



Specialty Medicine Compounding Pharmacy

Competent Compounding

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May 2005 Ben Demongey, PharmD (cand)

Expiration Dates and the United States Pharmacopeia

The most recent update of the United States Pharmacopeia's (USP) guidelines for pharmaceutical compounding have listed several responsibilities of the compounding pharmacist. These responsibilities include the need to ensure that the ingredients used have their expected identity, quality, and purity. Compounded products are of acceptable strength, quality, and purity, with appropriate packaging and labeling. Appropriate stability evaluation is performed or determined from the literature for establishing reliable beyond-use dating, in order to ensure that the final products have expected potency, purity, quality, and characteristics up to the beyond-use date.

Stability is defined as the

extent to which a product retains the same properties and characteristics that it had at the time of its compounding, throughout its period of acceptable use. With compounding, since many times there is not stability testing readily available and the products are compounded for immediate use, their beyond-use date is typically much shorter than manufactured products. At all steps of the compounding process the pharmacist/compounder is responsible for observing signs of deterioration.

In the absence of stability information of a specific drug product the USP has issued recommended beyond-use dating to be used for non-sterile compounded drugs that are stored at room

temperature in light resistant containers.

For non-aqueous Liquids and Solid Formulations:

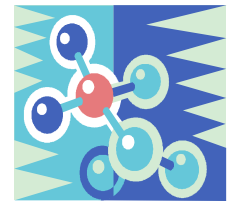
Those made from manufactured active ingredients, the beyond use date will be the lesser of <25% of manufactured products expiration or six months. For products made from USP or NF substances, the beyond use date is not longer than six months.

For water containing Formulations:

The beyond use dating is not longer than 14 days when stored at temperatures between 36-46°F.

For all other formulations:

The beyond use date is not longer than, the lesser of 30 days or the duration of therapy.



Many of the human and veterinary suspensions that we have compounded in the past were made in a water containing formula. With the new guidelines this would mean that they would have a beyond use date of only 14 days. Since many of the compounded medications are used longer than 14 days, patients are forced to get their prescription refilled every 2 weeks. This is both inconvenient and increases the overall cost to the patient. To reduce this problem most of the suspensions that are made in a water based formula have been switched over to oil based formulation. By making this switch, the beyond use date is increased from 14 days to greater than 1 month. This allows the patients the ability to get their prescriptions filled once monthly or even over a greater period of time. The oil based formulas are more convenient for the patient and work as effective as their water based counterparts.

Specialty Medicine Compounding Pharmacy

The demands of modern compounding have lead to the creation of pharmacies devoted solely to this art. Specialty Medicine Compounding Pharmacy has been serving your community for over 6 years. Here we specialize in bio-identical

hormone replacement therapies and veterinary medicine, to name a few. We have all the facilities and equipment needed to make anything from topicals to capsules and sterile injectables. We do not accept insurance, but do provide claims

forms with prescriptions we fill. So, next time a patient wants a compound you're unsure of - we'd be happy to serve them!

