Global Critical Materials Manufacturer for Pharmaceutical Applications

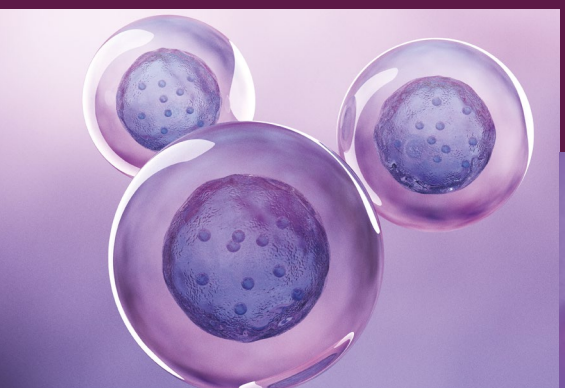
actylis

www.actylis.com

Actylis is a leading global supplier of niche, differentiated specialty materials for the life sciences and advanced technology end-markets.

With business operations in over ten countries, Actylis supplies over 4,000 chemical compounds used principally by the pharmaceutical, nutraceutical and specialty chemical industries.

Over the last 75 years, Actylis has established a leading distribution platform providing pharmaceutical intermediates and APIs that is now reinforced with R&D and manufacturing capabilities through our integrated centres of excellence facilities network in North America, Europe and India. Whatever your needs for regulatory starting material, active ingredients, early or late intermediates or excipients, for clinical or commercial manufacturing stages, we have a "Make or Buy" solution to propose.



Actylis' core competencies

- R&D & Custom Development
- GMP & Non-GMP Manufacturing
- Regulatory Compliance
- Supply Chain
- Global Sourcing
- Quality Assurance

Actylis Global Centres of Excellence

We are an industry-leading provider of products and advanced services to the small molecule marketplace. Chemistry is at the core of Actylis' DNA, and our recent acquisitions have only strengthened that competence.

With an R&D organization of over 50 individual facilities and 850+ staff globally, we provide customers with advanced development and contract manufacturing services globally, at both GMP and non-GMP.

Actylis also boasts a complete catalogue of GMP excipients, advanced intermediates, and generic APIs that can all be purchased as standard products or customized for your specific needs.

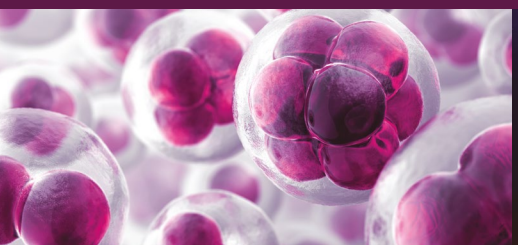
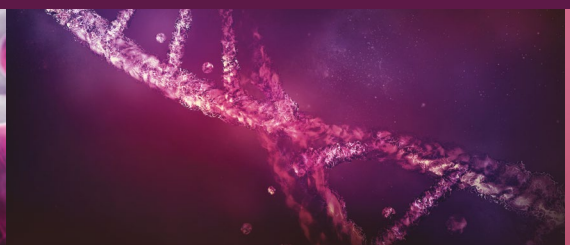
Actylis' Products and Services

Our Products

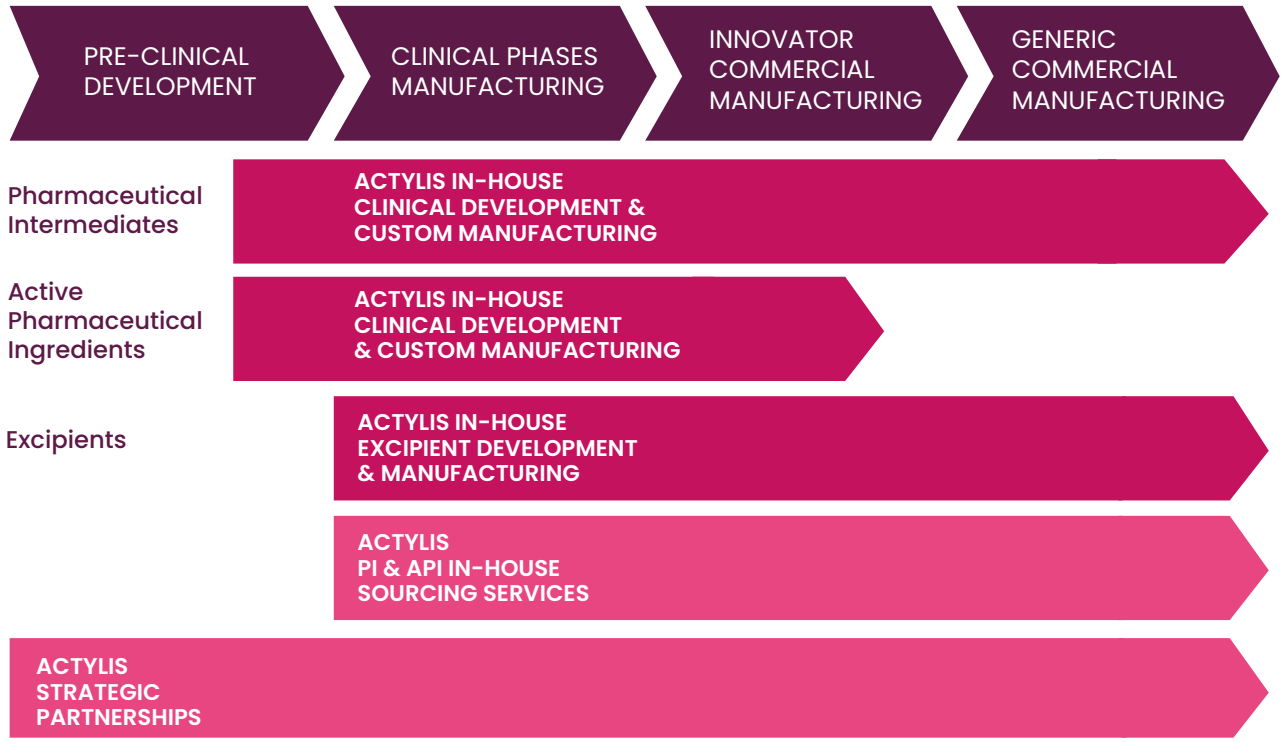
- Regulatory Starting Material
- Pharmaceutical Intermediates
- Active Pharmaceutical Ingredients
- Excipients

