



Stability Study vs. Predefined Time Point Testing

Often we are asked, "What is the difference between potency testing and stability studies?"

Potency testing gives you concentration information about your compounded product. It lets you know how well you compound a particular product by analyzing the active ingredient. This information can then be utilized to check your compounding process by having other people compound the product in the same way to see if the results are consistent. Potency information is helpful in determining that the active ingredient is at the expected concentration. HPLC or potency testing helps pharmacists develop proper processes but does not necessarily give information about beyond-use dating (BUD).

Stability Studies are much more complex than potency testing. Stability Studies are utilized to determine the beyond use date for your compounded product. Stability studies force degrade a product by heat, UV, acid, base and peroxide. The laboratory will develop an HPLC stability indicating method and validate that method to separate the active ingredient from its degradant product. This stability indicating method will then allow the laboratory to test your active ingredient, stored in stability chambers, at predetermined time points to determine potency and beyond-use dating. A typical stability study will encompass the following:

1. Method development (HPLC method specific for the formulation. This method will separate the active ingredient from its degradant and the products excipients)
2. Method validation (ensures that the method meets the following criteria; specificity, system suitability, precision, accuracy, linearity, robustness, ruggedness, sensitivity, and freeze thaw)
3. Stability Study: Product is stored at specific conditions in stability chambers: (refrigerated, ambient and/or accelerated conditions), The product is tested in duplicate at particular times. (Ex. initially, 1, 2, 3, 6, 9, 12, 18, 24 months.) These time points can be decided by the customer or may be dictated by the product.

Ⓜ This stability information will then allow you to put a true beyond-use date (stability) on the product.

As indicated, more information is gained through a stability study than a potency test. While both offer information on the concentration of a product, only a stability study can give you accurate beyond-use dating. To determine the BUD,

each product that is compounded needs a stability indicating method to ensure that the degradant is not calculated in the analyte's concentration. Often times a lab can determine the potency of a product without using a stability indicating method. Which means that the potency results that you receive may not distinguish between the analyte of interest and its degradant product. Ask your lab about their potency determination methods. Are they stability indicating? What do the potency testing results tell me about my product? Is the method validated? What does that mean?

Laboratory testing is an important part of Quality control and assurance for each compounding pharmacy. Know and understand what the information is actually reflecting. Talk to your lab and make sure that they meet the quality standards that you require.