



GLP BCS Drug Product Dissolution Determination

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

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| Required from Customer | <ul style="list-style-type: none">• A study design defining all study aspects documented in a sponsor approved study protocol.• Highest human dose strength.• Minimum 5g of test compound in powder form and an appropriate number for final dosage forms.• MSDS or handling and storage information, e.g., store at -20°C, light-sensitive, etc. |
| Deliverables | <ul style="list-style-type: none">• Method validation and study report including QA statement and GLP compliance statement. |
| Assay System | <ul style="list-style-type: none">• 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">○ 0.1 N HCl or Simulated Gastric Fluid USP without enzymes○ pH 4.5 buffer○ pH 6.8 buffer or Simulated Intestinal Fluid USP without enzymes.• For capsules and tablets with gelatin coating, Simulated Gastric and Intestinal Fluids USP (with enzymes) can be used. |
| Assay Condition | <ul style="list-style-type: none">• A minimum of 12 dosage units of a drug product will be evaluated.• 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)• Concentration of the drug substance will be determined using a validated stability-indicating assay that can distinguish the drug substance from its degradation products. |
| Data Analysis | <ul style="list-style-type: none">• The percentage of labeled claim dissolved at each specified testing interval reported for each individual dosage unit.• The mean percent dissolved, range (highest and lowest) of dissolution, and coefficient of variation (relative standard deviation).• A graphic representation of the mean dissolution profiles for the test and reference products in the three media.• 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 ≤ 15 min in all dissolution media, the f2 metric is not performed. |
| Quality Control | <ul style="list-style-type: none">• QC review of raw and processed data• In-study inspection and post-study audit of data and report by QA |