



**Łukasiewicz**

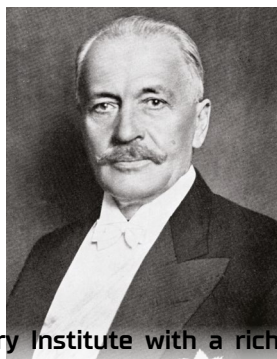
Industrial  
Chemistry  
Institute



**Solutions to the challenges  
of modern chemistry and pharmacy**

<https://ichp.lukasiewicz.gov.pl/en/>

# From tradition to modernity



**Łukasiewicz Research Network – Industrial Chemistry Institute with a rich tradition spanning over a century, is a leading research institution in Poland. It is particularly renowned for its outstanding achievements in applying and implementing research solutions in chemistry, chemical technology, biotechnology, and pharmacy.**

One of the Institute's earliest and significant scientific and technological achievements was the synthesis of artificial rubber (KER) in 1935, leading to the establishment of the world's fourth synthetic rubber factory in 1938. The subsequent decades were marked by other remarkable achievements, such as the global development and implementation of Polish technology to produce cyclohexanone from benzene, a blend of c-none and c-nol, and caprolactam. In 1962, the Institute commissioned the first semi-technical installation at Zakłady Azotowe (Nitrogen Works) in Tarnów.

The Institute made waves in the pharmaceutical industry in the 1990s by introducing BIODRIBIN®, an anti-leukemia preparation based on cladribine. Another pioneering achievement followed in 2000 when BIOTON S.A. implemented the Institute's proprietary technology for the production of human insulin and its ready-to-use forms under the GENSULIN® series. This was the first Polish drug produced using genetic engineering. Today, Łukasiewicz – ICI stands as a comprehensive hub for the development and implementation of technologies for manufacturing pharmaceutical products and active pharmaceutical ingredients (APIs), according to the highest standards (GMP, CEP and ASMF). The Institute is positioned as a key player in the Polish market (ranking second in production volume according to IQVIA) with a portfolio that includes eight active substances.

Continuing its drive for innovation, the Institute has made a significant contribution to polyurethane production with the introduction of a novel TDA phosgenation process, purchased by BASF in 2012. Other notable achievements include the implementation of PVC nanocomposites in collaboration with Anwil SA in 2015; the development of a technology for co-hydrogenation of crude oil fractions with vegetable oils or animal fats to obtain biocomponents for diesel for Orlen S.A. in 2019; a technology for obtaining liquid hydrocarbons from natural oils (HVO technology - 2022).

## Strategic areas of operation

- ✓ Development of scientific and industrial research works in the field of chemical sciences, pharmaceutical research and biotechnology
- ✓ Modern materials and polymer composites
- ✓ Recycling and zero-emission technologies
- ✓ Electromobility – hydrogen fuel cells and electrochemical energy sources
- ✓ Development of formulations and technologies of manufacturing medicinal products, incl biopharmaceuticals, medical devices, dietary supplements and remedies, foodstuffs for special purposes
- ✓ Production of Active Pharmaceutical Ingredients (API) based on own solutions
- ✓ Pharmaceutical analytics including testing of API and medicinal products, excipients, pharmaceutical raw materials and research pharmacokinetic
- ✓ Production of cytostatic drug BIODRIBIN® used against hairy cell leukemia
- ✓ Genetic engineering and biosynthesis
- ✓ Commercialization and implementation of research and development work results into industrial practice
- ✓ Modelling of technological processes (Ansys Fluent, ChemKin, ChemCad)

## Additional areas of activity

- ✓ REACH and CLP services
- ✓ Actions to protect the Ozone layer and Climate
- ✓ Publishing activities (magazine POLIMERY)



## SUSTAINABLE CHEMISTRY CENTER



## Polymer Technology RESEARCH GROUP

Processing Polymers Materials Section  
Polymer Synthesis and Modification Section  
Biomaterials Section  
Advanced Polymer Materials Section  
Vinyl Polymers Section

