

THE MEDINGEL™ DELIVERY PLATFORM

- Controlled-release of peptides & small molecules
- Release duration ranging from days to months
- Efficient use of API cargo to minimize burst
- Ideal for emerging markets with low cost of goods

FLEXIBLE POLYMER TECHNOLOGY

Our MedinGel technology is a proprietary combination of block copolymers that are dissolved in a wide range of excipients. MedinGel is stored in a liquid state, but phase separates after subcutaneous injection to form a semi-solid depot. Hydrolytic biodegradation mediates release of the APIs throughout the 3-D network.

By varying the characteristics of the PEG and PLA components, we can significantly alter the release profile and duration of your API. This flexibility also enables broad compatibility with peptides and small molecules.

INJECTABLE, LONG-ACTING DELIVERY

MedinGel formulations are designed to protect peptides or small molecules during the course of their subcutaneous release. Many formulations can be custom designed with durations of days, weeks, or months—all using the same technology!

REDUCE C_{MAX} (BURST)

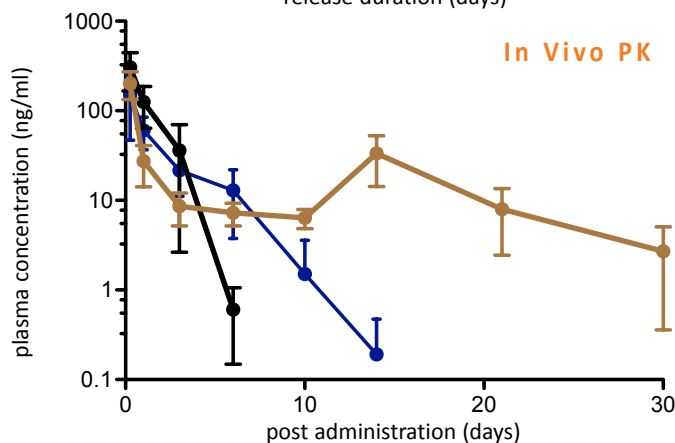
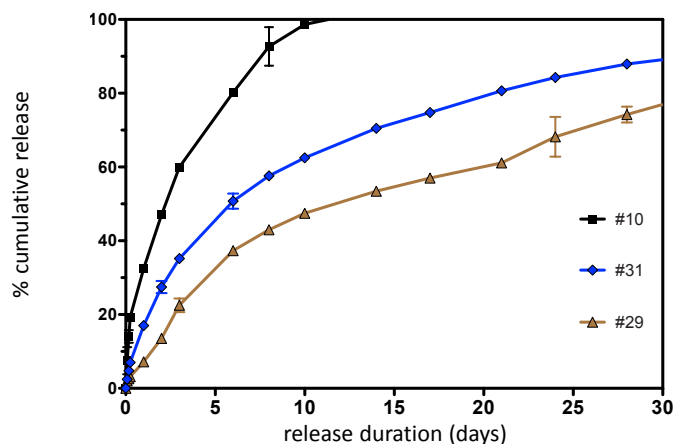
By designing controlled-release formulations that deliver steady release rates, MedinGel can reduce off-target effects to improve patient safety, compliance and administration costs.

API CONSERVATION SAVES COSTS

MedinGel's subcutaneous formulations can lead to substantial reductions in API requirements. This translates into lower production costs and reduces environmental impact.

FORMULATION EXAMPLE: RISPERIDONE

In Vitro Release



MedinGel formulations are prepared to target a specified delivery duration, and are optimized through iterative rounds of in vitro release (IVR) and PK experiments. Drug release is measured over time as the IVR medium is refreshed. Release kinetics obtained in this way typically reflect the in vivo environment. The magnitude of the difference between in vitro and in vivo release will depend upon the drug and its in vivo metabolism.

