



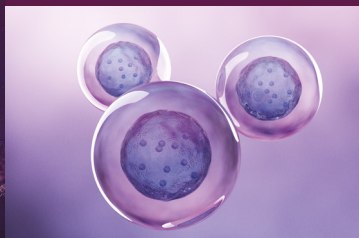
# Critical Materials for Biopharmaceutical Applications



# 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
- Supply Chain
- GMP & Non-GMP Manufacturing
- Global Sourcing
- Regulatory Compliance
- Quality Assurance



# Empower Your Business by Focusing on Your Core Competencies

Unlock unparalleled efficiency by reducing time, effort and transactional costs with our manufacturing, R&D capabilities, and global sourcing network.

We deliver high-quality, customized solutions while expertly solving your operational problems, eliminating the need for a dedicated sourcing office, freeing you to focus on your core competencies –driving innovation, fostering growth, and achieving market success.



## Our Products

- Excipients
- Buffers
- Process Solutions
- Amino Acids & Cell Culture Ingredients
- APIs

## Our Services

- GMP Custom Ingredient Development
- GMP Custom Manufacturing
- GMP Custom Packaging
- Regulatory Support
- Analytical Services

# GMP Custom Ingredient Development & Manufacturing

We can fulfill the need for custom or novel raw materials development through a practical process development approach at one of our global R&D centres of excellence.

We utilize one of the world's leading project management tools to provide cost-effective, robust and timely solutions for all of our partners.

Should you require a specific excipient or other raw material to be manufactured within a fully compliant GMP process, we offer this service with transparency and full supporting documentation.

Once the process development is completed and validated, the product is manufactured, packaged and released under full GMP compliance.

All products will be supplied with a full dossier of documents to support your regulatory filings.



We specialize in providing tailored solutions through an innovative and highly personalized approach.

# GMP Custom Packaging

At Actylis we understand the need of the biopharmaceutical manufacturers for batch-specific packaging to reduce risk and waste, and ensure product integrity.

We offer a variety of custom GMP packaging formats meeting FDA packaging requirements, and batch-specific container sizes for both liquids and powder raw materials. Volumes and specifications are defined to meet customers' specific requirements.

Product packaging is completed in an ISO Class 8 cleanroom environment.

Custom GMP packaging formats range from 100 ml to 1,000 L, and include:

- **Glass Bottles (Clear & Amber)**
- **Plastic Drums HDPE (Various Formats)**
- **Stainless Steel Drums (Various Formats)**
- **Single-Use Bioprocess Bags**
- **IBCs**



# Quality & Supply Chain

Actylis is renowned for its high quality standards and provides full transparency in the supply chain, which is vital for compliance with GMP and GDP.

We provide regulatory support for all products by having a full product dossier, including a detailed supply chain statement (available upon request). Customers are notified of significant changes through a strict change control program.

We hold all the major certifications and applicable licences from the main accreditation bodies and agencies:

- **ISO 9001:2015**
- **EXCiPACT (GMP and GDP)**
- **Drug Establishment Licenced for manufacture of APIs**
- **FDA and Health Canada audited**



# Analytical Services

Actylis performs routine and non-routine analytical testing for biopharmaceutical 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 in chemical R&D and chemical manufacturing, Actylis consistently exceeds customers' expectations.

## ■ Full compendial testing

Standard analysis required by ASTM, USP, EP, JP, BP, FCC, AOAC and other regulatory methods

Analytical equipment includes Amino Acid Analyzer, HPLC, LC-MS, GC-MS, ICP-AES, and others

## ■ Stability study on formulated products and raw materials

Material degradation

Shelf-life evaluation

Packaging integrity evaluation

## ■ Product-related impurity characterization

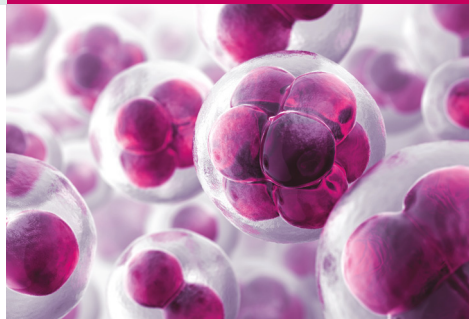


# Partner Service Organization

At Actylis, we understand the critical need for tailored solutions for our biopharmaceutical customers. To align with this, we have developed the Partner Service Organization (PSO) approach which enables us to be a strong strategic partner for our customers.

Understanding our partners' needs from the start allows us to find unique solutions to their specific challenges.

We encourage extensive communication between our various departments and those of our customers to ensure a full understanding and smooth progress of projects at all times.



