



HIGHEST QUALITY ACTIVE PHARMACEUTICAL
INGREDIENTS (APIS)
SINCE 1980



FOCUS ON RESPIRATORY

High-added-value active pharmaceutical ingredients
for use in respiratory therapies such as:

- ARFORMOTEROL · FORMOTEROL
- GLYCOPYRROLATE · INDACATEROL
- SALMETEROL · TIOTROPIUM



13 RESPIRATORY APIS
FOR INHALATION

In continuous international expansion since 1998, Inke provides full support to its customers worldwide



9 CEPs
GRANTED



13 DMFs
FILED



8 DMFs
FILED



7 DMFs
FILED



4 DMFs
FILED



IN-HOUSE MICRONISATION

More than 20 years' experience in **micronisation**

We have built this capability in-house to ensure quality results from our customised products



Inke is part of Neuraxpharm, a leading European specialty pharmaceutical company in the treatment of central nervous system disorders (CNS).

Neuraxpharm develops and commercializes branded and generic CNS pharmaceuticals and nutraceuticals related to the prevention of CNS indications.

Additionally, through its manufacturing companies Inke and Lesvi, Neuraxpharm has an international presence in more than 50 countries. It provides industry partners with niche active pharmaceutical ingredients (APIs) and finished dosage forms (FDFs) across multiple technologies.

