

Food Studies

Alcami's scientists have substantial experience designing and executing food studies that comply with the highest quality standards, which have expedited formulation selection and regulatory approval for a variety of pharmaceutical dosage forms.

Why are Food Studies needed?

Alternate methods of administering solid oral formulations are necessary to meet the needs of all patients. Geriatric, pediatric, and patients suffering from gastroesophageal reflux disease are often administered pharmaceuticals mixed with food or liquids due to difficulty swallowing tablets or capsules. For immediate release, enteric coated, modified release, or extended release dosage forms, a Food Study is required to evaluate whether the alternate route of administration impacts the therapeutic dose.

THE FDA-2018-D-2544 GUIDANCE STATES:

- "In the absence of availability of a dosage form that is appropriate for the targeted patient population (e.g., pediatric, geriatric), small amounts of liquids and/or soft foods as described in the FDA-approved product labeling can be used as a suitable vehicle for oral administration and immediate ingestion of the specific drug product."
- Proper analytical studies are required to include alternative methods of administration.

What are the requirements for Food Studies?

Effective, compliant Food Study design must include:

- An understanding of the chemical characteristics of the active and excipient components, as well as the foods and drinks to be evaluated

- An evaluation of drug functionality, after exposure, compared to a control
- An evaluation of the stability of the product in the food or drink being evaluated
- Complex analytical methodology effective for a wide variety of matrices

For solid formulations that may be administered by sprinkling the drug product on a liquid or soft food vehicle, the FDA requires food studies on any foods intended to be listed on the drug product. The guidance strongly recommends scientifically rigorous, in vitro manipulation and extraction studies be performed to evaluate the effect of any indicated foods on the therapeutic dose. Alcami has experience designing in vitro studies that meet FDA requirements, which include the following:

- Integrity (e.g. testing changes in polymorphic form via XRPD and loss of bead integrity via dissolution)
- Potency (assay)
- Stability
- Homogeneity (dose uniformity)
- Additional dissolution/drug release testing



*by Amanda Connor
Senior Supervisor of Pharmaceutical Development
Food Studies SME*



Why partner with Alcami for Food Studies?

Alcami is an experienced partner for performing food studies using a variety of dosage forms, including tablets, capsules and suspensions. Our teams have designed and executed many successful studies to home administration by using foods and drinks such as orange juice, apple sauce, infant formula, yogurt, and smoothies. Our experience with these studies enables us to provide our customers with expedited timing from study design through execution, and issuance of the final report.

ALCAMI HAS THE CAPABILITIES AND EXPERTISE NEEDED FOR EFFECTIVE, COMPLIANT FOOD STUDIES:

- Onsite XRPD capabilities for integrity testing
- Experience developing and modifying analytical methods for use in food studies with various dosage forms
- Scientific expertise to aid in the selections of foods/drinks for regulatory acceptance and technical success
- Experience interpreting the general guidance to design Food Studies for FDA filed & approved products
- Exemplary record of cGMP compliance with robust quality systems
- Experienced Project Management team which ensures scope and timelines are communicated and achieved
- Reputation for responsiveness, problem solving, and reliability
- Range of complementary development and manufacturing services capable of supporting full product development

