

SUSTAINABLE FUTURE STARTS WITH CHEMISTRY

PHARMACEUTICAL ANALYSIS



Łukasiewicz
Industrial
Chemistry
Institute



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



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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

Gas chromatography
(GC, GC/MS)

**Thin layer
chromatography**

**Spektrometria
absorpcji atomowej**

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

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

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

**Differential scanning
calorimetry (DSC)**

NMR spectroscopy

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

**Laser diffraction
(PSD)**

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

WHAT SETS US APART

We work with passion, based on

Professionalism

Commitment

Reliability

Partnership

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



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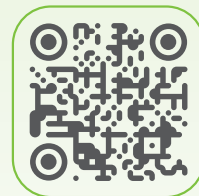
Industrial Chemistry Institute

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

LET'S MEET!

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