Adding New Dissolution Tests to USP Monographs: Frequently Asked Questions

[Note - These approaches apply to all new Dissolution tests, including the ones added by a Revision Bulletin (for approved application holders), by NITRs to be posted as a part of Pending Monograph Program, or as a part of a new monograph development

1. Will USP include a new Dissolution test with tighter tolerances than the existing test(s)?
    a. For immediate release dosage form monographs, our approach is <u>not</u> to proceed with this revision request and not to add a new Dissolution test with tighter tolerances to a monograph. [Note - The term "tighter tolerances" covers two possible scenarios: (1) higher % dissolved at the same sampling time and (2) earlier sampling time with the same % dissolved.]
    b. For delayed release and extended release dosage form monograph, there may be a need to introduce a test with tighter tolerances, for example with several additional timepoints. In these cases, USP would seek FDA feedback regarding the need to include an additional test.
2. How will USP address a request to include a description of a sinker, or to add a statement "use suitable sinkers if needed", when the currently official Dissolution test(s) do not specify the use of sinkers?
    a. USP approach is not to include additional Dissolution test if all other conditions and tolerances are the same as in existing Dissolution test(s).
    b. USP's current practice is to add "use suitable sinkers if needed" (or a description of a specific or an unusual type of sinkers) to an existing Dissolution test.
    c. It is our understanding the FDA expects this information to be included in a monograph as an important part of the Apparatus description.
3. When will USP add a description of the Medium for Tier 2 (to overcome cross-linking)?
    a. USP will add a description of Tier 2 Medium when it deviates from what is stated in <711> *Dissolution* in the section titled *For Dosage Form Containing or Coated with Gelatin.* Examples could include a Medium containing a different type of the enzyme, or a different amount of the enzyme than described in the Chapter.
    b. If a dissolution test already contains description of the Medium for Tier 2 as described above, the following statement may be added to the monograph to accommodate other sponsors : "Alternatively, the types and amounts of enzymes as stated in *Dissolution <711>, For Dosage Form Containing or Coated with Gelatin* can be used."
4. How will USP address a request to include a test with the same dissolution conditions and tolerances but with a different analytical procedure?
    a. USP approach is not to include additional Dissolution test if the conditions and tolerances are the same as in existing Dissolution test(s).
    b. Please see *General Notices* 6.30. Alternative and Harmonized Methods and Procedures for additional information about alternative analytical procedures.