Actylis' global GMP manufacturing facilities allow us to complete a variety of projects simultaneously with rapid response and completion times. Thanks to our PSO approach, our partners experience R&D, project management, GMP documentation and production lead times that surpass the industry norm.



## Actylis Ingredients for Biopharmaceutical Applications

Product	CAS No.
<b>AMINO ACIDS</b>	
Glycine	56-40-6
L-Alanine	56-41-7
L-Arginine	74-79-3
L-Aspartic Acid	56-84-8
L-Cysteine	52-90-4
L-Cystine	56-89-3
L-Glutamic Acid	56-86-0
L-Glutamine	56-85-9
L-Histidine	71-00-1
L-Isoleucine	73-32-5
L-Leucine	61-90-5
L-Methionine	63-68-3
L-Phenylalanine	63-91-2
L-Proline	147-85-3
L-Serine	56-45-1
L-Threonine	72-19-5
L-Tryptophan	73-22-3
L-Tyrosine	60-18-4
L-Valine	72-18-4

Product	CAS No.
<b>AMINO ACIDS DERIVATIVES</b>	
N-Acetyl-DL-tryptophan	87-32-1
N-Acetyl-L-tyrosine	537-55-3
L-Arginine Monohydrochloride	1119-34-2
L-Cysteine Hydrochloride Monohydrate	7048-04-6
L-Glutamic Acid Monosodium Salt	6106-04-3
L-Histidine Hydrochloride Monohydrate	5934-29-2
L-Lysine Hydrochloride	657-27-2
L-Asparagine Monohydrate	5794-13-8
L-Glutathione reduced	70-18-8
Cysteamine HCl	156-57-0

If the desired grade of product is not listed or you have interest in a product not listed, please contact our sales team

Product	CAS No.
<b>CHELATING AGENTS</b>	
EDTA	6381-92-6
Ethylenediamine	107-15-3
Citric acid anhydrous	77-92-9
Citric acid monohydrate	5949-29-1
Trisodium citrate dihydrate	6132-04-3

Product	CAS No.
<b>CARBOHYDRATES</b>	
Sucrose	57-50-1

Product	CAS No.
<b>SURFACTANTS</b>	
Propylene glycol	57-55-6
Polyethylene glycol	25322-68-3
Polysorbate 20	9005-64-5
Polysorbate 80	9005-65-6
Sorbitan trioleate	26266-58-0
Benzalkonium chloride 50% Solution	8001-54-5
Benzethonium Chloride	121-54-0
Cetrimonium Bromide	57-09-0

Product	CAS No.
<b>BIOLOGICAL BUFFERS</b>	
BIS TRIS	6976-37-0
HEPES	7365-45-9
Hepes Sodium Salt	75277-39-3
MES Monohydrate	145224-94-8
MOPS	1132-61-2
MOPS Sodium	71119-22-7
Tricine	5704-04-1
Tris (Hydroxymethyl) Amino Methane HCl	1185-53-1
Glycyl-Glycine	556-50-3
MOPSO	68399-77-9

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Product	CAS No.
<b>BUFFERS &amp; SALTS</b>	
<b>Phosphates</b>	
Sodium Phosphate Monobasic Anhydrous	7558-80-7
Sodium Phosphate Monobasic Monohydrate	10049-21-5
Sodium Phosphate Monobasic Dihydrate	13472-35-0
Sodium Phosphate Dibasic Anhydrous	7558-79-4
Sodium Phosphate Dibasic Heptahydrate	7782-85-6
Potassium Phosphate Monobasic	7778-77-0
<b>Acetates</b>	
Sodium Acetate Trihydrate	6131-90-4
Sodium acetate anhydrous	127-09-3
<b>Citric Acids &amp; Citrates</b>	
Citric Acid Anhydrous	77-92-9
Citric Acid Monohydrate	5949-29-1
Ferric Ammonium Citrate Brown Powder	1185-57-5
Sodium citrate dihydrate	6132-04-3
<b>Carbonates</b>	
Sodium carbonate	497-19-8
<b>Amines &amp; Amines Derivatives</b>	
Diethanolamine	111-42-2
Diisopropanolamine	110-97-4
Ethylenediamine	107-15-3
Trolamine (Triethanolamine)	102-71-6
Tromethamine (Tris)	77-86-1
Meglumine	6284-40-8
Glycine	56-40-6
L-(+)-Lactic acid	79-33-4
<b>Chlorides</b>	
Calcium Chloride Dihydrate	10035-04-8
Potassium Chloride	7447-40-7
Sodium Chloride	7647-14-5
Magnesium chloride	7791-18-6
<b>Other Salts and Compounds</b>	
Sodium Hypochlorite 5%	7681-52-9
Sodium Saccharin	128-44-9
Magnesium sulfate 7-hydrate	10034-99-8
Calcium saccharate	5793-89-5
Succinic acid	110-15-6
Pyruvic Acid Sodium Salt	113-24-6
<b>Water For Injection</b>	
WFI	7732-18-5

