usp.org/support-home/frequently-asked-questions/compounding> under Frequently Asked question number 4.

What do you think is unique about the way compounding is done in your country?

Compounding is performed by multiple practitioners in multiple locations. For example, community pharmacies, hospitals, physician’s offices, veterinary hospitals and clinics, surgery centers, home healthcare locations etc.

Do all pharmacists have the ability to compound? **Yes, by licensure all pharmacists have the ability to compound.** Or, does it take additional special training? **Most** compounding, beyond simple reconstitution of an oral antibiotic or combination of two creams required additional special training beyond that provide by schools of pharmacy.

Are you allowed to compound non-prescriptions medications for sale?

Do you compound the following dosage forms? **N/A**

	<u>Yes</u>	<u>No</u>
NONSTERILE		
Oral liquids (solutions, suspensions, emulsions)	_____	_____
Topical liquids (solutions, suspensions, emulsions)	_____	_____
Oral solids (capsules, tablets)	_____	_____
Suppositories	_____	_____
Troches/Lozenges	_____	_____
Ointments, Creams, Lotions	_____	_____
STERILE		
Ophthalmic preparations	_____	_____
Nasal preparations	_____	_____
Injections	_____	_____
Intravenous admixtures	_____	_____

Do you compound for the following therapeutic categories? N/A	<u>Yes</u>	<u>No</u>
Pain management	_____	_____
Dermatology	_____	_____
Hormone replacement therapy	_____	_____
Veterinary	_____	_____
Neuropathy	_____	_____
Dental	_____	_____
Podiatry	_____	_____
Ophthalmic	_____	_____
Steroid therapy	_____	_____
Oncology	_____	_____
Rheumatology	_____	_____
Parenterals	_____	_____
Inhalation/respiratory	_____	_____
Surgical	_____	_____

Other information you would like to share with compounding pharmacists internationally about compounding in your country? Please add here.

References

Acknowledgment