Adding New Dissolution Tests to USP Monographs: Frequently Asked Questions

[Note - These approaches apply to all new Dissolution tests, including the ones added by Revision Bulletins (for approved application holders), by Notices posted as a part of Pending Monograph Program, or as a part of a P*harmacopeial Forum* (*PF*) proposal for a new monograph.]

1. Will USP include a new Dissolution test with tighter tolerances than the existing test(s)?

   For immediate-release dosage form monographs, USP will not add a new Dissolution test with tighter tolerances to a monograph. [Note - The term "tighter tolerances" covers three possible scenarios: (1) higher % dissolved at the same sampling time; (2) earlier sampling time with the same % dissolved; and (3) higher % dissolved at an earlier sampling time.]

   Due to the higher complexity of dissolution tests for delayed-release and extended-release dosage forms which typically include multiple time points, USP may introduce a new Dissolution test with tighter tolerances at certain time points.

2. How will USP address a request to revise an official Dissolution test to permit the use of a sinker?

   If the only difference between an existing test and the proposed new test is the use of a sinker, USP will add "use suitable sinkers if needed" (or a description of a specific or an unusual type of sinkers) to an existing Dissolution test.

3. When will USP add a description of Tier 2 Medium (to overcome cross-linking)?

   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 enzyme, or a different amount of the enzyme than described in the Chapter. USP may also add a description of Tier 2 for a Medium containing surfactant or other ingredients known to denature the enzyme.

   If a dissolution test already contains description of the Medium for Tier 2 as described above, the following statement will 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?

   USP will not include additional Dissolution tests if the conditions and tolerances are the same as in existing Dissolution test(s). Please see *General Notices* 6.30. Alternative and Harmonized Methods and Procedures for additional information about alternative analytical procedures.