### Research topics

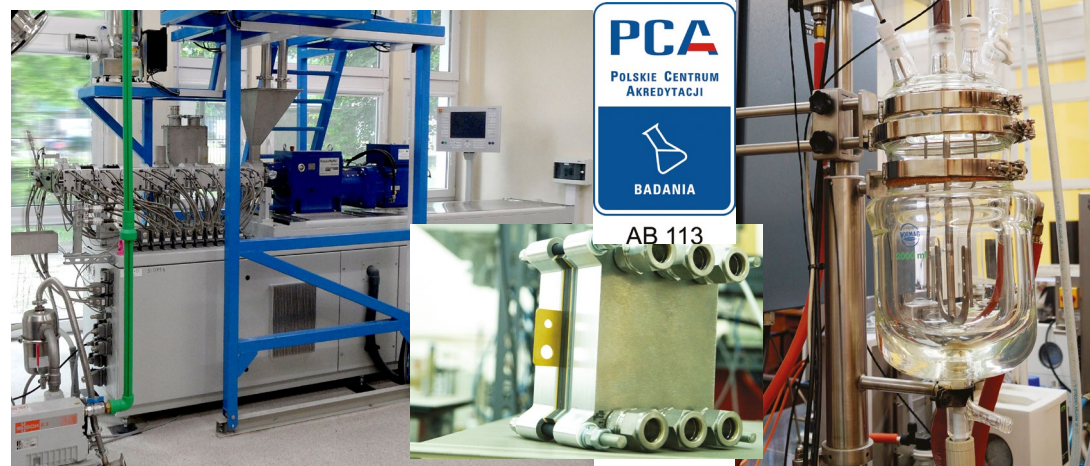
- ✓ Modern materials and polymer composites
- ✓ Building materials with low energy and material consumption
- ✓ Green chemistry: designing safe and sustainable chemicals, use of renewable raw materials
- ✓ Sustainable agriculture: minimizing the use of pesticides, ecological fungicides and bactericides
- ✓ Packaging: intelligent, active, biodegradable, recyclable
- ✓ Designing new biopolymers with competitive properties antibacterial, antifungal and antioxidant
- ✓ Developing new plasticizers for polymeric materials
- ✓ Reactive polymer processing
- ✓ Plastic recycling

## Chemical Technology RESEARCH GROUP

Organic Synthesis and Separation Processes Section  
Catalytic Processes Research Section  
Petro-Bio-refinery Processes and Recycling Section  
Industry Analytics and Biodegradation Section  
Electrochemical Processes Section  
Pilot installations Section

### Research topics

- ✓ New, sustainable processes and technologies for the chemical industry (including for the needs of modern biorefineries) balanced in terms of raw materials
- ✓ Recycling of metals and elements crucial to the development of the economy of Poland and Europe
- ✓ Processes and their components related to the Circular Economy (including those compensating for the deficit in the circulation of „elemental carbon” in the chemical industry)
- ✓ Clean and efficient technologies for energy generation, transmission and storage – effective use of surplus energy from renewable energy sources
- ✓ Modern zero-emission fuels for means of transport, waste-derived energy carriers and hydrogen technologies
- ✓ Electromobility, electricity transformation, storage, generation, drives, intelligent charging infrastructure
- ✓ Aviation, military and space technologies: multifunctional protective layers and nanolayers
- ✓ Technologies increasing water retention in agricultural and urban areas
- ✓ Design and optimization of technological processes and production techniques, diagnostics, monitoring, control and management systems



## PHARMACY AND BIOTECHNOLOGY CENTER



### Pharmacy, Cosmetic Chemistry and Biotechnology RESEARCH GROUP

Bioactive Materials and Cosmetics Section  
Formulation Technologies Section  
Chemistry Section  
Genetic Engineering and Biosynthesis Section

### Research topics

Research and development of medications and products covering the following:

- ✓ low molecular weight drugs, APIs, dietary supplements, medical products, fortified foods, specialty foods
- ✓ medical biotechnology products in the drug therapies
- ✓ therapeutic solutions for antimicrobial drug resistance
- ✓ innovative antimicrobial agents, novel antibiotics, new polymers and their composites for use in medicine and pharmacy
- ✓ development and validation analytical methods

New medical technologies:

- ✓ diagnostic tests
- ✓ advanced materials, technologies for medical use, prevention and health protection

## Manufacturing plant (TECHNOLOGY PARK) for production of SOLID FORMS of MEDICINAL PRODUCTS

Modern technological facility (modernized in 2019) ensures the highest production standards, in line with the FDA and the EMA guidelines.

