



Your Partner for Contract Synthesis

SANOCHEMIA
Pharmazeutika AG

The Specialty Pharma Company



Sanochemia Your API Partner

Advanced | Professional | Innovative

In depth

Sanochemia is committed to setting new benchmarks in the search for excellence in the API and intermediate fields of the pharmaceutical industry. Our focus on selected areas has allowed us to achieve a unique level of expertise, and to consistently push forward the boundaries of possibility to offer leading-edge qualitative standards and technologies in:

- Chiral synthesis and resolution
- Hydride reactions
- Heterocyclic chemistry

In breadth

Our constantly upgraded facilities are fully cGMP and FDA compliant. Cutting-edge multi-purpose synthesis installations and extensive ancillary facilities are in place to enable us to offer a wide range of contract synthesis development and manufacturing services including:

- Technology, route & process development
- Scale-up – from grams to commercial-scale manufacturing

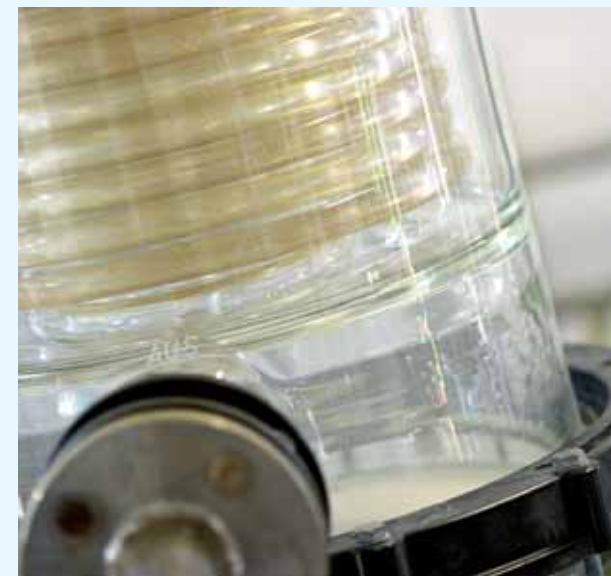


In tune

Drawing on our own experience in marketing pharmaceuticals, we at Sanochemia are well aware that there is a lot more to contract synthesis than merely scientific and technological input. Meeting our customer's synthetic requirements is just one link in a chain of service provision and commitment we regard as essential to forming long-term business partnerships. The other links:

- Information flow and technology transfer
- Confidentiality
- Dedicated project manager
- Site inspections
- An "open cards" policy

It is this multi-faceted approach, blending selected expertise and breadth with a corporate philosophy attuned to the needs of our customers, has made Sanochemia a unique niche player fit to be your Advanced Professional Innovative partner.





Sanochemia Your API Partner

Based in Vienna, Austria, Sanochemia Pharmazeutika AG specialises in the field of synthetic API research, development and manufacturing. The company has evolved to become a vertically integrated outsourcing partner with the experience and technology to meet all your synthesis requirements.

The company's primary focus is on the development and manufacture of innovative therapies for CNS disorders. Sanochemia was a forerunner in recognising the potential of extracted galantamine in the treatment of Alzheimer's disease and demonstrated its in-house expertise and dynamism by becoming the first and only economically viable source of the synthetic drug under worldwide synthesis patent protection.

An outstanding level of competence in complex chemical synthesis coupled with one of Europe's most modern plants has secured Sanochemia worldwide recognition in this field. This has culminated in a number of existing partnerships with the major pharma players more of which are in the pipeline.



In addition to the synthesis of its own products, Sanochemia has established an excellent reputation for contract manufacture from gram-scale to commercial manufacturing volumes in a cGMP compliant plant for active pharmaceutical ingredients. Production is accompanied by documentation procedures which not only meet current public health registration requirements, but which are constantly reviewed to ensure future compliance.

Its firm financial footing has enabled Sanochemia to invest heavily in the future not only in terms of its leading-edge synthesis and production facilities, but also in the company as a whole. A key facet of this corporate-wide approach has been funding and establishing a commitment to attaining a level of customer-orientation and service that sets us apart from others. The long-standing partnerships we aim to build are founded on a combination of competence, an open two-way exchange of



information, confidentiality, frequent updates, a dedicated project manager, site inspections and a policy of "playing with open cards". Should a problem arise, despite all our efforts to ensure against this, we commit to advise you and provide regular updates on progress towards a solution.

Our many years of experience in producing finished products are an extra component built into your API. We appreciate the growing demands the market is placing on producers and the importance of achieving cost-efficiencies and cutting time-to-market in order to maximise the potential of finished products.

