

Clinical Research & Development

Analytical Services & Formulation Development

Bilcare provides innovative solutions for all of your processing needs. Our dedicated personnel provide technical support during each phase of your product's development and manufacturing. GMP qualified scientists oversee comprehensive development and testing of your materials. We take extra steps to ensure that your products comply with international regulatory standards.

Formulation Development

The Bilcare Team of experienced formulation specialists is always ready to provide you with high-speed throughput of innovative formulations for clinical trials. Our broad range of formulation development services includes:

Pre-Formulation

- + Physical properties
- + Product characterization
- + Chemical compatibility and reactivity to packaging substrates
- + Accelerated degradation
- + Excipient compatibility studies

Formulation Development

- + Clinical supplies manufacturing
- + Blending and encapsulation
- + Over-encapsulation and blinding
- + Phase I-IV development and reformulations
- + Placebo manufacturing/comparator supplies
- + Develop both ethical and over-the-counter products: tablets (normal and controlled release), powders, liquids, suspensions, emulsions, creams and ointments, lotions
- + Develop line extensions in the above dosage forms

Technical Services

- + Provide experienced professionals to troubleshoot commercial products
- + Evaluate new raw materials in existing products
- + Transfer of products from research to production facilities
- + Assess current products and recommend improvements to modernize existing manufacturing processes

Analytical Research

Bilcare provides the best solutions for every stage of your product development. Our comprehensive package of analytical services for the drug, as well as the packaging materials, components and systems include:

- + Accelerated drug stressing
- + Chromatographic impurity profiling
- + Cleaning validations for manufacturing equipment
- + Dissolution profile testing
- + Extractable studies for parenteral products
- + Competitor analysis for unbiased de-formulation
- + Hygroscopicity studies
- + Method development and validation for all phases and all components in development of drug substance, non-compendial excipients and drug product
- + Process development support
- + Release testing
- + Reference standard qualification testing
- + Stability study protocol design (ICH and custom)
- + Mapped environmental chambers including 25°C/60% RH, 30°C/65% RH, 40°C/75% RH, 25°C/40% RH, 40°C/25% RH, 5°C, and photo stability

Our quality process demands that all R&D documentation is reviewed and approved by our quality team.

Controlled Substance Management

Bilcare is registered with the DEA as a Manufacturer, Distributor, Exporter, Importer and Analytical Laboratory of Controlled Substances.