



NEW OPTIGEL BIO™ TECHNOLOGY

Innovative oral macromolecule delivery with RP Scherer Softgel technology

Catalent continues its legacy of innovation with OptiGel Bio™ technology—expanding the versatility of softgel technology to enable the potential oral delivery of macromolecule therapies.

Preferred by innovators, healthcare professionals and patients, oral dosing offers numerous advantages over intravenous (IV) therapy, including:

CONVENIENCE & ADHERENCE Self-administration and painless dosing

DOSING FLEXIBILITY Access to frequent dosing to maintain or extend therapeutic efficacy

COSTS Lower manufacturing and treatment costs, and a more efficient clinical path

Macromolecular Formulation Challenges

Macromolecule therapies have traditionally been limited to injectable and infused dose forms due to a number of challenges that limit their bioavailability including:

- Absorption due to rigid molecular geometry and flexibility
- Permeation limitations with tight junctions and limited transcellular pathways
- Proteolytic enzymes of the stomach and lumen
- Harsh acidic gastric conditions

Innovative Oral Macromolecule Delivery Technology

With its lipid-based drug delivery system, OptiGel Bio™ technology provides a versatile solution to the development challenges traditionally associated with the oral delivery of macromolecules.

With targeted delivery, enhanced permeation and improved absorption, OptiGel Bio™ technology enables an optimal oral formulation while maintaining an effective PK profile.



DEVELOPMENT



DELIVERY



SUPPLY

Targeted Delivery, Better Absorption

OptiGel Bio™ technology incorporates enteric coating and permeation enhancers to first deliver active macromolecules to the absorption site and then pass through the absorption site to enter circulation.

TARGETED DELIVERY	ENTERIC COATING	Delivery of active macromolecule to absorption sites critical to achieve therapeutic levels Protection from degradation in harsh gastric environment
ABSORPTION & PERMEABILITY	CHEMICAL MODIFICATIONS	Modifications to API can improve absorption in the small intestine
	PERMEATION ENHANCERS	Incorporation of a wide variety of permeation enhancers in formulation improves transport through the tight junctions of the lumen

Expert Capabilities, Integrated Services

Deep Development Expertise As the global leader in drug development solutions and advanced delivery technologies, we can help you bring your macromolecule therapy to market faster and improve its total value. Our expert development services include:

- Pre-formulation and feasibility studies
- Solubility screening of new chemical entities (NCEs)
- Fill formulation and shell development
- Small-scale lab encapsulation for early stability data and final formulation selection
- Extensive technical support in softgel capsule product development

Global, Reliable Supply Our proven track record of quality and consistency ensures confidence in the reliable supply of your products through:

- Rigorous cGMP, EHS, security and operational controls across entire network
- Long-standing partnerships and transparent scorecards with top innovators for 80+ years
- One global QMS, extensive supplier assurance and world-class inspection readiness
- Global inspection outcomes 2x better than industry average from all relevant agencies

We can improve the total value of your treatments with OptiGel Bio™ technology for challenging macromolecules.

more products.
better treatments.
reliably supplied.™

Discover more solutions at www.catalent.com

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