Upperton
Pharma Solutions

Analytical Services

Supporting Preformulation, Formulation Development, Quality Control and Stability Testing of APIs and Final Dosage Form

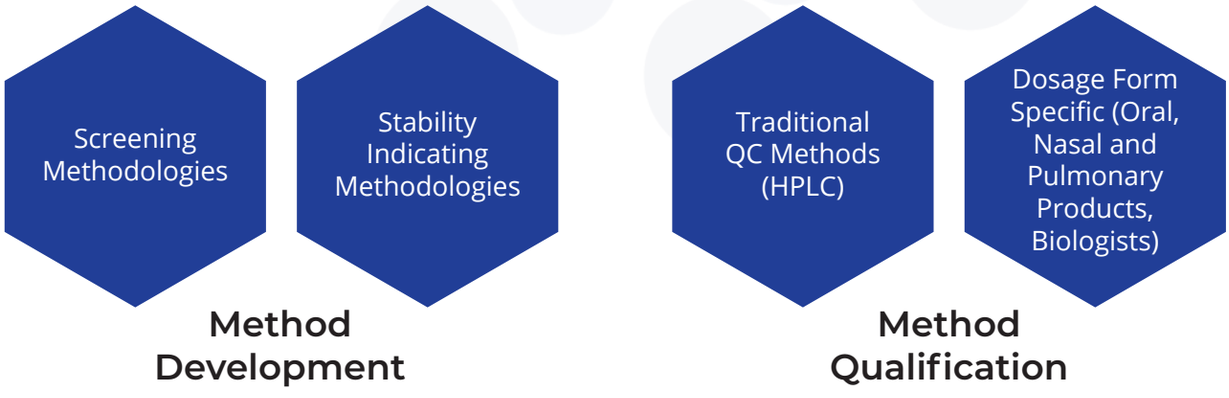
Upperton provides an extensive range of analytical techniques to generate critical product data from the early stages of development through to QC testing of clinical supplies. This data guides formulation development and is used to assess stability and evaluate the performance and quality of the final dosage form.

Preformulation/Formulation Development

Our scientists recognise that successful development programmes begin with a thorough understanding of the physico-chemical characteristics of the API, and any potential stability or excipient incompatibility challenges.

Traditional Methods	Physical Characterisation
HLPC Dissolution Spectrophotometric Analysis FTIR Karl Fischer	Laser Particle Sizing Electron Microscopy Differential Scanning Calorimetry X-Ray Diffraction Dynamic Vapour Sorption Powder Rheology
Dosage Form Testing	**Biologics**
NGI Powder Deposition (Pulmonary) AINI Deposition (Nasal) Nasal Spray Characterisation Dissolution Testing (Biorelevant & Traditional)	Gel Electrophoresis Western Blotting ELISA Spectrophotometric Analysis Sub-Visible Particulates

Assays are developed and qualified to a phase-appropriate level to provide confidence in the data generated.



All of Upperton's Development and Manufacturing Services are underpinned by our experienced analytical team and capabilities.

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

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Stability Testing

Stability assessment is critical to a successful development programme, regardless of stage.

During the early stages of formulation development, Upperton uses Accelerated Stability Assessment Program (ASAPprime®) to generate phase-appropriate stability data. **The use of ASAPprime® helps us to rapidly pinpoint potential instability issues associated with our customers' API and identify formulation strategies to overcome these stability challenges.**

Preformulation and Formulation Development

ASAPprime® Stability Screening

ICH Stability

Stability of Clinical Product and Shelf-Life Assignment

During the final stages of clinical formulation, more formal ICH stability studies on the Technical and Clinical batches will be performed to generate stability data to support regulatory submissions.

GMP Manufacture: In Process and Finished Product Release Training

Any analytical methods used need to be robust, yet phase-appropriate and of sufficient quality to support the appropriate regulatory submissions.

QC in process and release testing of clinical products confirm the dose strength/assay in the drug product and the level of any impurities derived from the API. Performance testing may include tablet/capsule dissolution or impaction testing (NGI) to assess the aerodynamic delivery of powder nasal and pulmonary devices. Microbial limits testing is used to ensure that the drug product complies with the relevant specification for microbial quality for the dosage form.

Driven by experts, led by science

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