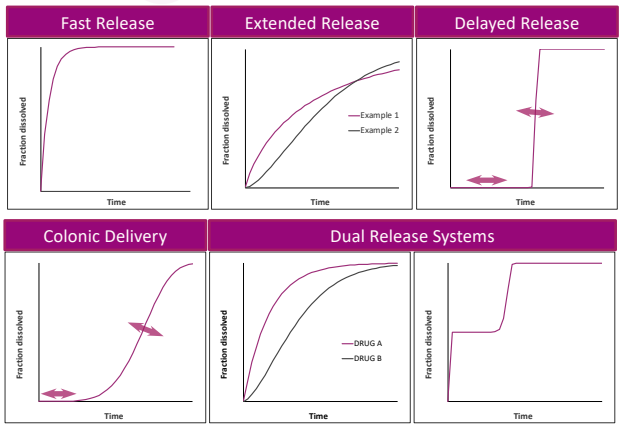
PENSATECH PHARMA

Your Partner for Innovative Drug Delivery Solutions

Oral Modified Release Drug Delivery

Introduction

Oral dosage forms are the predominant delivery system due to ease of use and patient acceptability. Modified release systems are being used to circumvent gastric degradation, improve pharmacokinetics, reduce dosing frequency or adverse drug reactions as well as to enable oral dosing for drugs with a very short biologic half-life or achieve additional clinical benefits e.g., new indications.

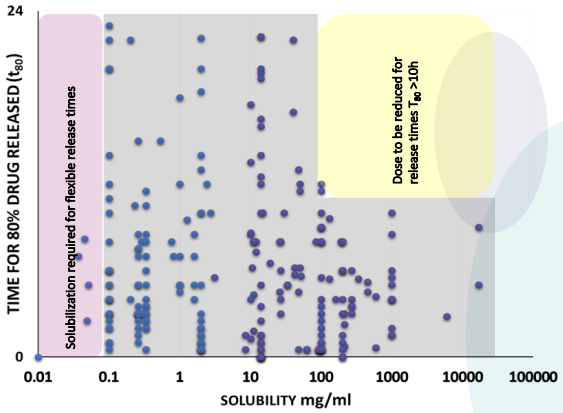


Our approach:

Based on physicochemical and biopharmaceutical characteristics of a drug, we use our expertise in modified release technologies to develop commercially viable products to our customer needs. These include:

- ✓ Modified release dosage forms
  - Multiparticulates (granules, pellets, minitablets)
  - Single unit tablets
  - Osmotic tablets
  - Matrix and coated systems
  - Hydrophilic and lipophilic polymeric matrix and coating materials
- ✓ High dose modified release DDS
- ✓ Fixed dose combinations with independent release adjustment for each API
- ✓ Reduced food or alcohol effect (robustness against intestinal forces, fluids and food/food degradation products)
- ✓ Enteric / colonic delivery dosage forms
- ✓ Pulsatile drug delivery

Technology applicability map - Example: Single units



Knowledge-based formulation: Discriminat. dissolution

- ✓ Rationale selection of dosage form, formulation and processes based on expertise in drug delivery and biopharmaceutics
- ✓ Defining target release profile based on PK analysis
- ✓ Risk-based approach to decision making within a Quality-by-Design framework

Single units | Coated multiparticulates

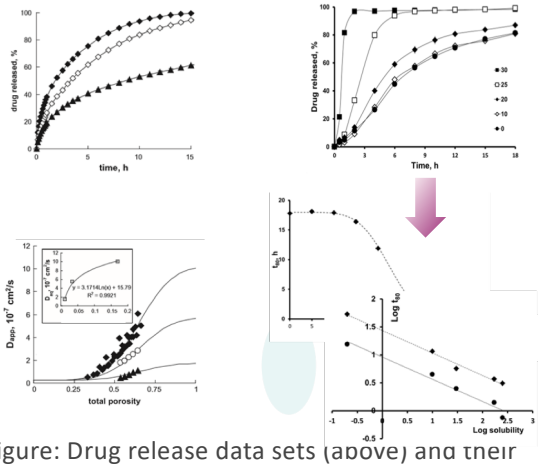


Figure: Drug release data sets (above) and their mechanistic evaluation (below) of oral DDS

Summary

- ✓ Formulation selection and development starts with an in-depth analysis of the characteristics of the API.
- ✓ The Target Product Profile is defined, and formulation approaches are selected based on science and data.
- ✓ Formulation options are evaluated, and the most suited dosage form is developed by QbD principles.

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