



What are you allowed to compound?

It is allowed to compound all drug categories. The pharmacy is allowed to compound and store a minimum quantity of compounded preparations and/or formulations outside the National Formulary in quantities that have been estimated based on demand

Pharmacies are classified into 6 (six) groups according to type of activity.

Types of activities developed by the compounding pharmacy according RDC 67/2007:

Groups	Activity/Origin of compounded ingredients	Regulations to meet
Group I	Compounded preparations with ingredients/raw materials, including those of vegetal origin	Appendix I
Group II	Compounding of narrow therapeutic index substances	Appendix I and II
Group III	Compounding of antibiotics, hormones, cytostatics, and controlled substances	Appendix I and III
Group IV	Sterile product compounding	Appendix I and IV
Group V	Compounding of homeopathic substances	Appendix I (when applicable) and V
Group VI	Unit-dose dispensing and repackaging of unit dose forms for health care services (hospitals)	Appendix I and IV (when applicable) and VI

What are you not allowed to compound?

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Describe your compounding pharmacy.

All Brazilian pharmacies must comply with the minimum standards required by Resolution RDC 67/2007 to obtain operating license. Such standards include minimally adequate physical infrastructure, materials and precision instruments calibrated, PSP's and documents of the updated quality system, qualified and trained personnel

List some unique equipment that you commonly use.

Technology is an important part of the arsenal of tools that compounding pharmacies use in Brazil. Among the instruments used are precision and analytical balances, pH meters, temperature gauges and humidity, calibrated glassware and cabins compounding controlled pressurization.

Can you compound or manufacture large quantities to provide to other pharmacies?  
 Pharmacies cannot sell compounded preparations to other companies, they can only dispense the compounded medications directly to patients

How do you assign beyond-use dates, or expiration dates to your compounded preparations?  
 The shelf life of the preparations are preferably time-based patient care for each formulation. However, the pharmacist may determine the validity of each preparation based on their pharmacotechnical and pharmacological knowledge, supported by references. This practice is permitted by current regulations in the country.

What do you think is unique about the way compounding is done in your country?  
 In Brazil, licenses and operating permits are annual. What is unique in the country is the requirement for qualification of suppliers through presencial audits in these establishments.

Do all pharmacists have the ability to compound? Or, does it take additional special training?  
 Yes, all pharmacies have need of expeditious operating licenses by the competent health authorities.

Are you allowed to compound non-prescriptions medications for sale?  
 Yes, but there are clear rules about which drug categories and products can be compounded without requiring prescriptions of qualified professionals such as doctors, nutricionistras and others.

Do you compound the following dosage forms?

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

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

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

References

[Resolution RDC 67, of October 8, 2007](#)

Acknowledgment