Discovery BCS Solubility Determination

This assay is used to determine the solubility characteristics of a test article in aqueous media under physiological pH conditions.

Required from Customer	• A study design defining all study aspects documented in a sponsor approved study protocol. • Highest human dose strength. • Minimum 10g of test compound in powder form (can vary based on available solubility information). • MSDS or handling and storage information, e.g., store at –20 ºC, light-sensitive, Certificate of Analysis, etc.
Deliverables	• The pH-solubility profile of the test article at 37 ± 1°C in aqueous media with a pH in the range of 1-7.5. • Stability of test article under the experimental conditions used for the solubility determinations.
Substrate	• Excess amount of test article added to the respective buffer solutions.
Assay System	• Solubility determinations will be conducted using the shake-flask method, or other appropriate methods such as acid or base titration methods.
Assay Condition	• The number of pH conditions tested are based on the ionization characteristics of the test drug substance. For example, when the pKa of a drug is in the range of 3-5, solubility will be determined at pH = pKa, pH = pKa +1, pH = pKa-1, and at pH = 1 and 7.5. A minimum of three replicate determinations of solubility in each pH condition will be tested. • Concentration of the drug substance will be determined using an appropriate stability-indicating analytical method. • The solubility class will be determined by calculating the volume of an aqueous medium sufficient to dissolve the highest dose strength in the pH range of 1-7.5.
Data Analysis	• A drug substance will be classified as highly soluble when the highest dose strength is soluble in < 250 ml of aqueous media over the pH range of 1-7.5.
Quality Control	• QC review of raw and processed data