

Selection of Dissolution Medium for QC Testing of Drug Products

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Selection of the dissolution medium to be used for quality control dissolution testing is the most critical part of dissolution method development. The analytical target profile (ATP) and drug substance solubility are key factors in dissolution medium selection. The ATP should indicate the type of dosage form for which the test is being developed. Drug substance solubility should be characterized over the physiological range of pH values. Soluble drugs exhibit good solubility across the physiological pH range (e.g., sink conditions at pH 1.2, 4.5, and 6.8 or BCS Class I/III). Drugs with pH-dependent...

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