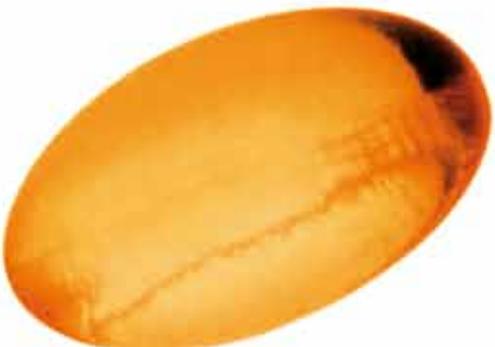


LIFE SCIENCE –
PHARMA

WACKER

CREATING TOMORROW'S SOLUTIONS

ENGLISH



Life Science – Pharma: The future depends on ideas. WACKER ranks among the world's most research-intensive technology companies. In our laboratories, we develop customized products and comprehensive technical support. This enables us to ensure new market potentials in this global growth sector, for today, tomorrow, and beyond.

Pharmaceutical Industry

4



Product Solutions for the Pharmaceutical Industry



6

Building Blocks

8

Auxiliaries

Services for the Biopharmaceutical Industry



10

Process
Development

11

Expertise

11

Quality
Management



13

Secretion
Technology

13

High-Cell-Density
Method

WACKER at a Glance

14



See also: www.wacker.com ▶ Products and Markets ▶ Life Science ▶ Pharma Industry

State of the Art Technology for the Pharmaceutical Industry

Pharmaceutical Industry

WACKER is an important pacesetter for the pharmaceutical industry. It is a leading producer of chlorine, ketene and silicon-based fine chemicals, of silicones, as well as biotech products such as the amino acid cysteine and cyclodextrins. In addition to specialized products such as building blocks and auxiliaries for organic synthesis WACKER also offers comprehensive contract manufacturing services. In exclusive partnerships with our customers, we produce active pharmaceutical ingredients in the highly innovative area of recombinant proteins (i.e. biologics). Here, we give our customers access to our fully integrated contract development and production for clinical test samples and commercial market supply.

We Care about You

WACKER subscribes to Responsible Care®. That's why we've compiled WACKER's healthcare guidelines for the proper use of silicones. These guidelines will give you an overview of the applications we support in this area. More information about this is available on the webpage: www.wacker.com/pharma, under "WACKER Healthcare Guidelines."

WACKER FINE CHEMICALS is a member of the Responsible Care® program and is certified to ISO 9001 and ISO 14001. Our Biologics Contract Manufacturing Service is available to you through Wacker Biotech GmbH. WACKER Biotech has a Good Manufacturing Practice (GMP) certificate and a GMP manufacturing permit from the local authorities.



Applications

Building blocks for organic synthesis
Formulations for pharmaceuticals
Active pharmaceutical ingredients
(antiflatulents)
Therapeutic proteins (e.g. for cancer)

Products

Amino acids (L-Cystine, L-Cysteine)
Carboxylic acids (acetic acid)
Chiral alcohols
Dimethicones
Esters
Heterocycles
Ketones (acetylacetone)
Organochlorines
Pyrogenic silicas
Recombinant proteins (biologics)
Silanes
Silazanes
Siloxanes
Simethicones

Services

Contract manufacturing of protein active
ingredients (biologics)
Process development (via ESETEC® or
DENSETEC® technology)

FOR INFILTRATION
epidural and cauda
Each mL contains
anhydrous 10 mg
methylparaben 1 mg
contain HCl and/or
65 (5.0 to 7.0).
dosage: See insert
temperature 15° to 3

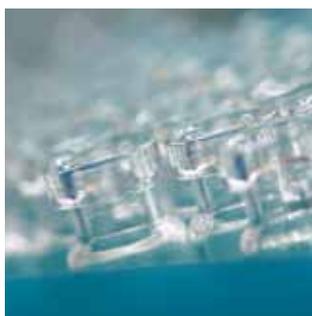
Innovative Product Solutions for the Pharmaceutical Industry

Building Blocks for the Synthesis of Pharmaceuticals

With a comprehensive product portfolio and many years of experience, WACKER has established itself as a reliable supplier of fine chemicals within the pharmaceutical industry. WACKER offers you a wide variety of products based upon the core technologies of chlorination, ketene reactions, synthesis of heterocycles, silane chemistry and enzymatic reductions. In addition to extensive expertise, a high level of backward integration is one of WACKER's significant strengths and gives our customers a large measure of supply reliability. Our main products include acetylacetone, chloroacetaldehyde, chloroacetones, hexamethyldisilazane and chloromethylsilanes. Our fine chemicals are deployed in organic synthesis as raw materials, building blocks and reagents. Furthermore, WACKER offers you specially engineered long-chain alkylsilanes (C8 – C18 hydrocarbon chains) for the production of chromatographic materials.

