



Khezr Beach, Hormoz Island, Persian Gulf, Iran

## PIC QUESTION OF THE WEEK: 7/12/10

Q: Please provide some basic guidelines for beyond-use dating of *non-sterile* compounded pharmaceuticals?

A: The United States Pharmacopeia (USP) defines beyond-use date (BUD) as “the date after which a compounded preparation is not to be used and is determined from the date the product is compounded.” Chapters 795 and 797 of the USP define the guidelines for stability testing and beyond-use dating of non-sterile and sterile products respectively. Information regarding beyond-use dating of *sterile* products is extensive and the reader is referred to USP Chapter 797 ([www.usp797.org](http://www.usp797.org)) for review of these requirements. If valid stability data is not available for a specific *non-sterile* preparation, the USP provides labeling guidelines based on the water content of the final product. The compounder must also consider other factors such as storage requirements, duration of use of the given product, the mechanism by which the drug is normally degraded, and the container in which the drug will be packaged. The following USP recommendations apply to maximum beyond-use dates for preparations that are packaged in tight, light-resistant containers and stored at controlled room temperatures unless otherwise stated in the USP. Please refer to the complete USP statement on *non-sterile* beyond-use dates for additional information on this complex topic.

### Non-Aqueous Liquids and Solids

- *Solid* preparations with active ingredients from a *manufactured product* should be labeled with a beyond-use date of 25% of the time remaining until the manufactured product expiration or 6 months, whichever is earlier.
- If the solid preparation is formulated from *USP products*, a 6 month beyond-use date should be assigned.
- The BUD for a *non-aqueous liquid* with active ingredients from a *manufactured product* is 25% of the time left until the manufactured product expires or 6 months, whichever comes first.
- Non-aqueous liquid preparations made from *USP products* should bear a beyond-use date of 6 months.

### Aqueous (Water-Containing) Formulations

- For aqueous (water-containing) liquid preparations prepared from solid ingredients a beyond-use date of 14 days is acceptable if the product is refrigerated (5 degrees Celsius).
- If all ingredients are liquids, the BUD is 30 days or the intended duration of therapy, whichever is less.

### Other Formulations

- For all non-solid and non liquid dosage forms, the beyond-use date is 30 days or duration of therapy, whichever is less.

### References

- Allen LV. Beyond-use dates and stability indication assay methods in pharmaceutical compounding. *Secundum Artem*. 2009;15(3):1-6.  
<http://www.paddocklabs.com/html/resource/pdf/Sec%20Artem%2015.3.pdf>. Accessed July 1, 2010.
- United States Pharmacopeia (32/27). Chapter 795. Stability criteria and beyond-use dating.  
[http://www.pharmacopeia.cn/v29240/usp29nf24s0\\_c795.html](http://www.pharmacopeia.cn/v29240/usp29nf24s0_c795.html). Accessed July 1, 2010.

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