ALMAC

Partnering to Advance Human Health

Preformulation services at Almac

Early drug candidate evaluation and preclinical formulation development

- Physicochemical profiling
- Oral developability assessment
- Enabling preclinical formulations

Preformulation services

In Almac Physical Sicences our preformulation service is equipped with advanced, small-scale instrumentation and expertise of the discovery–development interface for small molecule drugs.

We offer solutions in early development by assessing, predicting and formulating with delivery of a drug candidate in mind.

Physicochemical Profiling
- Compound characterisation
- Small-scale assays

Oral developability assessment
- Biorelevant testing
- Prediction of developability risk
- Inform formulation requirements

Early preclinical formulation
- Rapid excipient screening protocols
- Rational formulation development
- Enhance exposure for preclinical studies

Our experience and technical knowledge can rapidly identify molecule challenges with protocols which emphasise efficient use of resources. Applying our understanding of drug physicochemical properties we can offer tailored and rational preclinical formulation development.

Physicochemical profiling

Performed using small-scale analysis techniques, we can determine key characteristics of drug molecules even when solubility is low and drug material is limited.

Ionisation determination (pKa)
- Spectrophotometric and potentiometric assays and co-solvent techniques for poorly soluble compounds

Lipophilicity evaluation (LogP and LogD)
- Shake flask and potentiometric assays to determine drug lipophilicity

Intrinsic, equilibrium and kinetic solubility
- Conventional thermodynamic and rapid potentiometric solubility (CheqSol)

Permeability assessment
- In vitro models to evaluate drug permeability (PAMPA, MDCK and Caco-2)

Small-scale dissolution testing
- Intrinsic dissolution rate and biorelevant dissolutions

Oral developability assessment

Orally delivered pharmaceuticals make up over 80% of the best-selling products on the market. Developability assessment examines how the unique physicochemical characteristic of a compound may affect oral absorption and bioavailability, determining risk and informing formulation strategies.

We utilise a biopharmaceutical classification approach which is adapted for early development to predict the risks and challenges of developing an oral drug. Evaluations can reveal the effects of salt formation and polymorphism, drug compound precipitation and examine potential food effects which may occur in vivo.

A variety of small-scale techniques allows prediction of compound in vivo performance with minimal material consumption:

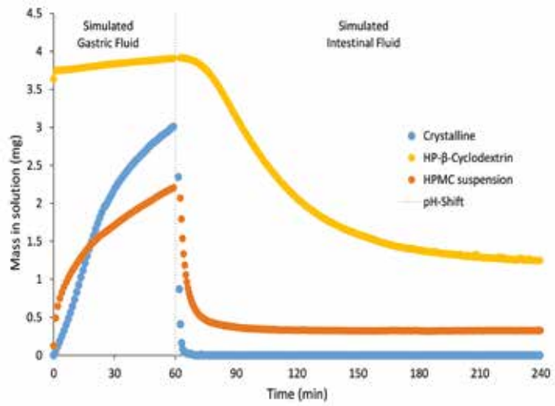
- Biorelevant solubility testing
- Permeability prediction
- Biorelevant dissolution testing
- Examination of food effects
- Supersaturation and precipitation evaluation

Early preclinical formulations

Obtaining adequate and consistent bioavailability in early preclinical studies can be challenging. Almac can provide solutions to overcome inherent poor pharmaceutical properties such as low solubility, unlocking the potential of a candidate compound.

Using rapid excipient screening approaches (Formufast™), we can provide robust preclinical formulations which enhance drug solubility and overcome in vivo sources of pharmacokinetic variability.

Extensive in vitro testing using biorelevant dissolution assays can demonstrate formulation abilities to promote supersaturation and resist effects such as pH-mediated precipitation and food effects.



Partnering to Advance Human Health

Almac's Physical Sciences group unites chemists, analysts and formulators in one team adding value through synergy.

Our multidisciplinary team can help shorten the timeline of your pre-clinical projects. Enabling the development of your API through optimal solid form selection & appropriate early formulation strategies in early development.

almacgroup.com

Get in touch

Global HQ
+44 28 3833 2200

US HQ
+1 215 660 8500

Athlone, Ireland
+353 90 646 0200

almacanalytical@almacgroup.com