Top Quality Biotech Commodities

WACKER's portfolio of building blocks for organic synthesis also includes biotech products in addition to the fine chemicals derived from classical chemical manufacturing processes. Particularly important biotech products are the amino acids L-Cystine and L-Cysteine. L-Cystine is e.g. employed in the manufacture of expectorants such as N-acetylcysteine and S-carboxymethylcysteine. WACKER produces highly purified cystine and cysteine by a patented fermentation process, based on raw materials of vegetable origin.





Active Ingredients and Auxiliaries for Pharmaceutical Formulations

Many pharmaceuticals such as antifatulents would not be obtainable as they are impossible to produce without simethicones and dimethicones. For this purpose, WACKER has developed the SILFAR® product line. The raw materials we use in our SILFAR® products (simethicones and simethicone emulsions) are manufactured in accordance with GMP guidelines and meet the highest government quality standards.

Optimized Production

HDK® pyrogenic silica is an effective flow enhancer and an established processing auxiliary for the preparation of tablets. HDK® is used in production to prevent deposits on the tableting machines. As a component of tablets, HDK® promotes disintegration of the tablets by absorbing water. HDK® is used for rheology control in creams and pastes, and acts as an anti-caking agent and flow enhancer in powdered solid formulations. Because of its extreme purity, HDK® pyrogenic silica fulfills the requirements set by various international pharmacopeias.

Molecular Sugar Cones

CAVAMAX® cyclodextrins and CAVASOL® cyclodextrin derivatives are used for the controlled release of pharmaceuticals. These WACKER products, when complexed with an active agent, enhance that substance's solubility and bioavailability. Cyclodextrins are cyclic sugar molecules that have a hydrophilic (water-loving) outer surface and a lipophilic (fat-loving) interior cavity. This cavity can encapsulate other lipophilic molecules (e.g. pharmaceutical actives) as "guests". Molecular encapsulation improves the active agent's solubility in hydrophilic environments (such as within the body), which in turn, increases its bioavailability – i.e. the speed and extent to which the medication is resorbed by the body.

An Important Processing Auxiliary

L-Cysteine from WACKER is used as a high-quality processing auxiliary (redox agent) in the synthesis of active agents (e.g. insulin). It is produced according to a proprietary method, via fermentation from nonanimal and non-human raw materials.





Future-Oriented Services for the Biopharmaceutical Industry

Your Partner For Biologics Manufacturing

With more than 20 years of R&D competence in the field of microbial systems, WACKER is your qualified partner for the contract-manufacturing of therapeutic proteins (biologics). Our focus here is two-fold: the GMP-compliant development of stable and efficient processes, and our exclusive collaboration with you, in order to produce an innovative product suitable for the market. All the while, our top priority is integrated project management. In addition to the flexibility to take on projects at any stage, we have committed ourselves to delivering the highest quality of products and comprehensive services throughout the entire project, from process development, quality control and quality assurance, to production. Excellent, state-of-the-art technology is the key to your market success: ES-ETEC® E. coli secretion technology employs E. coli K12 for the effective, extracellular production of protein, and DENSETEC®, a high-cell-density fermentation process, produces space-time yields far greater than typical industry standards. Our technologies are also ideal for the production of antibody fragments – here, too, with exceptional yields.

Process Development

In our state-of-the-art production plants, we either work with our proprietary high-performance technologies or transfer your existing process to our facilities. All the while, our efforts are concentrated on providing a cost-effective and robust manufacturing process that can be validated and that maximizes yield. We offer multifunctional skills, including process control development, process parameter optimization, process scale-up and process validation, which we deliver in an integrated approach to ensure continued project success.

