



THE FIRST CRO

SPECIALISED IN PHARMACEUTICAL DRUGABILITY

Modern drug candidates are expected to show strong physico-chemical and biopharmaceutical profiles as well as consistent delivery options before accessing preclinical development.

In order to improve candidate quality, research programs are more and more relying on early physicochemical properties monitoring and rational formulation design for in vivo experiments.

Over the last decade, the need for new methodologies to earlier identify more drugable molecules has clearly emerged in the pharmaceutical industry as a key element to secure return-on-investment in discovery and accelerate research-to-development transition.

Drugabilis is the first CRO specialised in pharmaceutical drugability for research. We deliver both experimental support and consulting services to our customer's research efforts, by promoting the emergence and selection of highly drugable compounds and suitable delivery systems, from idea to preclinical candidate.



DRUGABILIS
from molecules to drug candidates

PHYSICOCHEMICAL PROFILING

This part of our activities includes:

- Early routine screening: thermodynamic aqueous solubility, chemical stability in solution...
- Equilibrium solubility versus pH, ionic strength, temperature...
- Stability assessment of bulk active under various stress conditions...
- Screening methodology design and set-up, at request, for early assessment of specific properties...

Any other specific physicochemical characterisation testing set may be designed at request, in order to secure, at each step of a given research program, that series selection, lead optimisation, candidate selection or formulation development will have taken drug-like properties and drugability criteria into account.

EARLY PHYSICAL CHARACTERISATION

This part of our activities includes:

- Crystallinity,
- Thermal profile assessment,
- Hygroscopicity measurement,
- Hot-stage microscopic observations,
- Active physical form stability evaluation under stress conditions,
- Hydrate and solvate identification,
- Salt and polymorph screening,
- Salt selection,
- Relative stability of polymorphs.

Specific characterisation issues related to formulation studies, physical compatibility between drug and excipients, active physical form change upon scale-up or synthetic route modification, proprietary drug delivery technologies and others should be raised to us. They will give **Drugabilis** the opportunity to design, every time possible, fast and adapted answers.

FORMULATION FOR BIOLOGY

We can behave as a remote early formulation support group, designing, manufacturing and shipping well characterised and ready-to-use samples for any routine or pivotal in vivo study.

Typical research formulation support includes:

- IV/PO formulations for Pharmacokinetic or pharmacological studies,
- High drug-content solutions development for toxicological studies,
- Formulations for unusual routes of administration,
- Formulations for unusual animal models...

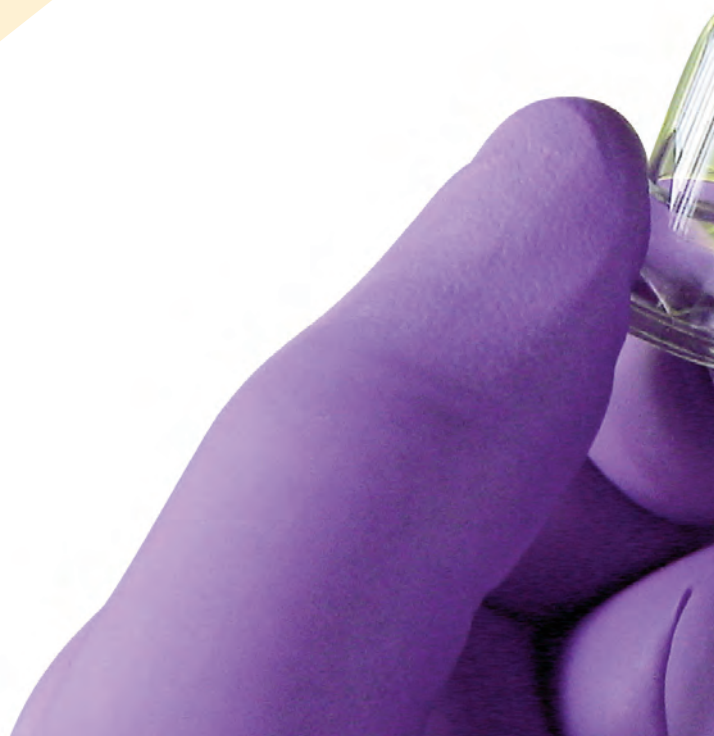
- Drugability of preclinical development candidates,
- Drug Delivery Systems and technologies,
- Physico-chemistry of research compounds,
- Formulations strategies for animal experiments,
- Formulation impact on animal experiment findings,
- Discovery support and drug candidate selection criteria,
- Active solid state, salts and polymorphism,
- Formulations for exploratory development...

CONSULTING AND DUE DILIGENCES

At any time of their projects, research organisations as well as investors have the possibility to seek scientific expertise and technical/strategic advice from **Drugabilis**. Most of our consulting activities refer to the following types of technical domains and areas of expertise:

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RESEARCH SUPPORT

Stability of drug candidates has to be built along the Discovery process, from idea to preclinical development candidate selection. This is why **Drugabilis** expertise and unique experimental capacities are accessible for short-term to long-term collaboration through "Research Support" collaborations.

CLIENT PROJECT

Research programs may be facing issues for which they are lacking resources, time or expertise. Because of its experience, capabilities and proactive way of working, Drugabilis can be used as a reactive and efficient problem-solving research partner. The following situations are listed as examples of problems we can take care of:

- Solubility-limited bioavailability issues,
- Irreproducibility of in vivo efficacy results,
- Lack of acceptable vehicle for intravenous dosing,
- Suspected active physical form change upon re-synthesis or scale-up,
- Set-up of a specific physicochemical screening methodology...



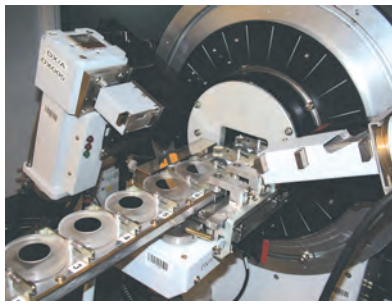
drugability
for research
consulting
and experimental
studies

1. Powder X-ray diffraction

2. Sample preparation robots

3. HPLC-UV

4. Raman microscope



T E C H N I C A L P L A T F O R M

The technologies we use and the methodologies we develop are specifically adapted for Discovery support. Whenever possible, we design and set-up micro-methods, minimising the drug substance quantities required for characterisation of research compounds or early formulation studies.

Thanks to a very comprehensive technical platform and to its strong characterisation capabilities and thanks to an original expertise in early formulation design, **Drugabilis** delivers high added-value support at all stages of the Discovery process.

We allow Discovery teams to secure their candidate selection process and to smoothen the transition of their projects to development, maximising the "return-on-research-investments" chances...

- HPLC-UV
- Sample prep robots
- TGA & TGA-FTIR
- DSC
- Optical microscopy
- Hot-stage microscopy
- Raman microscopy
- Water sorption & hygroscopicity
- Powder X-ray diffraction
- Light scattering granulometry...

5. TGA-FTIR



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