ChemCon
Good Manufacturing Partner

Generic APIs

Organic, inorganic, and polymer chemistry
HPAPIs and controlled substances
cGMP process development
Analytical method development
Commercial manufacturing

We serve your individual product list and file a dossier for you!

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About ChemCon: Generic APIs on demand

ChemCon is a German research and manufacturing partner producing generic and novel APIs for various applications on demand. We are looking back on two decades of experience with cGMP process development and production and manufacture for multiple active DMFs. Generic APIs produced by ChemCon are used worldwide as material for the registration process and subsequently as commercial drug substances. Applications are, for example, oncology, ophthalmology, and emergency or postoperative care.

Although unusual in the generics business, we have deliberately decided against a product catalogue. Instead, our scientists will develop a process for the particular generic compound you require. The reason is our focus on niche products with a low annual demand in top cGMP quality that are otherwise difficult to source.
Our team is always prepared to take on generics that have not been part of our portfolio in the past. Beside APIs, ChemCon also produces advanced excipients, delivery agents, provocation substances, or dietary supplements (trace elements) to cGMP standards.

+ Special competences

You will benefit from ChemCon's multidisciplinary team of scientists, bringing comprehensive expertise in cGMP-compliant chemistry to your project:

- small-molecule organic substances
- inorganic substances
- polymers for medical applications
- HPAPIs and controlled substances
- purification/derivatization of natural compounds

+ cGMP process development and manufacturing

Our key competence is the development and validation of cGMP-compliant processes:

- route scouting and optimization or technology transfer
- establishment of a synthesis process
- seamless upscale from gram to multikilogram
- transfer to cGMP
- analytical method development and validation
- process validation
- manufacturing of registration batches
- commercial routine supply (grams to hundreds of kilograms per year)

+ Quality control

ChemCon's comprehensive and fully cGMP-compliant in-house analytical services ensure thorough quality control quality and process control.

- impurity profiles
- microbiological testing and monitoring
- analysis to monographs (e.g. Ph. Eur., USP)
- ICH-compliant stability studies

+ Quality assurance

ChemCon's independent quality assurance team ensures full cGMP compliance at any stage and attends your project with comprehensive regulatory support:

- registration documents
- CEPs for APIs with a pharmacopoeial monograph
- ASMFs and DMFs

Over 100 successful customer audits confirm ChemCon's quality assurance. ChemCon has been inspected by the FDA and European health authorities numerous times without deficiency.

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