

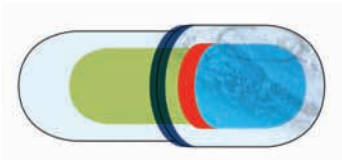


## DuoCap for Controlled Release Combination Products

Over recent years, controlled release combination products have become increasingly popular within the pharmaceutical industry. A number of products have reached global markets and several high-profile brands have generated considerable revenues. Controlled release combination products present complex challenges to formulators and manufacturers such as physico-chemical and biological compatibility, process scale-up and packaging. An ideal solution is Encap’s DuoCap delivery system.

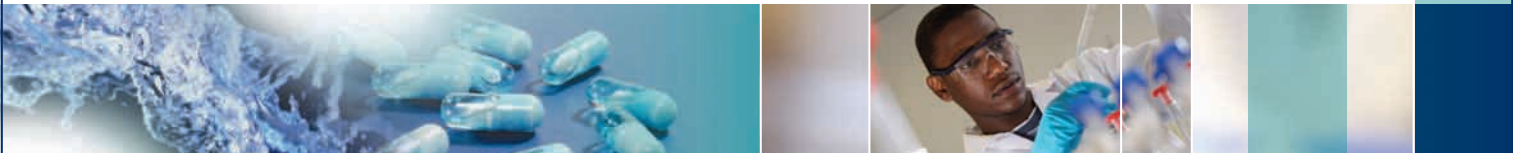
At Encap, we have 20 years’ experience with global new product development and life-cycle management programmes. Based on our liquid-fill two-piece capsule technology, DuoCap is a single oral dosage unit that comprises a “capsule-in-a-capsule.” Patent protected, DuoCap provides controlled and multi-phase release for single or combination prescription and over-the-counter medicines.

### Encap’s DuoCap Delivery System



- Two independent compartments in one dosage unit
- Inner capsule contains liquid, semi-solid or powder formulation
- Outer capsule contains liquid or semi-solid formulation
- Drug delivery targeted to two different regions of GI tract
- Sustained, pulsed or delayed release profiles

Advantages of DuoCap Delivery System	
Controlled & multi-phase release	Delivery of incompatible APIs
Single oral dosage unit	Broad therapeutic applications
Novel formulation combinations	Patent protected line extensions
Pilot to commercial manufacture	Reduced-time-to-market
Patient convenience & compliance	Simplified drug regimen
Cost-effective therapy	Brand differentiation



## Innovative Solutions - World Class Services

Encap Drug Delivery, the World Leaders in Liquid Filled Capsules, offers a complete range of services to support pharmaceutical product development, drug delivery and manufacturing.

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
- ENCODE™ (Encap Colonic Delivery Technologies)
- Controlled and multi-phase release

### Expert CMC Consultancy

### Project Management

### Pre-formulation and Formulation Development

- API and material characterisation
- pH-solubility profile
- Solution and solid-state stability
- API / Excipient compatibility studies
- API / Shell compatibility studies
- Prototype formulations for early safety studies
- Prototype formulation for early clinical studies
- Probe stability studies

### Pharmaceutical Analysis

- Analytical method transfer
- Method development, optimisation and validation
- Cleaning method development
- Dosage unit analysis
- Dissolution evaluation
- Stability services
- Microbiological monitoring

### Clinical Development and Manufacturing

- Formulation design and optimisation
- Fast Track to Man clinical supplies
- Product characterisation
- Process development
- Global Phase I-III clinical supplies
- Phase III scale-up, validation and technology transfer
- Stability testing
- International registration support

### Commercial Manufacturing

- Largest commercial manufacturer of pharmaceutical liquid filled hard capsules
- Approved by FDA and MHRA
- Prescription, over-the-counter medicines and high-value nutraceuticals
- Branded and generic products
- High-potency and cytotoxics
- Product packaging
- QP Batch release and product stability
- Capsule coating

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

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