

[Drug Dissolution Testing Guidance Documents](#) (Accessed July 10, 2010)

1. Guidance for Industry: Dissolution Testing of Immediate Release Solid Oral Dosage Forms. **August 1997.** ([Link](#)).
2. Guidance for Industry: Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations. **September 1997.** ([Link](#)).
3. Guidance for Industry: Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System. **August 2000.** ([Link](#)).
4. Guidance for Industry: Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions. Annex 7 Dissolution Test General Chapter. **April 2010** ([Link](#))
5. Guidance for Industry: Q8(R2) Pharmaceutical Development. **November 2009** ([Link](#)).
6. Guidance for Industry: Immediate Release Solid Oral Dosage Forms Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls, *In Vitro* Dissolution Testing, and *In Vivo* Bioequivalence Documentation. **November 1995.** ([Link](#)).
7. Guidance for Industry: SUPAC-MR: Modified Release Solid Oral Dosage Forms Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; *In Vitro* Dissolution Testing and *In Vivo* Bioequivalence Documentation. **September 1997.** ([Link](#)).
8. ICH Topic Q 6 A: Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances. **May 2000.** ([Link](#)).
9. ICH Harmonised Tripartite Guideline: Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Dissolution Test General Chapter Q4b Annex 7. October 2009. ([Link](#)).
10. Mechanical Qualification of Dissolution Apparatus 1 and 2. June 2006. ([Link](#)).
11. Guidance for Industry: The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2 – Current Good Manufacturing Practice (CGMP). Jan 2010. ([Link](#)).
12. Dissolution Toolkit: Procedures for Mechanical Calibration and Performance Verification Test Apparatus 1 and Apparatus 2. March 2010. ([Link](#)).