ChemCon
Good Manufacturing Partner

Analytical Services

Comprehensive chemical testing for organic, inorganic, and polymeric substances:

- Chemical characterization
- Process monitoring
- Method development and validation
- Quality control and release
- Reference standards
- cGMP and ICH compliant

CHEMCON'S STORY

Chemical services for more than two decades

Initially operating as contract manufacturer of pharmaceutical ingredients, ChemCon started incorporating in-house analytical support very early on. Since 2016, ChemCon's comprehensive analytical services are also available to you independently from synthesis projects.

1992: ChemCon's roots date back to API synthesis at the University of Freiburg
1997: Dr. Vogler and Dr. Gockel found ChemCon
1998: API production (GMP) in own cleanroom facilities
1999: Development services are added
2000: First and successful FDA inspection
2001: In-house analytical services are established
2006: First and successful inspection by regional German authorities
2016: Analytical services are made available to external customers
2018: Most recent and successful FDA inspection

ChemCon – Analytical Services

Your partner laboratory for comprehensive chemical testing and release

Comprehensive, well-documented characterization and quality control is indispensable to develop, use, or sell cGMP-compliant active pharmaceutical ingredients (APIs) as well as high-quality fine chemicals. For more than two decades, ChemCon has been a reliable service partner for innovative development, manufacturing, and analytical solutions. We operate in the field of organic, inorganic, and polymer chemistry. The main focus lies on chemicals for pharmaceutical applications.
Our analytical chemists support you not only with routine testing but also with intelligent, tailor-made solutions to your challenges. The extent of analyses and documentation is individually adjusted to your requirements: From purity certifications of fine chemicals to fully cGMP-compliant release documentation of pharmaceutical ingredients.

We strongly believe in the benefits of a close partnership with instant and transparent communication: Project-based evaluations of the most suitable methods in agreement with you, as well as instant communication of results assure a transparent and efficient progress. You will receive a comprehensive report from ChemCon's quality control team. ChemCon's in-house quality assurance team releases your sample with documentation and certificates, if required.

Routine testing and beyond . . .

CHEMICAL ANALYSIS

ChemCon's equipment:

- NMR
  (400 MHz, quantitative, multinuclear, multidimensional)
- ICP–MS, ICP–OES
- HPLC (UV, DAD, RI, ELS, MS)
- GC and headspace GC (FID, NPD, TCD, MS)
- IC (suppressed conductivity)
- GPC (UV, RI, MALS)
- FT–IR (KBr, ATR, film)
- UV–vis photospectrometer
- reaction calorimeter
- rheometer
- titration equipment (including KF)
- MP, bulk density determination equipment
- TOC determination equipment
- ovens for LOD, ROI
- polarimeter
- equipment for microbiological control
- microscopes (classical and polarized-light)
- stability chambers

Characterization of components and reactions

Organic, inorganic, and polymeric substances

Characterization

Spectroscopic measurements, such as nuclear magnetic resonance (NMR), Fourier-transform infrared (FT–IR), near-infrared (NIR), or UV–visible (UV–vis) spectroscopy and their accurate interpretation are essential to identify your compound and to describe its molecular structure.
Substance-specific material properties, such as melting point (MP), density, solubility, or specific rotation, can be determined to fully characterize your compound. In addition, viscosity and rheological behavior can be determined, in particular for polymers. Titration is available for pH and pKa measurements.

Structure elucidation

Identifying unknown organic molecules is one of the most challenging tasks in analytical chemistry. ChemCon combines its expertise in advanced multinuclear and multidimensional NMR spectroscopy with complementary information from liquid chromatography mass spectrometry (LC–MS). The latter determines the molecular weight and fragmentation patterns of organic molecules.
NMR spectroscopy is also a powerful tool to determine the structure of polymers, and with diffusion-ordered spectroscopy (DOSY) low-molecular-weight components in your polymers can be determined.

Process control and monitoring

Between testing starting materials, intermediates, and products, ChemCon is able to support your synthesis development with in-process controls. Contact us for a quick and practicable arrangement.
Continuous process monitoring can be advantageous to better understand the thermodynamic and kinetic properties of chemical reactions and to determine safety limits for process scale-up. ChemCon offers reaction calorimetry with integrated IR spectroscopy, real-time calorimetry, as well as heat-flow, pH, and turbidity measurements.

QUALITY CONTROL

Reference standards:

Qualified reference standards are essential for many quality control methods. If you require standards that are not readily available, we can both synthesize and/or qualify reference standards for your substances. ChemCon combines the expertise and facilities of an analytical service provider with those of an experienced custom synthesis development and manufacturing organization:

- chemical synthesis
- isolation, purification, or enrichment of by-products or impurities
- comprehensive analysis
- qualification of reference standards

Quality control and release analysis

Fine-chemical or API release to your requirements

Method development and validation

For all technologies described in this brochure, ChemCon develops and validates analytical methods to your requirements, ensuring full compliance with cGMP and ICH guidelines. Of course you may also transfer your established methods for validation at our site or approach us for analyses according to current monographs.

