

Product Development (R&D), Analytical, and Consultant Services



The Campbell University Pharmaceutical Sciences Institute (CUPSI), which operates in the Pharmacy Research Facility, is currently equipped to aid pharmaceutical companies by increasing their effectiveness in providing timely and accurate product development (capsules, tablet-to-capsule conversions, oral solutions, etc.), analytical (cGMP compliant), and consultant services.

We offer a level of flexibility, customization, and direct communications unequaled in the service industry. By focusing on partnership and relation-building activities, CUPSI seeks to anticipate the client's needs and ensure that customer awareness is a major concern.

Quality Control Testing

- Dissolution testing and evaluation for instant or sustained release finished products
- High Performance Liquid Chromatographic (HPLC) for finished products or APIs
- Spectroscopic (UV/Vis) testing for finished products and APIs
- Thin-Layer Chromatographic testing and evaluation for finished products and APIs
- Specific USP testing of APIs, excipients, and finished materials

Stability Studies

- Complete formal stability studies for APIs and finished products
- Informal R&D preliminary studies
- Storage and monitoring of stability studies with qualified and controlled chambers with alarms

De-formulation Services

- Profile an innovator product through in-house and outside analytical resources to develop a generic equivalent
- Search for a formulation that matches the innovator preparation

Pre-formulation Services

- Research required to enhance the development of a stable product by testing the compatibility of API with different excipients
- Using small-scale research methods to examine factors that may contribute to the chemical and physical stability of the product

Formulation Development

- Develop a generic formulation that can match the innovator product in analytical testing attributes (e.g., content uniformity and dissolution)
- Consideration of factors essential for translation of development scale to production scale formulations

Formulation Scale-up Services

- Generate a validated methods package from material produced on small scale production equipment
- Ensure that all steps are considered to allow the production or manufacturing of the developed formulation

Other Services

- Draft analytical methods and other documents that meet cGMP requirements
- Draft Standard Operation Procedures (SOPs) to meet cGMP and client demands
- Draft Stability Protocols as required to meet stability requirements and cGMP guidelines
- Provide consultant services for analytical and R&D to support testing and innovator product development for new chemical entities and other finished products
- Expertise in pharmacology, pharmaceuticals, pharmacokinetics, and biostatistics is also available
- Network of related companies to allow subcontracting of testing or evaluation as required and approved