Expertise

Some of the comprehensive expertise we offer:

- Fast generation and optimization of cell lines
- Production and characterization of master and working cell banks
- Efficient process development and optimization
- Development and validation of analytical methods for process control
- Fermentation and purification technologies
- PEGylation of proteins
- Process validation including comprehensive documentation

Quality Management

Our GMP plant in Jena provides efficient and complete services for the development and manufacture of biopharmaceuticals – from clinical samples to commercial market supply. We will guide you competently through the validation of your process. Our quality assurance and control systems meet state-of-the-art technical standards for microbiology, biochemistry and analytical chemistry, and offer certified, product-specific analytical methods for protein characterization. As part of our quality assurance network, we focus on creating the required specifications for GMP-compliant implementation of work processes and validation tasks. An additional priority is meticulous employee training. Wacker Biotech has certificates from the relevant authorities for its GMP-compliant production of recombinant proteins. Our quality systems are continuously assessed by internal, customer and official audits.



ESETEC® E.coli Secretion Technology

The ESETEC® expression and secretion system developed and patented by Wacker Biotech is based on the E. coli K12 strain and a series of high-expression plasmids. The E. coli secretion strain can transfer proteins in native conformation across the outer cell membrane into the culture medium. It is extremely stable during fermentation and is routinely employed in commercial-scale production using fermenters with capacities of up to 4 m³. Product yields can already exceed 10 g/l. The ESETEC® E. coli secretion technology is ideally suited for antibody fragment production.

DENSETEC® High-Cell-Density Method

Our highly efficient processes with yields of up to 400 g wet biomass/liter are the result of decades of research and expertise in the high-cell-density fermentation of E. coli. Moreover, these fermentation processes developed by Wacker Biotech can be validated, and they permit high, reproducible yields. The DENSETEC® high-cell-density fermentation method already attains yields of more than 10 g/l of active product.

Conclusion

The combination of ESETEC® secretion technology and DENSETEC® high-cell-density fermentation accelerates process development and simplifies the purification procedure, thus ensuring that your products are manufactured efficiently and cost-effectively.

Expertise and Service Network on Five Continents

WACKER is one of the world's leading and most research-intensive chemical companies. In 2008, its sales totaled € 4.3 billion. Products range from silicones, binders and polymer additives for diverse industrial sectors to bio-engineered pharmaceutical actives and hyperpure silicon for semiconductor and solar applications. As a technology leader focusing on sustainability, WACKER promotes products and ideas that offer a high value-added potential to ensure that current and future generations enjoy a better quality of life based on energy efficiency and protection of the climate and environment.