Clinical trials include:

- ✓ short series for rare diseases
- ✓ products for bioequivalence studies
- ✓ formulations for preclinical studies



**Pharmaceutical Analysis LABORATORY**

Quality Control Section  
Chemical Analysis Section  
Research Analytical Section  
Pharmacokinetics Section  
Microbiological Analysis Section

**Cooperation offer**

**Testing of active substances, medicinal products, excipients, pharmaceutical raw materials in accordance with Ph. Eur., USP, FP in GMP standard:**

- ✓ Certification of the series for compliance with GMP (certificate) in the field of quality control of medicinal products, active substances, auxiliary substances and raw materials
- ✓ Pharmaceutical availability for various pharmaceutical forms studies
- ✓ Stability studies of active substances and medicinal products
- ✓ Impurity profile analysis – detection, identification and quantification of contaminants
- ✓ Determination of trace elements (ICP-MS)
- ✓ Standardization of standards of active substances and their impurities
- ✓ Sterility test
- ✓ Examination of microbiological purity
- ✓ Testing of bacterial endotoxins
- ✓ Tests for efficacy of antimicrobial preservation and effectiveness of disinfectants
- ✓ Environmental monitoring of clean rooms
- ✓ Development and optimization of analytical methods
- ✓ Verification and validation of analytical and microbiological methods
- ✓ Validation of methods for the determination of substance residues in the washing process of the production line
- ✓ Transfer of analytical and microbiological methods

**Pharmacokinetic tests, including tests of the bioequivalence and bioavailability of medicinal products in the GLP standard**

- ✓ Study design
- ✓ Development or adaptation of a bioanalytical method for the determination of drug substances and/or metabolites in biological material
- ✓ Bioanalytical method validation in accordance with EMA requirements
- ✓ Testing biological material (HPLC, LC/MS/MS)
- ✓ Pharmacokinetic calculations (WinNonlin)
- ✓ Study documentation (CTD format Module 5)
- ✓ Expert opinions



Procedures and services intended for comprehensive analytical services for manufacturing processes of active substances and medicinal products as well as quality control analysis and bioequivalence tests.



## PHARMACEUTICAL PRODUCTS DEPARTMENT

### Cooperation offer

The Pharmaceutical Products Department ensures innovation and the highest quality in pharma production. We are a manufacturer of Active Pharmaceutical Ingredients (API), present in global markets, including the demanding Japanese market. We are the IP owner and MAH for BIODRIBIN® (cladribine) 1mg/ml – infusion solution.

We have two production departments in GMP standard – one handling gram-scale production up to 1 kg, and the other operating on a pilot-plant scale, enabling production up to 100 kg batches. As a Contract Development and Manufacturing Organization (CDMO) in the field of Active Pharmaceutical Ingredients (API), we offer flexible scaling-up production from grams to hundreds of kilograms, in accordance with the highest GMP standards.

Our pharmaceutical services include, among others:

- ✓ Development of API route of synthesis
- ✓ Substance production on a laboratory scale
- ✓ Development of manufacturing technology
- ✓ Analytical methods development
- ✓ Validation of analytical methods and manufacturing processes
- ✓ Production scale-up (from grams to hundreds of kilograms)
- ✓ Regulatory documentation development
- ✓ Active substance manufacturing / technology transfer
- ✓ API sales

With us, you gain a partner with experience, innovation, and advanced infrastructure in the dynamic pharmaceutical world.

### List of substances

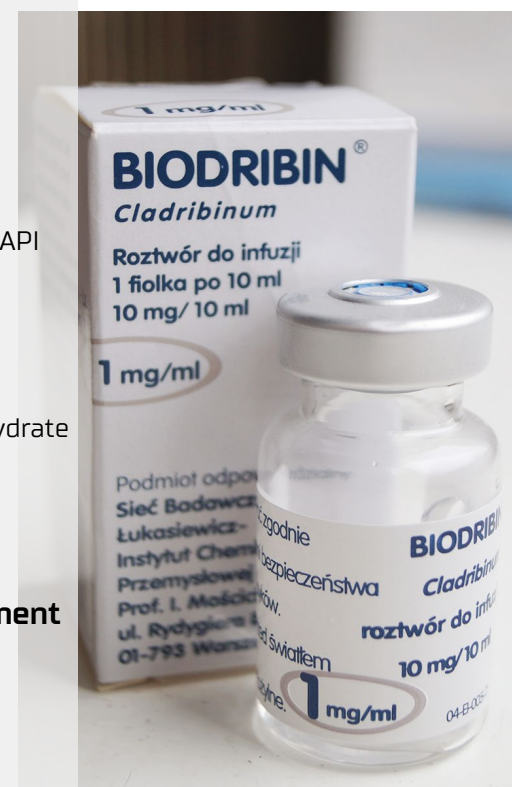
Alfacalcidol API (certificate CEP)  
Anastrozole API  
Brinzolamide API  
Calcifediol API (certificate CEP)  
Carvedilol API  
Cilostazol API  
(+)-Clopidogrel Hydrogen sulfate, polymorphic form I API  
Genistein synthetic API  
Imatinib mesylate polymorphic form I API  
Latanoprost API  
Nitrendipine API  
Olanzapine polymorphic form I API  
Paricalcitol API  
Pramipexole dihydrochloride, monohydrate API  
Tacalcitol API (certificate CEP)  
Cladribine API