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Product	CAS No.
<b>TRACE ELEMENTS</b>	
Ferric Ammonium Citrate Brown Powder	1185-57-5
Manganese sulfate monohydrate	10034-96-5
Cobalt chloride hexahydrate	7791-13-1
Nickel sulfate hexahydrate	10101-97-0
Sodium selenite anhydrous	10102-18-8
Ammonium metavanadate	7803-55-6

Product	CAS No.
<b>VITAMINS</b>	
Ascorbic acid	50-81-7
D-Biotin	58-85-5
Folic Acid	59-30-3
Thiamine hydrochloride	67-03-8
Pyridoxine hydrochloride	58-56-0
Nicotinamide	98-92-0

Product	CAS No.
<b>NUCLEOSIDES / NUCLEOTIDES</b>	
2-deoxyadenosine monohydrate	16373-93-6
Adenosine	58-61-7
Cytidine	65-46-3
Inosine	58-63-9
2'-desoxyinosine	890-38-0
Thymidine	50-89-5
2'-Deoxycytidine Hydrochloride	3992-42-5
2'-Deoxyguanosine	961-07-9
Guanosine	118-00-3
Uridine-5-MP, disodium	3387-36-8
Inosine-5'-MP, disodium	4691-65-0
Adenosine-5'-triphosphoric Acid Disodium Salt	987-65-5
Hypoxanthine	68-94-0
Adenine	73-24-5
Ribonucleic acid sodium salt	9010-05-3

If the desired grade of product is not listed or you have interest in a product not listed, please contact our sales team

Product	CAS No.
<b>CLEANING-IN-PLACE SOLUTIONS</b>	
Sodium Hydroxide 50% (w/w)	1310-73-2
2N NaOH	1310-73-2
Hydrochloric Acid solution (10% w/v)	7647-01-0
2N HCl	7647-01-0
Sodium Hypochlorite 5%	7681-52-9
20mM Peracetic Acid Solution	79-21-0
20% Ethanol	64-17-5
Acetic acid glacial	64-19-7
Isopropyl alcohol	67-63-0

Product	CAS No.
<b>pH ADJUSTERS</b>	
Hydrochloric Acid solution	7647-01-0
Acetic acid	64-19-7
Sodium Hydroxide solution	1310-73-2
Potassium hydroxide	1310-58-3

Product	CAS No.
<b>ALCOHOLS</b>	
Benzyl alcohol	100-51-6
Ethanol	64-17-5
Isopropyl alcohol	67-63-0

Product	CAS No.
<b>PROTEIN DENATURANTS</b>	
Guanidine Hydrochloride	50-01-1
Urea	57-13-6

Product	CAS No.
<b>SOLVENTS / DETERGENTS</b>	
Polysorbate 80	9005-65-6
Tri-n-butyl phosphate	126-73-8

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Product	CAS No.
<b>ACIDS (LOW pH TREATMENT)</b>	
Acetic acid glacial	64-19-7
Citric Acid Anhydrous	77-92-9
Citric Acid Monohydrate	5949-29-1

Product	CAS No.
<b>STABILIZERS</b>	
L-arginine	74-79-3
Glycine	56-40-6
L-histidine	71-00-1
Sucrose	57-50-1
Glycerol	56-81-5

Product	CAS No.
<b>ANTIOXIDANTS</b>	
Ascorbic acid	50-81-7
L-Glutathione reduced	70-18-8
L-Methionine	63-68-3

## Actylis is your Partner of Choice



### Product regulatory

- General Product Information
- Manufacturing, Packaging, Release Site & Supplier Information
- Physico-chemical Information
- Regulatory Information
- Revisions
- Contact Information



### Site quality overview

- Site Overview
- Compliance Evidence
- PEC-PQG GMP
- Compliance Details
- Miscellaneous Site Information
- Revisions
- Contact Information



### Site & supply chain security overview

- Scope
- Supply Chain Security
- Security Information
- Safety & Environmental Information
- Business Continuity Plan
- Miscellaneous Site Information
- Revisions
- Contact Information

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# Your Partner of Choice



**Manufacturing  
& Sourcing**



**Customization  
& Flexibility**



**Customer  
Intimacy**



**Quality  
& Reliability**



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