The unique combination of the above factors has created an API synthesis contractor both equipped and prepared to meet the challenges of the pharmaceutical industry in the 21st century.

SANOCHEMIA – your API partner





Sanochemia Your R&D Partner

Our own research efforts have given rise to a wide range of existing products in our core therapeutic area, the central nervous system.

These have culminated in a research & development structure with the experience, equipment and focus to continue this trend.

Our expertise in chemical R&D enables us, for example, to establish best synthetic routes and ensure the successful realisation of industrial scale-up and production projects.

We offer outstanding levels of competence in the following complex organic synthesis fields:

- chiral synthesis and resolution
- hydride reactions
- heterocyclic chemistry



Sanochemia has established numerous successful and longstanding partnerships with academic research and external research institutions. These form the basis of research efforts to bring new products to market, but also to develop novel and cost-efficient routes and improvements in existing manufacturing processes.

A high degree of flexibility and rapid implementation are cornerstones of our research and development service provision.

A number of leading international figures in the CNS field serve on Sanochemia's Scientific Advisory Board providing R&D with invaluable strategic inputs.

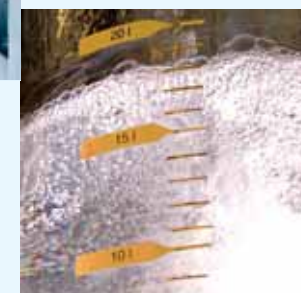
Our innovative technologies and procedures enhance and improve product quality to bolster the long-term success not only of Sanochemia, but also of its partners.

Sanochemia Your Scale-up Partner

Scale-up expertise: a critical factor in ensuring the success of commercial scale API production.



- Many years of scale-up experience underpin our guarantee that process optimisation will incorporate all safety and efficiency aspects.
- Our versatile technological facilities enable us to carry out highly specialised reactions.
- Software-based scale-up procedures generate perfect simulations of industrial scale production conditions.
- Standardised or customised QA systems ensure consistent qualitative standards from scale-up through to either in-house or external GMP production.
- Our scale-up processes make for a seamless transfer from lab-scale development to industrial manufacturing.





Sanochemia Your cGMP Partner



1 | GMP

cGMP compliance and beyond

- A well-established SOP system and skilled chemists with continuous GMP training ensure constant GMP compliance
- Qualification and validation of equipment coupled with process and cleaning procedures guarantee outstanding quality levels in the end product
- All equipment and related processes are documented using validated cutting-edge computer software
- Sanochemia is a supplier of APIs for FDA licensed pharmaceuticals

2 | Chemistry

Our industrial chemistry know-how

- Extensive and in-depth experience in standard chemistry technologies
- Chiral synthesis and resolution
- Handling of allergenic compounds and/or air sensitive reagents
- Synthesis at temperatures ranging from -35°C to $+150^{\circ}\text{C}$
- Wastewater and scrubber air treatment systems combine with audited waste disposal to ensure environmental protection compliant with the highest standards

3 | Technology

Superior core technologies for customised synthesis

- Multi-purpose reactors with volumes ranging from 600 L to 4000 L and a total reactor volume of 12 m^3 (to double soon)
- Full computerisation ensures adherence to the most stringent production and environmental standards
- Sophisticated ventilation systems ensure class 100,000 in all production areas throughout all processing steps
- Heat exchange systems make it possible to work safely with water- and air-sensitive reagents
- Special buck valve systems and anti-contamination chambers in the production areas enable us to safely handle irritant and allergenic substances
- Parallel production steps – reactors, centrifuges, driers and vacuum pumps – make it possible to conduct multiple reactions simultaneously and avoid cross-contamination.





Sanochemia Your QC Partner

Sanochemia's expertise in analytical R&D of active pharmaceutical ingredients is based on validated equipment and processes combined with leading-edge QC methods.

- Highly trained personnel with extensive experience in the development and validation of analytical methods including complex separation problems underpin chemical research throughout all product development stages
- Compliance has been established with all relevant pharmacopoeias
- Our validated data management procedures ensure well-documented files (CTD) which meet all existing filing requirements – including those of the FDA and EDQM.



Sanochemia Your QA Partner

For full compliance with best cGMP practice Sanochemia's Quality Assurance . . .

- commits to meet International Standards and to manufacture and supply consistent quality of all our products to achieve customer satisfaction and continual system improvements.
- strives to meet changing customer expectations, to enhance our employee contributions and to develop and retain our suppliers, in order to sustain our organisational performance.
- ensures continuous GMP and on-the-job training for our employees.





Contact

For further information or for an appointment to discuss your API requirements, please contact:

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