ORAL MODIFIED RELEASE

Oral modified release drug delivery

Oral modified release (MR) drug delivery systems are developed to control the rate and/or the site of release of drugs in order to obtain the maximum therapeutic effect, ensure minimal side effects and improve patient compliance. These formulations are a versatile tool that can be adapted to different active pharmaceutical ingredients (APIs) and indications to get the most out of new and existing products.

At Recipharm, we have the expertise and equipment needed to develop, scale-up and manufacture oral MR products efficiently and reduce project complexity.

Main benefits of oral MR

- Prolonged release:
  - Longer therapeutic duration compared with conventional tablets, meaning less frequent dosing for the patient. This Once-a-Day (OD) treatment instead of twice-a-day (BD) increases convenience and compliance
  - Attenuation of side effects by obtaining flatter plasma concentrations. Meaning that peaks, which are often associated with side effects, are reduced
  - Oral MR technology can often improve the performance of APIs with a half-life that is shorter than desired and/or ensure delivery at the right site for optimal absorption
- Delayed release:
  - Drug release can be delayed until the dosage form has passed the stomach and has reached the gut
  - Protection of acid sensitive drugs can be achieved
  - Avoid excessive gastric irritation
- Oral MR technology is often well suited for repositioning existing APIs, a life cycle management opportunity
- Coated pellet technology offers the possibility to combine several drugs with different release patterns into one dosage form, Fixed Dose Combination (FDC)

Recipharm

Our dedicated team offers pharmaceutical companies an end-to-end service from early stage development through to commercial manufacture for MR products. Our areas of expertise include:

- Experience in developing and manufacturing coated pellets, as well as gel matrix tablets
- From lab scale to manufacturing supply, several Recipharm facilities are involved in the development of coated pellets, using fluid bed coating. Recipharm also offers commercial manufacturing of bulk coated pellets
- Aqueous films as well as organic solvent-based coatings can be applied. Manufacturing can be performed in controlled air humidity
- Experience in developing sophisticated products with several pellet and tablet components (FDC)
- A complete development package, comprising of formulation development, analytical method development and validation, manufacture of clinical trial material (CTM), stability studies and scale-up into commercial production
- Clinical trials can be arranged through a partner company
- The pharmaceutical quality is ensured by understanding and controlling formulation and process variables, by using Quality by Design (QbD) approaches as well as Design of Experiment (DoE) methods
- Seamless and smooth technology transfer capabilities

About Recipharm: Recipharm is a leading contract development and manufacturing organisation (CDMO) headquartered in Stockholm, Sweden. We operate development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden, the UK and the US and are continuing to grow and expand our offering for our customers.

Employing around 9,000 people, we are focused on supporting pharmaceutical companies with our full service offering, taking products from early development through to commercial production. For over 25 years we have been there for our clients throughout the entire product lifecycle, providing pharmaceutical expertise and managing complexity, time and time again. Despite our growing global footprint, we conduct our business as we always have and continue to deliver value for money with each customer's needs firmly at the heart of all that we do. That's the Recipharm way.

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