Quotient Sciences

Molecule to cure. Fast.™

Modified-Release Formulation Strategies

The popularity of modified-release (MR) dosage forms continues to rise due to the many therapeutic benefits that they offer for both drug developers and patients. Oral MR formulations are designed to control the rate and/or location of drug release in the gastrointestinal (GI) tract. In contrast to immediate-release (IR) formulations, MR dosage forms can offer:

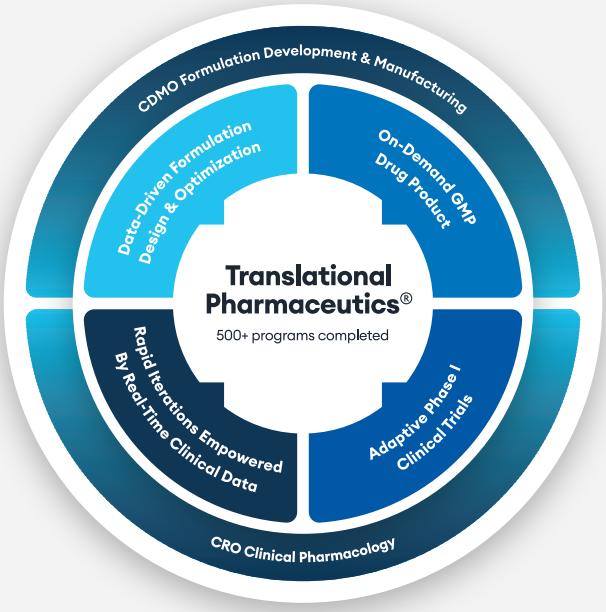
- ✓ Maintenance of drug plasma concentrations over a prolonged period to reduce dosing frequency
- ✓ Attenuation of drug peak-to-trough ratios to reduce peak-related adverse events (AEs) and improve efficacy
- ✓ Drug delivery to targeted regions of the GI tract for localized treatment

Although MR formulations offer many therapeutic benefits, there are many challenges to overcome when trying to develop this type of formulation. Our services span the entire development pathway, from candidate development through to commercialization, reducing development risks and simplifying the supply chain for our customers.

By taking a unique, integrated approach that is tailored to each program, we provide optimal results for our customers in the most efficient and cost-effective manner, getting new medicines to patients faster.

Extensive expertise brought to every program

At Quotient Sciences, we recognize that careful selection of appropriate delivery technologies is key to the design of successful MR formulations. We have extensive experience in using a wide variety of formulation technologies, having supported hundreds of modified-release formulations over the last three decades. Coupled with our agile and flexible approach to clinical and commercial manufacturing, this makes us the ideal partner to provide an end-to-end solution for the development of MR drug products.



Our unique, integrated approach to accelerate the development of modified-release dosage forms

Our unique Translational Pharmaceutics® platform integrates drug product development, real-time adaptive GMP manufacturing, and clinical testing. Flexible study protocols and rapid 'make-test' cycles enable optimization of MR formulations in real time based on arising clinical data.

As part of regulatory submissions, we obtain approval to make formulation adjustments within a mapped design space which is usually a 2-dimensional design space with ability to vary the dose and release rate for MR formulations.

This means that any formulation within certain defined parameters can be rapidly made and tested to determine the impact of the drug release rate on the pharmacokinetic (PK) profile, enabling us to efficiently identify the optimal formulation.

This reduces development risks, maximizes the probability of clinical success, and saves time and costs.

MR format	Objective	Formulation technology
Gastro-retention	› Keep the formulation in the stomach for an extended period to maximize the duration of absorption or therapeutic activity	Solutions
Gastro-resistant	› Prevent release of the drug in the stomach and/or upper GI tract › Overcome first-pass metabolism or gastric irritation	Minitablets
Sustained or extended release	› Extend the in-vivo release profile of the drug or enable once-daily dosing	Powders and granules for reconstitution
Targeted or controlled delivery	› Release the drug at or near the intended site of absorption or action › Have either IR or extended-release characteristics › Deliver time-, pH-, or microbially-triggered release	Minitablets
Biphasic release	› Eliminate the need for repeat dosing › Provide rapid therapeutic effect from an IR layer and extended dosing from a sustained-release layer	Suspensions
Pulsatile release	› Release the drug as a pulse after a pre-determined lag time, designed according to the body's circadian rhythm › Provide a release mechanism beneficial for drugs where timedependent dosing is required or those that undergo first-pass metabolism	Minitablets

For a list of our locations visit:
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I0019-062025