

This assay is used to determine the solubility 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 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°C, light-sensitive) Certificate of Analysis, etc. |
| Deliverables | <ul style="list-style-type: none">• The pH-solubility profile of the test article at $37 \pm 1^{\circ}\text{C}$ 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.• Study report including QA statement. |
| Substrate | <ul style="list-style-type: none">• Excess amount of test article added to the respective buffer solutions. |
| Assay System | <ul style="list-style-type: none">• Solubility determinations will be conducted using the shake-flask method, or other appropriate methods such as acid or base titration methods. |
| Assay Condition | <ul style="list-style-type: none">• 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 $\text{pH} = \text{pKa}$, $\text{pH} = \text{pKa} + 1$, $\text{pH} = \text{pKa} - 1$, and at $\text{pH} = 1$ 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 a validated stability-indicating assay that can distinguish the drug substance from its degradation products.• 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 | <ul style="list-style-type: none">• 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 | <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 |