



## Preliminary BCS Drug Product Dissolution Determination

This assay is used to determine the preliminary BCS drug product dissolution characteristics of a test article in aqueous media under physiological pH conditions.

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| <b>Required from Customer</b> | <ul style="list-style-type: none"><li>• Highest human dose strength.</li><li>• Minimum 5g of test compound in powder form and an appropriate number of final dosage forms.</li><li>• Any available solubility and stability data of test compound</li><li>• Molecular mass (exact mass) of test compound and its salt form</li><li>• MSDS or handling and storage information, e.g., store at <math>-20^{\circ}\text{C}</math>, light-sensitive, Certificate of Analysis, etc.</li></ul>   |
| <b>Deliverables</b>           | <ul style="list-style-type: none"><li>•</li></ul>  |
| <b>Assay System</b>           | <ul style="list-style-type: none"><li>• Dissolution testing is carried out in either USP Apparatus I at 100 rpm or Apparatus II at 50 rpm using 900 ml of the following dissolution media:<ul style="list-style-type: none"><li>○ 0.1 N HCl or Simulated Gastric Fluid USP without enzymes</li><li>○ pH 4.5 buffer</li><li>○ pH 6.8 buffer or Simulated Intestinal Fluid USP without enzymes.</li></ul></li><li>• For capsules and tablets with gelatin coating, Simulated Gastric and Intestinal Fluids USP (with enzymes) can be used.</li></ul>   |
| <b>Assay Condition</b>        | <ul style="list-style-type: none"><li>• A minimum of 12 dosage units of a drug product will be evaluated.</li><li>• Samples are collected at a sufficient number of intervals to characterize the dissolution profile of the drug product (e.g., 10, 15, 20, and 30 minutes)</li><li>• Concentration of the drug substance will be determined using a validated assay.</li></ul>   |
| <b>Data Analysis</b>          | <ul style="list-style-type: none"><li>• The percentage of labeled claim dissolved at each specified testing interval reported for each individual dosage unit.</li><li>• The mean percent dissolved, range (highest and lowest) of dissolution, and coefficient of variation (relative standard deviation).</li><li>• A graphic representation of the mean dissolution profiles for the test and reference products in the three media.</li><li>• When comparing a test and reference product, similarity in dissolution profiles in each of the three media will be assessed using the f2 metric. If both products dissolve 85% or more of the label amount in <math>\leq 15</math> min in all dissolution media, the f2 metric is not performed.</li></ul> |
| <b>Quality Control</b>        | <ul style="list-style-type: none"><li>• QC review of raw and processed data</li><li>• In-study inspection and post-study audit of data and report by QA</li></ul>  |