JOANNEUM RESEARCH HEALTH

Services for the pharmaceutical industry

Bioanalysis / Pharmaceutical analysis / Cleaning validation

We develop, validate, optimize and automate innovative bioanalytical methods for high-throughput analysis for medical research and the pharmaceutical industry. We can analyze microliter sample volumes with state-of-the-art bioanalytical methods.

Our competence

- long-term experience in analyses for preclinical and clinical trials
- long-term experience with various biological matrices (serum, plasma, interstitial fluid, tissue, cell culture) and pharmaceutical formulations
- flexible implementation from pilot studies to multicenter studies
- sampling logistics
- data management and data transfer
- validation of cleaning processes in pharmaceutical plants
- stability testing of pharmaceutical formulations
- batch release analysis
- we offer our services GLP compliant, if required

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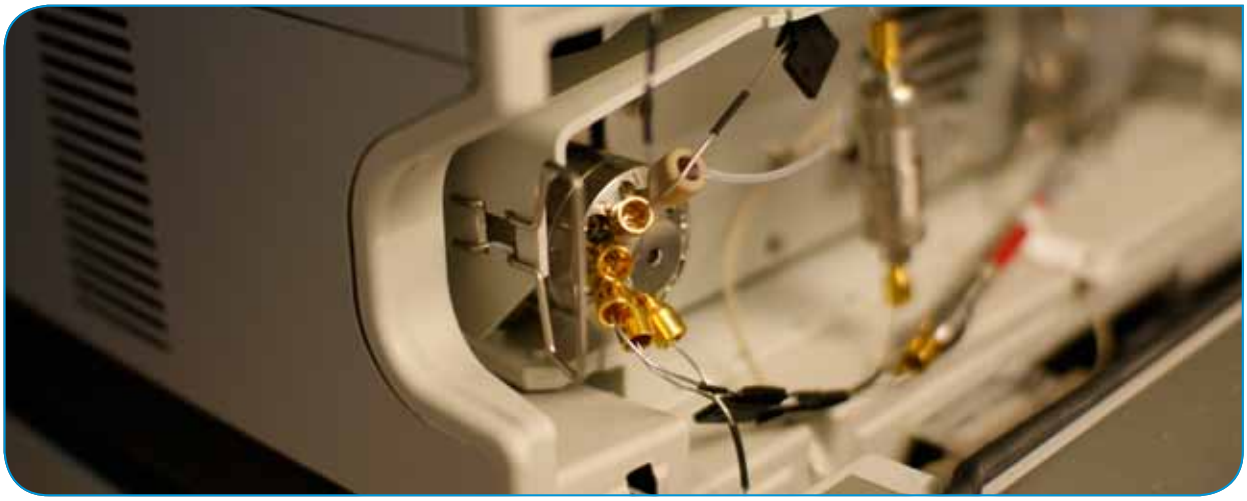

analytical expertise

- metabolites, e.g. acyl-CoAs, energy metabolism, isotope-labelled tracers …
- drug analysis
- polyamines

technologies

- HPLC - UV
- nano / cap / micro / conventional LC
- ELISA
- multiplex assays (Luminex): e.g. cytokines
- automated assays for clinical laboratory parameters (Cobas Mira)
- high-resolution mass spectrometers (Exactive Orbitrap, LTQ Orbitrap: FTMS)
- triple-quadrupole MSs: GC/MS, GC-MS/MS, LC/MS

sample preparation

- from various biological matrices (serum, plasma, interstitial fluid, tissue, cell culture) and pharmaceutical formulations
- automated for high troughput
- optimized for small volumes and low concentrations
- solid phase extraction
- solid-phase micro extraction
- liquid-liquid extraction
- tissue extraction
- protein precipitation
- ultrafiltration
- derivatisation

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Bioanalysis

Through our close collaborations over many years with research groups in fundamental medical research, and through extensive contract research for the pharmaceutical industry, our services now range from innovative analytical solutions to quality-assured analysis of samples; e.g. for clinical trials.

- optimizing processes with respect to sensitivity, time and cost
- qualification and validation of analytical methods
- development, optimization and validation of tailor-made solutions using the latest technologies

Pharmaceutical analysis

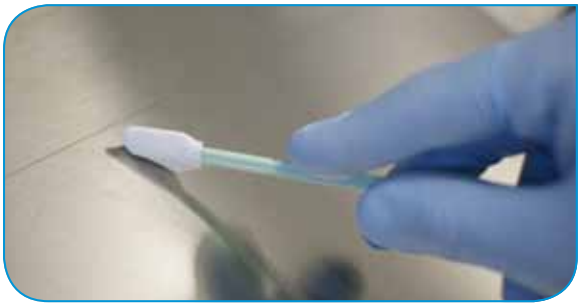
The pharmaceutical industry has broad requirements for analytical services, such as analysis of finished products, stability testing, identification of impurities/degradation products, etc. We can assist you with your internal analysis projects.

- method development/qualification/validation of assays (eg, for approval processes, stability studies)
- testing for impurities in raw materials, intermediates and final products
- identification of unknown impurities/degradation products using high-resolution mass spectrometry
- analysis for cleaning validation
- fingerprinting of complex products using metabolomics technologies

Cleaning validation

Companies producing pharmaceuticals must demonstrate that their cleaning processes remove residues to a defined level. To provide evidence, appropriate sampling procedures and highly sensitive and selective analytical methods are needed.

- optimizing sampling methods (taking swabs, rinse sampling, etc)
- developing suitable sample preparation
- combining sensitive and selective analytical methods (e.g. LC/MS, GC/MS) tailored to your cleaning process
- method validation according to international standards



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Quality standards

We set high quality standards for our services and products. As our partner, you can rely on the application of international quality standards right from placing your orders up to delivery of the final product/service. We operate and are certified according to the following guidelines:

- EN ISO 9001
- EN ISO 13485
- GLP – Good Laboratory Practice

Our partnerships for your benefit

We enjoy a synergistic partnership with the Medical University of Graz. Because of our collaboration with the Evidence-Based Medicine Review Center and with the Center for Medical Research (with its first-class laboratories, equipment and trained technical staff), we can provide excellent research services for your benefit.

CONTACT

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