### Technologies ready for deployment

Calcitriol API (certificate CEP)

### Medicinal product

BIODRIBIN®



## CERTIFICATES



### ✓ Certificate of GMP compliance of a manufacturer

Confirming the quality of manufacturing operations of API: Alfacalcidol, Calcifediol monohydrate, Calcipotriol anhydrous, Paricalcitol, Brynzolamide  
Publisher: Chief Pharmaceutical Inspectorate (GIF)  
No: IWSC.405.23.2019.ES.1-1/WTC/0079\_01\_02/133

### ✓ Certificate of GMP compliance of a manufacturer

Confirming the quality of manufacturing operations of active substances: Carvedilol, (+)-Clopidogrel bisulfate  
Publisher: Chief Pharmaceutical Inspectorate (GIF)  
No: IWSC.405.5.2020.ABU.1/WTC/0079\_01\_02/22

### ✓ Certificate of GMP compliance of a manufacturer

Confirming the quality of a medicinal product intended for humans.  
Publisher: Chief Pharmaceutical Inspectorate (GIF)  
No: IWSC.405.102.2022.IP.2/WTC/0079\_01\_01/238  
No: IWPS.405.102.2022.IP.1/ WTC/0079\_01\_01/237  
No: IWPS.405.118.2022.OP.1/ WTC/0034\_01\_01/260

### ✓ Certificate of GMP compliance of a manufacturer

Veterinary medicinal products  
Publisher: Chief Pharmaceutical Inspectorate (GIF)  
No: IWPS.405.9.2020.AL.2 WTC/0034\_01\_01/149

### ✓ Good Laboratory Practice (GLP) certification

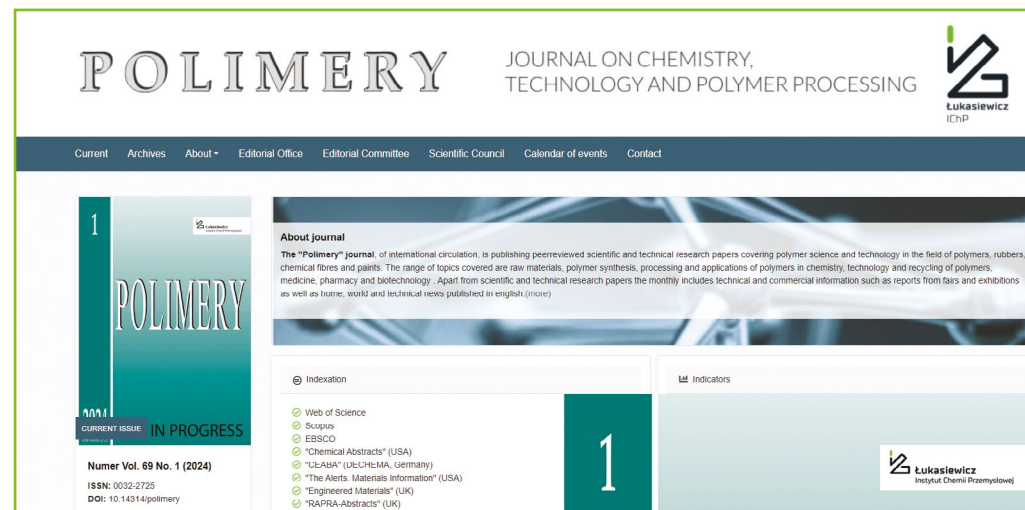
Confirming the quality of pharmacokinetic and bioanalytical studies, including equivalence and bioavailability studies.  
Publisher: Bureau of Chemical Substances  
No: 6/2022/DPL

### ✓ Accreditation in Japan

Accreditation of a foreign manufacturer of medicinal products  
Publisher: Ministry of Health, Labor and Welfare of Japan  
No: AG22300014