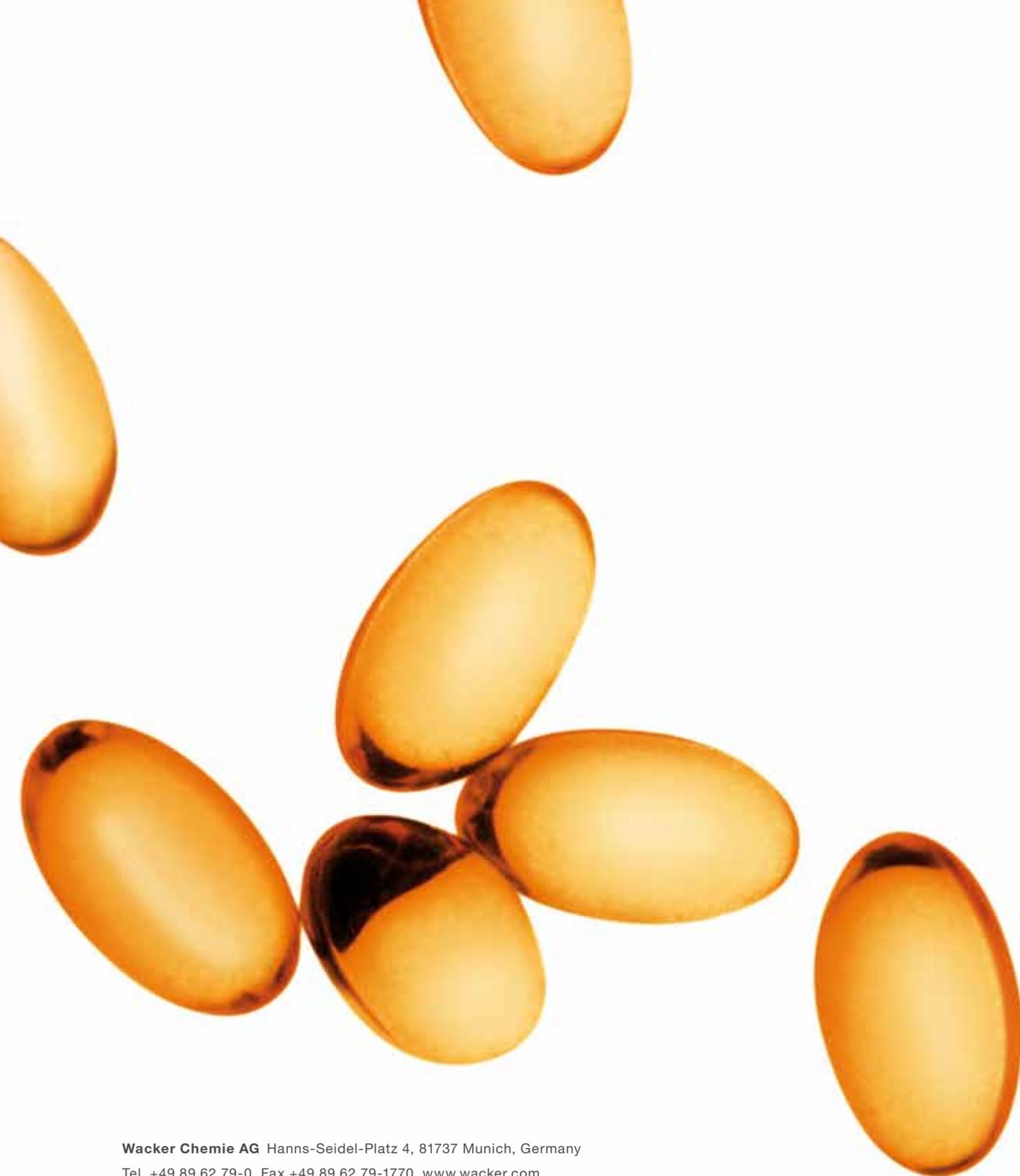
Spanning the globe via five business divisions, 27 production sites and over 100 subsidiaries and sales offices, we have established a presence in all key economic regions and growth markets. With a 15,900-strong workforce, WACKER sees itself as a reliable innovation partner that develops trailblazing solutions for, and in collaboration with, its customers. WACKER also helps them boost their own success. Our technical centers employ local specialists, who assist customers worldwide in the development of products tailored to regional demands, supporting them during every stage of their complex production processes, if required.

WACKER e-solutions are online services provided via our customer portal and as integrated process solutions. Our customers and business partners thus benefit from comprehensive information and reliable service to enable projects and orders to be handled fast, reliably and highly efficiently. Visit us anywhere, anytime around the world at: **www.wacker.com**



- Sales offices and production sites • Technical centers

WACKER Technical Centers: our worldwide state-of-the-art competence centers focus on finding the best possible solution for your needs. WACKER has 17 technical centers – in Adrian, Akeno, Allentown, Beijing, Burghausen, Dubai, Hikari, Hsinchu, Jandira, Kolkata, Melbourne, Moscow, Nünchritz, Portland, Shanghai, Singapore and Suwon.



Wacker Chemie AG Hanns-Seidel-Platz 4, 81737 Munich, Germany
Tel. +49 89 62 79-0, Fax +49 89 62 79-1770, www.wacker.com

The data presented in this brochure are in accordance with the present state of our knowledge, but do not absolve the user from carefully checking all supplies immediately upon receipt. We reserve the right to alter product constants within the scope of technical progress or new developments. The information given in this brochure should be checked by preliminary trials because of conditions during processing over which we have no control, especially where other companies' raw materials are also being used. The information provided by us does not absolve the user from the obligation of investigating the possibility of infringement of third parties' rights and, if necessary, clarifying the position. Recommendations for use do not constitute a warranty, either express or implied, of the fitness or suitability of the product for a particular purpose.