MANUFACTURING ASSETS

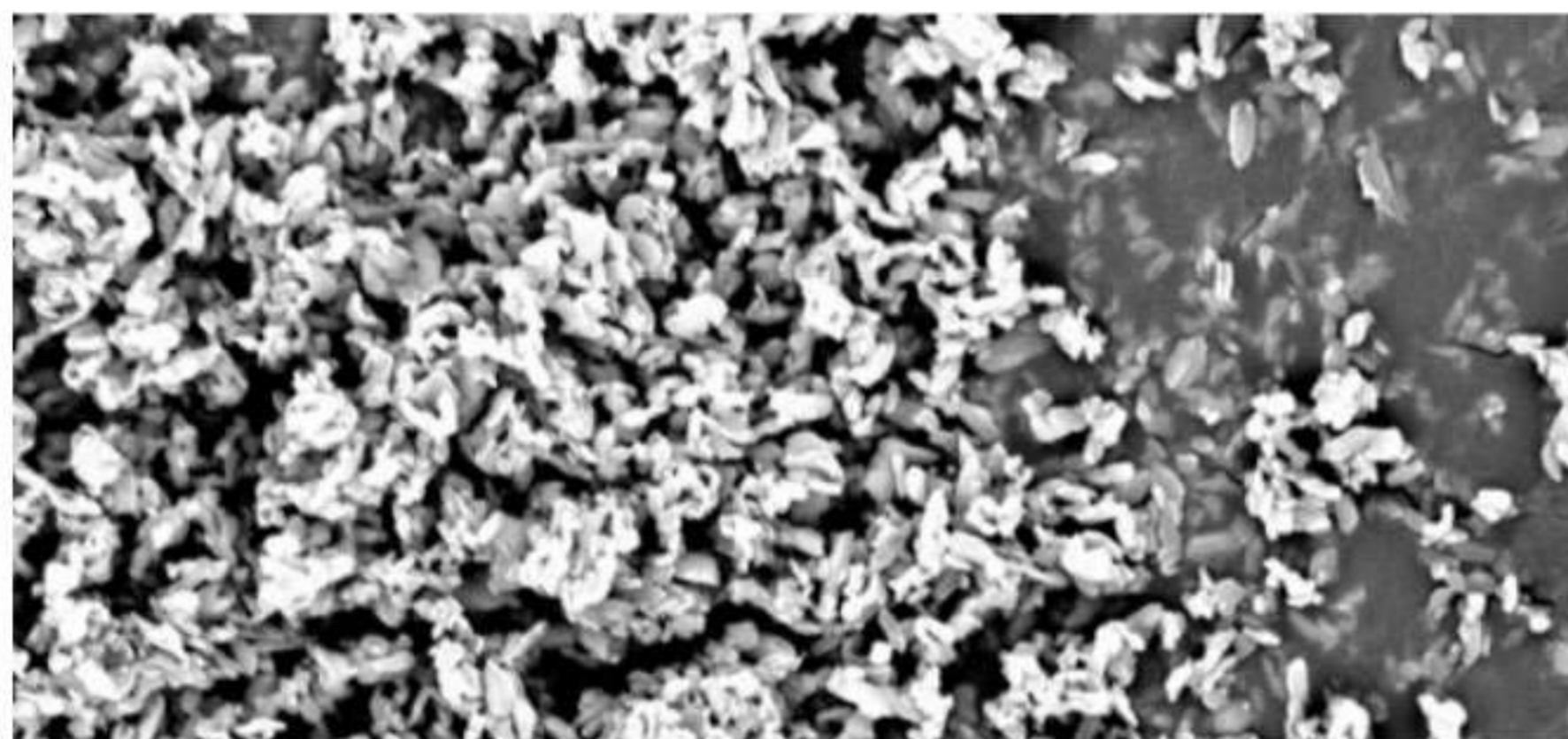


API MANUFACTURER

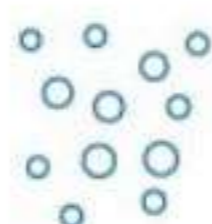
Inke's manufacturing plant specialises in the development of APIs with complex synthesis and extremely high GMP requirements



CAPABILITIES



- Manufacture of active ingredients in batches ranging from 1 to 300 kg
- Ability to perform all types of organic synthesis reactions (hydrogenation, reduction, oxidation, etc.) within a temperature range from -70°C to 200°C and pressures from 0 to 20 bar
- Over 20 years' experience in in-house micronisation technology
- Final isolation operations (centrifuging, filtering, drying, screening, micronisation and supplying) are performed in controlled environment rooms and allow the quality of the manufactured products to be adjusted to customers' needs



BROAD RANGE OF CHEMICAL REACTIONS

REACTIONS

- Organometallic chemistry
- Grignard reactions
- Organolithium
- Cyclization
- Friedel-Crafts

- High temperature reactions
- Hydrogenation (catalytic)
- Oxidation (H₂O₂, peracid...)
- Reduction with hydrides

HANDLING OF HAZARDOUS CHEMICALS

- Alkylating agents
- Bromine
- Chlorinating agents (SO₂Cl₂, SOCl₂, POCl₃, PCl₅)
- Hydrochloric acid gas

- Lewis acids (BF₃, AlCl₃...)
- Metal hydrides

INDEPENDENT AREAS

Charging, Sampling, Discharging, Drying, Sieving, Micronising, Milling and Packaging operations are carried out under environmentally controlled conditions (ISO 7) to keep contamination risks under control



IN-HOUSE MICRONISATION

Our manufacturing plant has full capabilities and qualified on-site experts who carefully oversee the process backed by more than 20 years of experience in micronisation

INKE IS ABLE TO PROVIDE SOLUTIONS FOR EARLY MARKET ENTRY OPPORTUNITIES OR FOR PRODUCTS REQUIRING IN-DEPTH KNOWLEDGE OF MICRONISATION TECHNIQUES



IN-HOUSE MICRONISATION EXPERTISE

Our experience in in-house micronisation technology at Inke means we can provide:

Isolation, final treatment and analysis of active ingredients for use in respiratory therapies performed in special containment facilities

Process control of micronisation grades achieved to ensure that each active ingredient conforms to custom particle size distribution specifications

Control of amorphous content and other relevant parameters for particle size stability for suitable formulation purposes

Customised products and technical support

Various patent applications



INKE

has more than 20 years of experience in differentiated micronisation capabilities

DRY MICRONISATION,

SINCE 2016, INKE HAS BEEN DEVELOPING WET MILLING, AN ALTERNATIVE APPROACH TO DRY MICRONISATION





INNOVATION

Our R&D area is made up of a team of highly-qualified experienced professionals specialised in the development of active pharmaceutical ingredients (APIs)



API DEVELOPMENT

In-house laboratories where professionals with a high level of training and experience develop and refine the processes for final transfer to Inke's manufacturing plant

Expert in customising products (PSDs) to meet each customer's technical and regulatory needs during the development and commercialisation of its medicinal products

EARLY MARKET ENTRIES

Early market entries in those regions without product patent constraints through



Patented synthetic processes (non infringing or improvement patents)



New patented polymorphic forms and salts



Independent expert reports validating our strong patent position

INKE DEVELOPS PATENTS AND IMPLEMENTS ITS OWN SYNTHETIC ROUTES AND POLYMORPHIC FORMS FOR THE MANUFACTURING OF ACTIVE PHARMACEUTICAL INGREDIENTS



INKE IS ABLE TO PROVIDE SOLUTIONS FOR EARLY MARKET ENTRY OPPORTUNITIES OR FOR PRODUCTS REQUIRING IN DEPTH KNOWLEDGE OF MICRONISATION TECHNIQUES

LEADERSHIP IN APIs

Inke is among the top 10 European API pharmaceutical manufacturing companies with

“THE HIGHEST NUMBER OF EUROPEAN PATENT FILINGS”