Upperton Pharma Solutions

Oral Solid Dosage Forms

Offering Expert Preclinical and Clinical Formulation Development of Oral Solid Dosage Forms

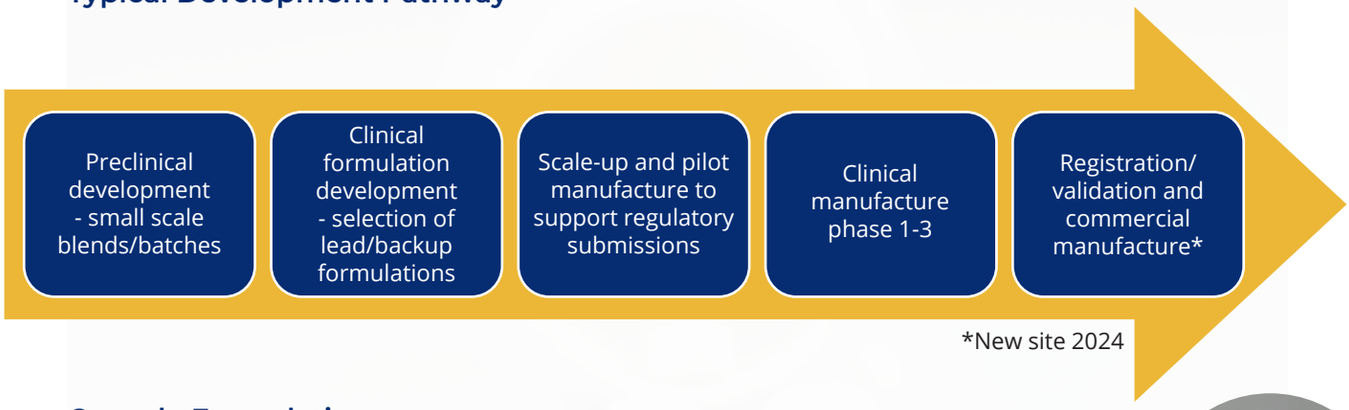
Oral administration remains the most widely used route for the successful delivery of active pharmaceuticals to patients. Dosage form design will be driven by a combination of factors including:

- Speed of development (fast into clinic)
- Anticipated dose
- Excipients required to improve API stability or enhance bioavailability
- Targeted (enteric) or modified (delayed) release profile requirement

Developing Oral Dosage Forms

Upperton can offer clients expert preclinical and clinical formulation development of oral solid dosage (OSD) forms; from early feasibility, right through to clinical manufacture. Formulations can range from simple **powder in bottle/sachet for reconstitution** to more complex **capsules and tablets.**

Typical Development Pathway



*New site 2024

Capsule Formulations

Capsule formulations are often the favoured dosage form for initial clinical studies as they offer a fast, convenient way to deliver the API to the pharmacy. Capsules may contain simple unformulated API or more advanced formulations, such as amorphous spray-dried dispersions designed to enhance bioavailability.

Tablet Formulations

Whilst capsule delivery represents the faster route into the clinic, tablets give more flexibility in the formulation and offer a more cost-effective solution for products entering later stages of development or commercial manufacture, as well as being a more established approach for targeted delivery.

Driven by experts, led by science

Get in touch to find out more: contact@upperton.com

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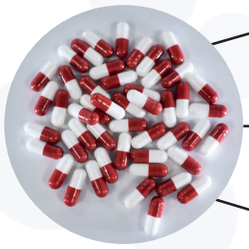
Analytical and Stability Testing

Phase-appropriate methods are developed for analysis of OSDs from early-stage development, through to GMP manufacture.

Characterisation of OSDs Typically Includes:

- Appearance - visual and microscopic
- Material identification - FTIR
- Assay and related substances - HPLC, UV, GC
- Water content - Karl Fischer
- Residual solvents - GC
- Blend homogeneity
- Blend density/ compressibility
- Content uniformity/ weight uniformity
- Tablet hardness/ friability
- USP disintegration and dissolution
- Discriminating/ clinically relevant dissolution
- Microbial limits (outsourced)

Capsule Formulation



API

- Dependent on API solubility/BCS class
- Chemical stability required
- API 'gelling'

Blend

- Common blend or range of blend strengths
- Determine excipient compatibility

SDD

- Poorly soluble molecules BCS II/IV
- Powder flow/need for compression
- Dispersion/drug release profile

Tablet Formulation

Conventional

- Particle size/soluble molecules
- Direct blending/dry granulation
- Coating (cosmetic or functional)

SDD

- Poorly soluble molecules
- Dose/API loading
- Disintegration, drug release profile

Stability

During the preclinical stage, accelerated stability studies focus on excipient compatibility, where API and excipients are blended together and stability assessed with ASAPprime®. More formal ICH stability studies are used during development to determine product stability/shelf life on technical and clinical batches manufactured under GMP conditions.

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