

SUSTAINABLE FUTURE STARTS WITH CHEMISTRY

PHARMACY



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Industrial
Chemistry
Institute



OFFER

Research and development of APIs, pharmaceuticals and related products

Laboratory and semi-technical scale API development

Development of medicinal and health-promoting products

Dietary supplements and foods for special purposes

Scale-up of API manufacturing processes with full validation

Commercial API production – batch sizes from grams to several hundred kilograms (accreditations (Japan), ASMF dossier, GMP, CEP certificates)

Manufacturing of active substances, investigational medicinal product and medicinal product (GMP)

Pharmaceutical analysis

LABORATORY AND SEMI-TECHNICAL SCALE API DEVELOPMENT

development of active substance (API) synthesis and technology pathways,

production of API impurity standards, production of polymorphic forms for API substances

development of innovative small-molecule drug substance technologies

on laboratory and large-scale and research into finding new compounds with biological activity

synthesis planning, laboratory trials, minisynthetic and semi-technical scale

production technology development

scaling with process validation

preparation of registration dossiers (ASMF, CTD)

carrying out a variety of chemical

(synthesis, catalytic reduction, oxidation, condensation, cyclization) and physicochemical processes (micronisation, crystallisation, large-scale liquid chromatography, fractional distillation) in qualified process equipment and installations

DEVELOPMENT OF MEDICINAL AND HEALTH-PROMOTING PRODUCTS

innovative, generic, value-added drug technologies (combo products, new form / route of administration, reduced dose, modified release)

innovative personalised forms for selected audiences (e.g. paediatric, geriatric)

preparation of IMPD, registration dossiers (CTD) and others

development of formulations and manufacturing technologies

for medical devices and dermocosmetic products, including: solid, semi-liquid and liquid formulations (tablets, capsules, syrups, liquids, ointments, creams, ophthalmic drugs)

post-authorisation changes to the marketing authorisation for medicinal products

(change of API supplier, excipient, packaging, change of batch size, etc.) – full range of cooperation



FOOD SUPPLEMENTS AND FOODS FOR SPECIAL USES

proprietary biologically active substances

of natural origin, synthetic and biotechnologically modified

encapsulation systems for bioactive plant compounds

improved bioavailability of active substances, protection against degradation

controlled delivery and release technologies, transport systems for active substances

personalisation of supplementation

in response to the specific needs of different consumer groups

technologies based on pharmaceutical standards (quality certification, confirmed composition and purity, standardisation of active substances and production methods)





SCALE-UP OF API MANUFACTURING PROCESSES WITH FULL VALIDATION

COMMERCIAL PRODUCTION OF APIs

**commercial production
of APIs** (in batches
from grams to several
hundred kilograms)

**contract
manufacturing of APIs**

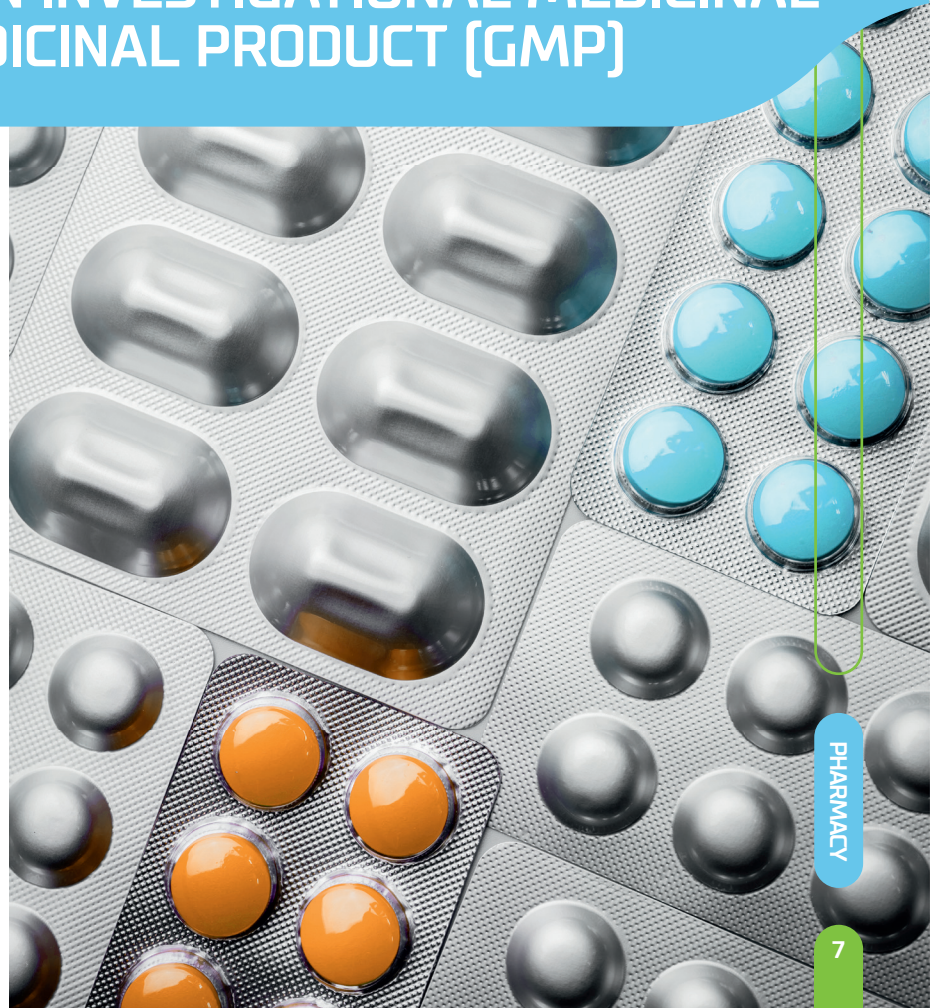
MANUFACTURE OF AN INVESTIGATIONAL MEDICINAL PRODUCT AND A MEDICINAL PRODUCT (GMP)

manufacturing the placebo and the investigational medicinal product

blinding and repackaging
of the investigational medicinal product, as well as storage and distribution to research centres

technological facilities for the manufacture of small batches of drugs
(bioequivalence studies, rare diseases, orphan drugs)

responsible entity for the drug Biodribin® (indicated in hairy cell leukaemia)



PHARMACEUTICAL ANALYSIS

safety assurance on the quality of APIs and finished products

equivalence and bioavailability studies for medicinal products in the GLP standard

testing for asepsis, microbiological purity, efficacy of antimicrobial protection, presence of endotoxins

development, optimisation, verification and validation of analytical and microbiological methods

batch certification for GMP compliance (certificate) for quality control of medicinal products, active substances, excipients and raw materials

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

standardisation of standards for active substances and their impurities

transfer of analytical and microbiological methods

pharmaceutical availability studies for various pharmaceutical forms

impurity profile testing
- detection, identification and quantification of impurities in accordance with the requirements of pharmacopoeial monographs (USP, Ph. Eur., FP) and ICH, EMA, FDA

monitoring of surfaces and air in classrooms

OUR API – REGISTRATIONS IN THE WORLD



VALUES

We work with passion, based on:

Professionalism

Commitment

Reliability

Partnership

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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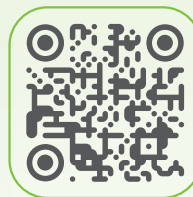
Industrial Chemistry Institute

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

LET'S MEET!

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