ALMAC

Partnering to Advance Human Health

Brochure

Preformulation development

As a world leader in pharmaceutical services, Almac delivers early formulation development work programs for DRF/PK/tox studies. Designed to maximise solubility and bioavailability without compromising on chemical stability, the studies accelerate drug development to the clinic and minimize risk in any downstream activities. Almac offer bespoke work packages specifically tailored to the physiochemical properties of the API (BCS class II, III, or IV) for solubility or permeability enhancement.

Early / enabling formulation screening

By collaborating closely with Almac's in-house drug substance and drug product teams, Almac's preformulation team are world leaders in performing rapid early and enabling formulation screening work programs in instances where material is limited. Generally performed as soon as the stable form of an API (free form, salt, or co-crystal) has been determined by polymorph screening, the early / enabling formulation screens perform the following assessments:

- Biopharmaceutical profiling (pKa / logP / logD determination) and permeability (Caco-2)
- Indicative stability testing using ICH conditions (including temperature, humidity, light, oxidative conditions, Cu2+, and Fe3+)
- Excipient compatibility assessments (solid excipients and lipids) for preclinical / toxicological profiling of oral and parenteral doses
- API solubility testing in common buffers, biorelevant media, and across a simulated GI tract pH range
- Assessment of the drug intrinsic dissolution rate (IDR) in biorelevant media systems
- Amorphous solid dispersions / amorphous API assessment
- Drug Classification System (DSC) assessment

Key instrumentation

- Comprehensive internal analytical chromatographic services (HPLC, UPLC, IC, GC)
- Sirius inForm preformulation platform for automated assays (including thermodynamic solubility profiling and intrinsic dissolution profiling) using small volumes
- On-line UV and pH probes
- Powder X-ray diffraction (PXRD)
- Polarised light microscopy (PLM) and high powered digital microscopy
- Thermal analysis (TG-DSC and DSC)
- Fourier transform infrared spectroscopy (FT-IR)
- Raman spectroscopy

formufast™ rapid early formulation development

Using as little as 25mg of an API, formufast™ screens allow for rapid evaluation of an API against a range of formulation vehicles to provide a simple formulation with improved solubility and bioavailability for PK and Tox studies, conducted within 72 hours.

The solubility of the molecule is screened in a tailored matrix of commonly used GRAS excipients, surfactants, cyclodextrins, polymers, co-solvents, physiologically relevant buffers and mixtures. The solubilising capacity is quantified for each of the excipients and suitable formulations are developed for the intended administration route.

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