Qualification of starting materials

The qualification of starting materials, in particular cGMP key starting materials, is becoming increasingly important. ChemCon uses all common quality control methods to analyze and release starting materials with full documentation for cGMP manufacturing.

Identity and purity testing

Your substances, intermediates, or starting materials are analyzed with identity tests against qualified reference standards (–› p. 6), quantitative, and limit tests.

Assays and impurity profiles are determined with high-performance liquid chromatography (HPLC) and gas chromatography (GC; GC-headspace). To test for ionic components, including common anions (chloride, bromide, phosphate, sulfate, nitrate) and cations (sodium, potassium, calcium, ammonium), ion chromatography (IC) is available. Polymers are analyzed with gel permeation chromatography (GPC). Following the size exclusion principle, this technology allows the separation of components by molecular mass as well as the quantification of residual monomer.

NMR spectroscopy, in particular quantitative NMR (q-NMR), provides a complementary method to chromatographic identity and purity determination. A particularly quick method of confirming identity and polymorphism is FT–IR spectroscopy.

Further confirmation of purity is obtained from loss on drying (LOD) and residue on ignition (ROI) measurements. The latter is also known as the sulfated ash test. Water content is quantified by Karl-Fischer titration (KF) including coulometric KF titration.

QUALITY CONTROL

Elemental analysis

The revised ICH Q3D guidelines for pharmaceutical ingredients require standard analysis for heavy metal impurities, which is available at ChemCon: Inductively coupled plasma mass spectrometry (ICP–MS) detects trace elemental impurities at concentrations down to parts per billion. Depending on analytes and matrix, inductively coupled plasma optical emission spectroscopy (ICP–OES), also known as inductively coupled plasma atomic emission spectroscopy (ICP–AES), can be used alternatively.

Of course, classic wet-chemistry methods widely established in elemental analysis are also available.

Impurity determination

Unknown impurities can delay the release of ultrapure fine chemicals or pharmaceutical ingredients and/or hinder the chemical process development on the way. Some impurities are easily determined with the above-mentioned methods. Others are more challenging and ChemCon will support you to select the most suitable techniques and to find satisfactory answers for your case. You will also benefit from the close in-house collaboration with our production team, set up to isolate, purify, or enrich impurities for analysis.

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Microbiological control

For microbiological monitoring and release, bioburden and endotoxin tests are performed on your substance. ChemCon additionally offers cleanroom monitoring and qualification by measuring surface and airborne microbiological contamination and airborne particles.

Aqua purificata

At ChemCon you can test the quality of your pure water for potential organic (total organic carbon, TOC) and microbiological contamination.

Release analysis

ChemCon provides you with comprehensive analysis and documentation to certify your substances for sale or for application as a pharmaceutical ingredient. All selected tests will ensure the clear determination of your required specifications according to validation protocols or international current monographs (including Ph. Eur., USP).
Drug substances and drug products for pharmaceutical application will be released by our independent quality assurance team, which reviews all related documentation before issuing your certificates of analysis (CoA) and compliance (CoC).

Stability studies

ChemCon's stability program comprises standard ICH Q1 protocols including long-term stability studies, stress and forced-degradation studies, photo stability tests, and temperature-cycle tests. Monitored stability chambers at all common temperatures and humidity are available.

QUALITY ASSURANCE

Inspection and audit history:

- FDA inspected successfully since 2000
- GMP inspected successfully by European authorities since 2006
- Successfully inspected regarding the safe handling of carcinogenic substances
- BImSchG (German Federal Immission Control Act) registration
- > 150 customer audits

Certificates issued by ChemCon:

- Certificates of analysis (CoA)
- Certificates of compliance (CoC)

Quality assurance and regulatory support

Trust is good – control is essential

As a partner for pharmaceutical, biotechnology, and chemical companies, quality is at the heart of ChemCon's activities. All our services are performed following or exceeding cGMP and ICH guidelines (in particular ICH Q7 and ICH Q3D, relevant for drug substances) and regulations for the protection of health, safety, and the environment. Internal audits ensure that each and every member of ChemCon's team is committed to current regulations at all times.

You will receive a comprehensive report for all analytical services. Certificates of analysis (CoA) will be issued, if required. All certificates of compliance (CoC) are released by a separate in-house team of quality assurance managers after thorough verification of results and documentation.
Our customers visit us on a regular basis to audit our facilities and quality systems. ChemCon has passed numerous inspections for GMP compliance by European and US authorities.
We have never received a critical observation in the company's history!

But there is more to your project than the quality control and quality assurance of your product. On demand, our regulatory affairs team attends your project with comprehensive regulatory support. For example, we can help you to file regional dossiers by providing all analytical results for your CMC section in the state-of-the-art eCTD or any other required CTD format.

CURIOUS?

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