We confirm quality, effectiveness and safety

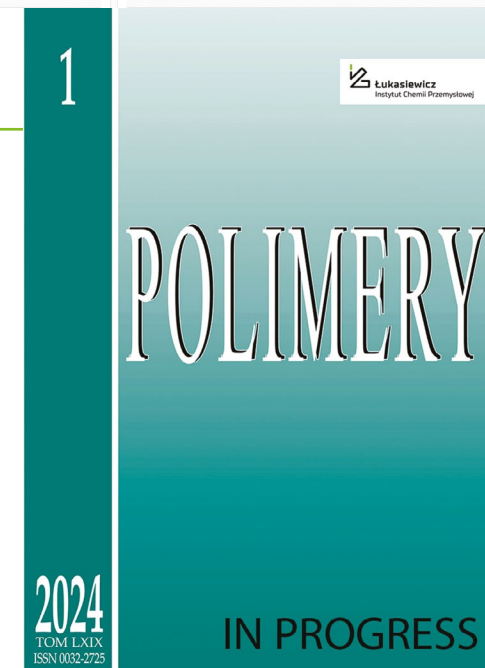


## POLIMERY journal

The „Polimery” journal, of international circulation, is publishing peerreviewed scientific and technical research papers covering polymer science and technology in the field of polymers, rubbers, chemical fibres and paints. The range of topics covered are raw materials, polymer synthesis, processing and applications of polymers in chemistry, technology and recycling of polymers, medicine, pharmacy and biotechnology.

Apart from scientific and technical research papers the monthly includes technical and commercial information such as reports from fairs and exhibitions as well as home, world and technical news published in english.

- ✓ IF 1.6 (2022)
- ✓ IF 5 1.2 (2017-2021)
- ✓ SNIP 0.342 (2022)
- ✓ CiteScore 3.5 (2022)
- ✓ SJR 0.229 (2022)
- ✓ MEIN 100 (points)
- ✓ Index Copernicus 172,41 (2021)
- ✓ h5index (Google Scholar) 31



## CHEMICAL SAFETY DIVISION



### TRAININGS AND WORKSHOPS on REACH and CLP

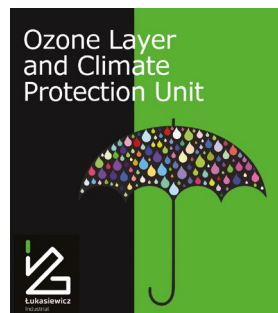
- ✓ General REACH and CLP trainings
- ✓ Trainings dedicated to companies of a specific industry (manufacturers, downstream users, distributors of substances, mixtures or articles)
- ✓ Workshops on classification in accordance with the CLP Regulation
- ✓ Workshops on preparing safety data sheets

### ADVICE, CONSULTATIONS, AUDITS, EXPERTISES, OPINIONS

- ✓ Compliance with REACH and CLP Regulations
- ✓ Marketing of substances, mixtures and articles
- ✓ Restrictions on marketing of substances, mixtures and articles (REACH Annex XVII, Annex XIV)
- ✓ Requirements for articles (SVHC, notification of substances in articles)

### REACH and CLP SERVICES

- ✓ Safety data sheets (preparation, updating, verification of correctness)
- ✓ Registration of substances in accordance with the REACH Regulation
- ✓ Updating of registration dossier
- ✓ Classification of chemical substances and mixtures (also verification of correctness, etc.)
- ✓ Labeling (preparation based on safety data sheet, correctness evaluation, updating, etc.)
- ✓ Notification of substances to the C&L Inventory
- ✓ Zgłoszenie mieszanin przeznaczonych do zastosowań przemysłowych do Inspektora ds. Substancji Chemicznych na portalu ELDIOM
- ✓ Notification of mixtures in accordance with Annex VIII to the CLP Regulation – PCN (Poison Center Notification)
- ✓ Product technical sheets (drafting based on the original, verification)



## OZONE LAYER AND CLIMATE PROTECTION UNIT (OLCPU)

The main goal of OLCPU is to ensure the fulfillment of Poland's obligations resulting from Montreal Protocol and European and national legislation on ozone depleting substances (ODS) and fluorinated greenhouse gases (F-gases).

### Coverage

- ✓ Managing the Central Registry of Equipment Operators (CRO) and Database of Reports (BDS); conducting the analyzes and studies of data contained in CRO and BDS
- ✓ Performing the current recommendations of the European Union in the field of controlled substances and fluorinated greenhouse gases
- ✓ Acting as a contact point for national entities and the European Commission
- ✓ Preparation of reports and documentation resulting from European Union legislation that are required to be submitted to the European Commission
- ✓ Conducting the analyzes and studies commissioned by public administration bodies (other than the minister responsible for the environment), economic local government organizations and employers' organizations

OLCPU operates in the Łukasiewicz Research Network – Industrial Chemistry Institute, performing the tasks of the Institute as a specialized unit indicated in art. 17 of the Polish Act on substances that deplete the ozone layer and on certain fluorinated greenhouse gases of May 15, 2015 (revised version published in Polish Journal of Laws of 2020, item 2065).







**Łukasiewicz**

Industrial  
Chemistry

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**PASSION  
CREATIVITY  
COURAGE  
RELIABILITY**

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