- **Pre-formulation and formulation**
- **Drug stability**
- **Drug dissolution**
- **Analytical support**
- **Drug metabolism**
- **Bioavailability/bioequivalence and Pharmacokinetic/ pharmacodynamic studies**
- **Pharmacometrics**
- **Therapeutic drug monitoring and Personalized therapy**
- **Consultancy/Training**

BP&PK@FFA

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Biopharmaceutics & Pharmacokinetics

Faculty of Pharmacy, University of Ljubljana

Do you need scientific answers to direct your compounds and therapeutic strategies a step further in the development process?

BP&PK@FFA collaborates with universities, pharmaceutical companies, research sites and hospital services in the drug discovery and development process.

Due to the expertise in biopharmaceutics and pharmacokinetics and extensive experience in bioanalytics, drug stability and compatibility analyses, pharmaceutical pre-formulation and formulation studies, drug dissolution, permeability, metabolism and pharmacokinetic/pharmacodynamic studies, **BP&PK@FFA** has performed many tailored high content studies to answer its partners' needs.

At **BP&PK@FFA**, we offer high quality, flexibility, rigor and short communication lines. Our innovative services and products can be applied to the various phases of drug development.

BP&PK@FFA provides bioanalytical support. Our state of the art and conventional laboratory methods allow quantification of a wide range of compounds in various matrices in all stages of pharmaceutical R&D process.

BP&PK@FFA offers know-how to optimise drug research and development using pharmacometric methods. With mathematical modelling and simulation we evaluate disease progression and summarise pharmacokinetic and pharmacodynamic information from various phases of drug development.

BP&PK@FFA is conveniently located at the Faculty of Pharmacy (FFA), University of Ljubljana in the centre of Ljubljana at the heart of University campus for natural sciences and technology. FFA was celebrating 50 years of tradition in 2010 and has been among the leaders in pharmaceutical sciences and education in Central and Southeastern Europe.

At **BP&PK@FFA** we accelerate flow across barriers.

BP&PK@FFA services include

Pre-formulation and formulation

- ***Physico-chemical characterization:*** evaluation of polymorphs, pKa, logP, solubility in water and physiologic media
- ***Amorphicity:*** detection and quantification of amorphous material content concerning suitability and stability of API and dosage forms
- ***Solubilization*** of poorly soluble compounds (solid dispersions, surfactants, hydrotropic substances)
- ***High throughput permeability screening*** with parallel artificial membrane permeability assay (PAMPA)
- ***BCS classification:*** determination of aqueous solubility, drug permeability mechanism and presystemic gut wall metabolism in Sweetana Grass side-by-side diffusion chambers with isolated intestinal tissue or Caco-2 monolayers
- ***Evaluation of pharmaceutical excipients potential to influence intestinal drug absorption***
- ***Prediction of drug-drug and drug-food interactions*** during intestinal absorption and pre-systemic metabolism (isolated intestinal tissue, precision-cut liver slices and HepG2 cell cultures)

Drug stability

- ***Compatibility:*** early assessment of (in) compatibility between API and excipients for shorter development timelines of experimental and finished dosage forms
- ***Water sorption:*** water content sorbed by API or excipients enabling anticipation of possible instability or wetting problems
- ***Chemical and physical stability:*** intrinsic stability characterization for scientifically based dosage form design, and confirmatory stability testing of API and finished products

Drug dissolution

- ***USP Apparatus I, II and IV, Custom designed biorelevant flow-through dissolution model***
- ***Physiological model of drug dissolution:*** dissolution experiments at conditions close to physiological (pH, volumes, flows, ionic strength)
- ***Mathematical models of gastric emptying and gastrointestinal transit***
- ***In vitro – in vivo correlation***

Analytical support

- ***Development of selective and sensitive assays*** for determination of drugs, metabolites, degradation products and endogenous compounds in various matrices
- ***Validation of analytical methods*** according to FDA and ICH recommendations
- ***State-of-the-art instrumentation and automation equipment*** for sample analyses including 2 LC/MS/MS, several HPLCs with DAD, FD, RI and ECD, micro DSC, automated SPE stations, etc.

Drug metabolism

- ***In vitro models of increasing complexity:*** recombinant enzymes, subcellular fractions, cell lines (Caco-2, Hep-G2), tissue slices (liver, intestine), side-by-side diffusion chambers

Bioavailability/bioequivalence and Pharmacokinetic/pharmacodynamic studies

Assistance through all stages of drug development (fundamental research, preclinical, clinical and post-marketing studies)

- ***Study design and protocol development***
- ***Study monitoring and coordination with clinical sites***
- ***Bioanalytical services***
- ***Biostatistics***
- ***Final report and preparation of documentation for regulatory submission***

Therapeutic drug monitoring and Personalized therapy

We collaborate with hospital services in TDM for drugs with a narrow therapeutic range and dose individualisation according to genetic polymorphisms and other factors

Pharmacometrics

Application of pharmacokinetic, pharmacodynamic, pharmacokinetic/pharmacodynamic and disease progression models for optimising drug development, and therapeutic strategies, thereby increasing the safety and efficacy of pharmaceuticals in clinical settings

- ***Pharmacokinetic and Pharmacodynamic data analysis***
- ***Population analysis using nonlinear mixed effects modelling***
- ***Target mediated drug disposition***
- ***Modelling and simulation***
- ***Clinical trials simulation***

Consultancy/Training

We offer consultancy, guidance and training on a broad spectrum of issues