

SUSTAINABLE FUTURE STARTS WITH CHEMISTRY

# PHARMACEUTICAL ANALYSIS



# RESEARCH OFFER

**Testing of active substances, medicinal products, investigational medicinal products, excipients, pharmaceutical raw materials** – we provide product series certification and quality control testing in accordance with GMP standards

**Development, validation and transfer of analytical and microbiological methods** – we ensure compliance with EMA, ICH, Ph.Eur., and USP guidelines

**Stability testing of active substances and medicinal products** in qualified climate chambers under accelerated and long-term conditions



# RESEARCH OFFER

**Determination of chemical and pharmaceutical substance content and identity**

**Polymorphism studies**

**Tests for** asepsis, microbiological purity, presence of bacterial endotoxins and effectiveness of antimicrobial protection

**Impurity profile testing**  
(e.g. determination of the content of degradation products and other impurities, including genotoxic and nitrosamine residual solvents, enantiomeric purity)

**Studies on the stability of substances and medicinal products** – tests in climatic chambers under accelerated and long-term conditions

## OUR CAPABILITIES

**Pharmaceutical availability studies** for different pharmaceutical forms

**Particle size distribution studies**

**Validation of process equipment cleaning** (using swabbing and washing)

# RESEARCH OFFER

## TECHNOLOGICAL BACKGROUND

**Liquid chromatography** – HPLC (UV/PDA/RI/Fluorescence/Electrochemical) on analytical, preparative and semi-preparative columns, UPLC, SEC, IEC, UPLC-MS/MS

**Mass spectrometry**  
(ICP-MS, AAS)

**Gas chromatography**  
(GC, GC/MS)

**Spektrometria  
absorpcji atomowej**

**X-ray powder  
diffraction (XRPD)**

**NMR spectroscopy**

**Laser diffraction  
(PSD)**

**Thin layer  
chromatography**

**IR, NIR, FTIR, UV/Vis  
spectroscopy**

**Differential scanning  
calorimetry (DSC)**

**Potentiometry, weight  
and titration analysis,  
classical methods**

# PHARMACOKINETICS, BIOEQUIVALENCE AND BIOAVAILABILITY

## OUR CAPABILITIES

**GLP-compliant bioequivalence and bioavailability studies for medicinal products**

**Development and validation of bioanalytical methods** – we adapt methods for the determination of the medicinal substance and metabolites in biological material, in accordance with EMA requirements

**Performance of assays in biological material (LC/MS/MS)**

**Pharmacokinetic studies management** – from project preparation to preparation of expert reports and study documentation in CTD format Module 5

## TECHNOLOGICAL BACKGROUND

**LCMS-2010 mass spectrometer** (Shimadzu) coupled to HPLC (LC/MS)

**UHPLC and HPLC with UV-VIS, electrochemical and fluorimetric detectors**

**UPLC Acquity with Xevo LC/MS/MS detector** (Waters)

**SOLO Version 8.37** sample preparation machine for analysis, from Hudson Robotics, Inc.

# VALUES

We work with passion, based on

**Professionalism**

**Commitment**

**Reliability**

**Partnership**

# WHAT SETS US APART

## Expertise

our team is made up of specialists with more than 20 years' experience in GLP bioanalysis and specialises in mass spectrometry

## Accuracy and precision

we guarantee the reliability of results, which is the foundation for safe drug development

## Flexibility

our services are tailored to the individual needs of each client and stage of product development

# POTENTIAL

## Product and process innovation

from pilot scale to production in our own process halls

## Analytical and registration support

for APIs and non-APIs

## Laboratories and equipment

developing research facilities with specialised laboratories and modern equipment

## Process scaling

scale-up and scale-down of chemical and biotechnological processes

## Development and competence

investment in technology and human resources with more than 170 scientists and specialists for companies investing in innovation

## Inventions and know-how

patented solutions and know-how in the field of modern chemical processes that can be commercialised

## Completion of technological line distributed on the market

from 'concept to product'

## High standards

GMP, GLP, ISO systems in place

## Research platform

implementation of R&D projects

## Cooperation with leaders

cooperation with Polish and foreign business and academic partners



**Łukasiewicz**

Industrial Chemistry Institute

We create innovations  
that shape a sustainable future.  
Trust our knowledge and experience!

## LET'S MEET!

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