The 2-week data shown above is for three formulations of Risperidone, a small molecule treatment for schizophrenia. Candidate 10 (black) is a 1 week formulation, Candidate 31 (blue) has a 2 week duration target, and Candidate 29 (brown) is a 2 month candidate. We expect the final products to have substantial benefits over other commercial long-acting therapies in the schizophrenia market, such as reduced pain of administration (SC instead of IM injection), steadier release rate, and multiple duration options.



RAPID FORMULATION DEVELOPMENT

MedinCell offers speed where it counts; we have delivered formulations for 3-month pre-clinical evaluations within a 1 year Proof of Concept.



IMPROVING PEPTIDE DRUG FEASIBILITY

MedinCell is dedicated to helping biotech and pharmaceutical companies realize the promise of therapeutic peptides by overcoming half-life and manufacturing challenges. With a single, low-cost administration, MedinGel can protect peptide APIs for release durations up to 3 months.



ENHANCING SAFETY

MedinGel formulations have been tested in a wide range of small and large animals—without signs of local or systemic toxicity. With its dose-sparing nature, we expect MedinGel to minimize both burst-related reactions (i.e. nausea) and long-term toxic effects when compared to more frequent doses at higher drug concentrations.

Additionally, in the event of an adverse reaction to an API, the MedinGel depot can be surgically excised. This safety feature is not feasible with IV or IM routes, and eases administration concerns for clinicians.

STRATEGIC DIFFERENTIATION

Reformulation with MedinGel enables you to design complementary long-acting products with low up-front costs, making it ideal for:

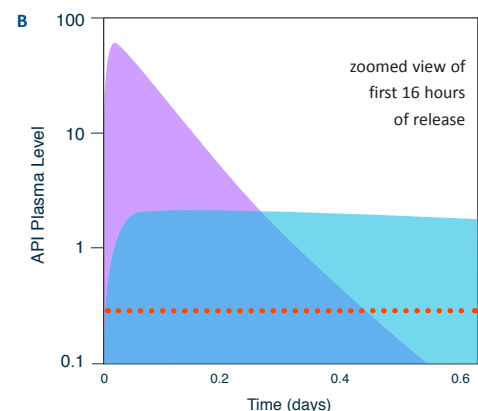
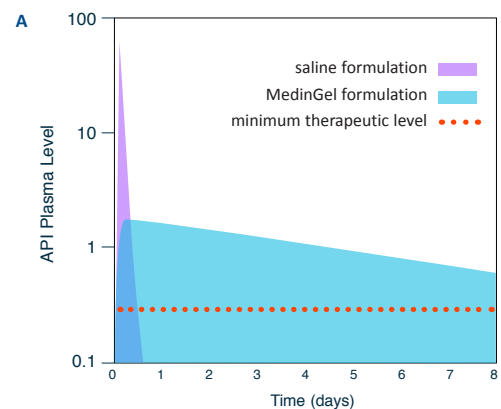
- Designing best-in-class NCE products
- Strategic improvements for product lifespan
- Competitive generics for emerging markets



We start each project with a complimentary *in silico* review of your APIs to assess compatibility with the MedinGel system. Then we establish extended-release product specifications and map out a Proof of Concept study to achieve these goals. By iterating between *in vitro* and *in vivo* release studies, plus injectability and stability validation, we can optimize lead formulations for your pre-clinical studies.

DOSE-SPARING PHARMACOKINETICS

In the graphs below, two small molecule formulations are compared. The MedinGel formulation exceeds the therapeutic threshold for 8 days, compared to 0.5 days for a marketed saline version (A). The MedinGel release peaks at 1/25 of the C_{max} of the saline formulation (B), which we expect will reduce burst-related side effects. Over the 8-day duration, MedinGel demonstrated twice the saline formulation AUC—using the same amount of drug. We expect these benefits to translate into a substantial reduction in materials and administration costs of the final product.



MedinCell S.A.
Cap Alpha
Avenue de l'Europe
34830 Clapiers, France
Tel: +33 467 419 974

MedinCell Corporation
10451 Roselle St., Suite 200
San Diego CA 92121 USA
Main: (858) 216-4573