Our Services

- Contract R&D
- Contract Manufacturing
- Analytical Services
- Global Sourcing


Pharma Small Molecule Workflow



Contract R&D Services

Whether you need help with MedChem, expertise in new-route scouting and process R&D before manufacturing clinical supplies, Actylis offers GMP and non-GMP specialty chemical R&D services by generating robust, safe, cost-effective, environment friendly and scalable chemistry.

Over the years our R&D team of 50+ people globally have worked in many different classes of compounds from prostaglandins to heterocycles. We aren't afraid of lengthy syntheses with carbon-carbon bond formations, asymmetric syntheses, and development of protecting group strategies.

As agile project managers and involved problem solvers, our chemists are with your project from Day One and every step of the way from intermediates synthesis through to API manufacturing for clinical phases and commercial manufacturing.

Contract R&D Services

Our capabilities include

- **New Route Development**
  Our team's deep experience with retrosynthetic analysis provides thoughtful new approaches to synthetic route development.

- **Process R&D & Critical Process Parameters**
  Gain the flexibility and experience necessary to optimize a single reaction or rework of a 17-step synthesis

- **Medicinal Chemistry**
  Get help with new synthetic routes, intermediate synthesis, lead scale-up, and patent coverage.

- **Scale-Up**
  From gram scale to commercial GMP manufacturing.

- **Chemical Specialties**
  These include Transition Metal Catalysis, Asymmetric Synthesis, Heterocycles, Protecting Group Strategies, Solid Phase Synthesis, Polymerization and others.

Contract Manufacturing

Actylis maintains a robust infrastructure of highly qualified staff and ISO 9001:2015 certified equipment to handle all aspects of chemical manufacture including GMP custom manufacturing. Significant reactor capacity and equipment for the purification of products exists in North America and India to serve our customers on a contract basis for exclusive manufacture of pharmaceutical compounds.

We can provide a comprehensive tailor-made service, ensuring process development, optimization and commercial scale-up of processes are carried out in an efficient , cost-effective and batch-consistent manner. We can manufacture batch sizes ranging from <1kg to ton scale.

The company's comprehensive array of analytical equipment and expertise assures that a complete profile of our products is known. Client confidentiality is also an essential feature of Actylis' contract manufacturing business strategy.

Our Capabilities Include:

- GMP innovative API
- GMP excipients and process solutions
- Pharmaceutical intermediates
- Fine chemical raw materials

Analytical Services

Actylis performs routine and non-routine analytical testing for pharmaceutical products, in support of manufacturing processes, QA/QC functions, R&D projects, and environmental applications.

Leveraging state-of-the-art instrumentation, extensive knowledge base, as well as internal cross-functional competence, our capabilities include:

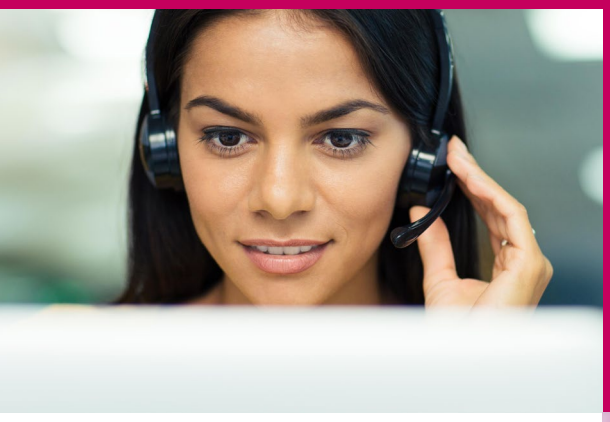
- **Method Development and Validation**
  Includes development of purity/impurity methods and wt/wt assays with phase appropriate validation
- **Quality Control Testing**
  Set specifications appropriate for the molecule and use testing to ensure that quality has been built into the system
- **Reference Standard Qualification**
  Synthesizing, purifying, and qualifying wt/wt reference standards, chiral standards, and impurity standards
- **Stability Studies**
  Includes forced degradation and stability indicating method development and packaging integrity evaluation
- **Impurity & Cold Label Standards**
  Essential step in meeting FDA standards, we provide the services of isolation, identification, characterization, and synthesis of process impurities, degradants, and metabolites

Partner Service Organization

At Actylis we believe our customers should be at the heart of every business decision we make and every department truly understands our customers' needs.

To align with this business approach we have developed the Partner Service Organization (PSO) approach. The PSO approach enables us to be a strong strategic partner for our global customers.

As a partner service organization, we encourage extensive communication between our various departments and those of our customers to ensure a full understanding of the project before commencing. Understanding the needs of our partners from the start allows us to find unique solutions to our clients' specific issues.



Why Work with Actylis?

- Responding rapidly and developing a deep understanding of customers' needs
- Knowing our customers' business intimately & understanding their challenges
- Offering a personalized service and tailored solutions as a result
- Creating strong and long-standing partnerships with our customers

Can’t find the product you need in our list?

Let us find the solution for you

Contact your local Actylis representative

Visit actylis.com

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