



## High-Potency and Cytotoxic Products

Selecting the best oral dosage form for high-potency and cytotoxic therapies is a complex decision that impacts your product's efficacy, safety, manufacturing costs and market-value. Encap has 20 years' experience with global new product development and life-cycle management programmes. We understand the problems and can help provide the solutions.

Our liquid-fill two-piece capsule technology is proven to overcome the most difficult of challenges in formulation development and manufacturing of high-potency and cytotoxic products. These drug substances require specialised delivery technologies, containment facilities, together with, scientific and manufacturing expertise for successful commercialisation. At Encap, we have all the resources, capability and know-how for the development and manufacture of high-potency and cytotoxic products. This is why the pharmaceutical industry selects Encap as its outsourcing partner-of-choice.

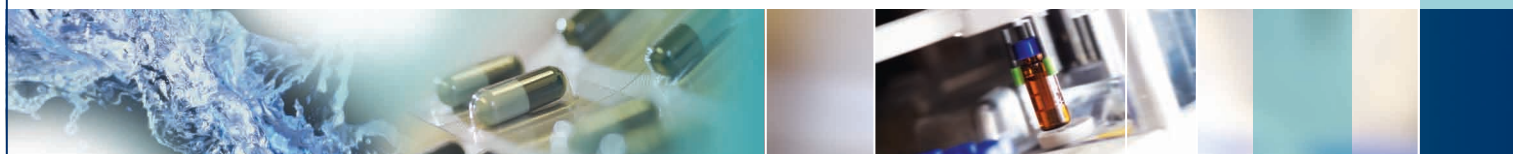
### Liquid-Fill Two-Piece Capsules

- Accelerated formulation development
- High dosage precision & homogeneity
- Optimised use of valuable API
- Minimised contamination risks
- Employee & environmental safety

Encap is committed to providing our Clients with high-quality commercial manufacturing services. Our new High-Containment Facility is exclusively designed with a dedicated high-potency and cytotoxic focus. The modern 14,500 ft<sup>2</sup> Facility offers integrated development and manufacturing services that will be fully-operational by June 2008. The combination of Encap's resources, quality systems and capacity ensures reliable delivery of your product to meet rigorous regulatory and market demands.

### Encap's High-Containment Facility

- Cleanrooms designed to meet EU Grade C & US Class 100,000
- Leading barrier-isolator technology for dispensing & mixing operations
- HVAC optimised environment
- Single-pass HEPA air filtration
- Pilot to commercial cGMP manufacture



## Encap is an international drug delivery solutions provider

We are a global leader in encapsulation solutions and a centre of excellence in liquid-fill two-piece capsules.

Talk to us, to understand how our innovative drug delivery technologies, specialised facilities and know-how can add-value to new product development and life-cycle management programmes.

### Oral Drug Delivery

- Liquid-fill two-piece capsules
- DuoCap
- Abusolve™
- LayerCap™
- Enteric coating technologies
- Controlled & multi-phase release

### Expert Consultancy

### Project Management

### Pre-formulation

- API & material characterisation
- pH-solubility profile
- Solution & solid-state stability
- API & excipient compatibility

### Pharmaceutical Analysis

- Analytical method transfer
- Method development, optimisation & validation
- Dosage unit analysis
- Dissolution evaluation
- Stability testing
- Microbiological monitoring

### Product Development

- Formulation design & optimisation
- Prototype formulations for fast-into-man
- Product characterisation
- Process development
- Global Phase I-III clinical supplies
- Phase III scale-up, validation & technology transfer
- Stability testing
- International registration support

### Commercial Manufacturing

- Liquid, semi-solid & powder-fill two-piece capsules
- Prescription, over-the-counter medicines & high-value nutraceuticals
- Branded & generic products
- High-potency & cytotoxics
- Product packaging
- Batch release & product stability

To receive more information on Encap's services, please contact:

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partner with the experts

