



Bertin Pharma, branch of Bertin Technologies-CNIM group, gathers 4 different entities:

- SPI-Bio & Biotec Centre
- Ellipse Pharmaceuticals & IDPS

No matter the challenge you are facing, a **single project manager** will assist you throughout your whole project **from screening of candidate drugs to manufacturing and distribution of clinical supplies**.

Our services are divided into 2 areas of expertise, **preclinical & clinical supplies and pharmaceutical development & clinical supplies**, and focus on:

Pharmaceutical development & clinical supplies

ADME & Immunogenicity

Biotransformation

Antiviral & Immune Pharmacology
Biosafety

Biomarkers

Explore your options with us

This expertise **focuses on the physicochemical and biopharmaceutical properties** of active compounds allowing the development of the most appropriate formulation of your drug candidate.

Adapted services throughout the drug development

- **Constant optimisation** of the formulation taking into account the physico-chemistry features, the permeability and the kinetics & metabolism properties of the compound.
- **Selection** of the appropriate quality of active principle source (*choice of salts, size distribution, polymorphisms ...*)
- **Development of adequate formulations to enter clinical phases** (*especially phases from I to III*)
- **Optimisation of existing formulations**
 - *Dose, bioavailability, release profile, stability, acceptability...*
- **Added value formulation proposals** as part of a product life cycle management process

Our strengths

- a **single project manager** as your dedicated contact
- a constant respect of **quality** of services, **cost** and **planning**
- an in-depth knowledge of regulatory requirements
- a high level and experienced multidisciplinary teams
- dedicated & state-of-the-art platform



A wide range of techniques & expertise

ADDRESSING THE API ISSUES

Physico-Chemistry profiling

- pHa, Log P/D,
- Solubility (buffer, fluids)
- Flowability,
- Density,
- Particle size distribution,
- Water content,
- Polymorphism,
- Hygroscopicity,
- Intrinsic solubility over a range of dissolution media,
- ICH stability & stress degradation studies (impact of light, temperature, oxidative conditions, pH variations, in buffers and fluids).

Permeability characteristics

Assessment is carried out using *in vitro* models:

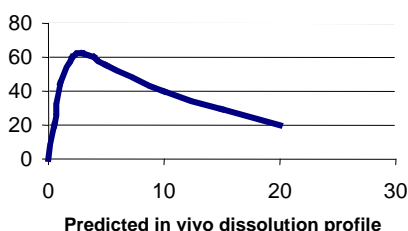
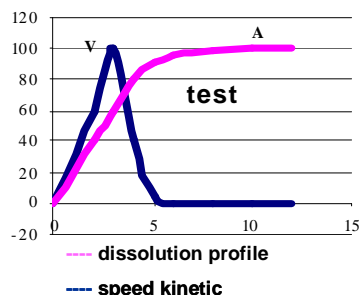
- Caco-2 cells
- MDCK cells
- Human blood-brain barrier

Evaluation of the active principle according to the FDA **biopharmaceutics classification system (BCS)**

Kinetics & Metabolism profiling

- ***In vitro* drug metabolism profiling** on hepatocytes or subcellular fractions (microsomes, S9 fractions), whole intestine or subcellular fractions from various species, human keratinocytes, fibroblasts
- **Cyp inhibition** can be tested using a wide range of human CYPs 450
- Protein binding

ADDRESSING THE DRUG FINISHED PRODUCT ISSUES



- Comprehensive bibliography study, **evaluation of available *in vivo* data** in order to set **specifications for *in vitro* dissolution / absorption profile**.
- Evaluation of the first pass effect and impact on the formulation development strategy especially for sustained release formulations.
- ***In vivo* / *in vitro* correlation study** allowing the development of an adequate *in vitro* tool for the screening of formulations.
- Development of a **predictive *in vitro* dissolution method** of the *in vivo* behaviour of the formulation.
- Development of **formulation prototypes** at the lab and pre-pilot scale.
- **Screening of the formulation prototypes based on *in vitro* dissolution profiles** and stability data.
- Manufacturing of formulated product to be tested in pre-clinical phases.
- Process validation and transfer onto a GMP site.

Related services

Pharmacokinetics & bioanalysis
Early ADME assessment & metabolism profiling

Formulation Development
Regulatory Affairs