



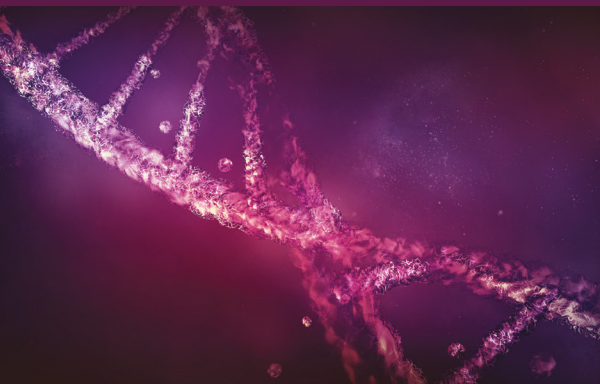
**Global GMP Manufacturer
of Critical Materials
for Biopharmaceutical
Applications**



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



Actylis Global GMP Manufacturing

Through our integrated centre of excellence facility network in North America, Europe and Asia, Aceto is a global GMP manufacturer of raw materials suitable for biopharmaceutical applications.

Should you require a specific excipient or other raw material to be manufactured within a fully compliant GMP process, Actylis offers this service with full supporting documentation, at our GMP facilities globally.

Our global R&D team has over fifty years of experience in custom ingredient development for the Life Sciences industry.



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

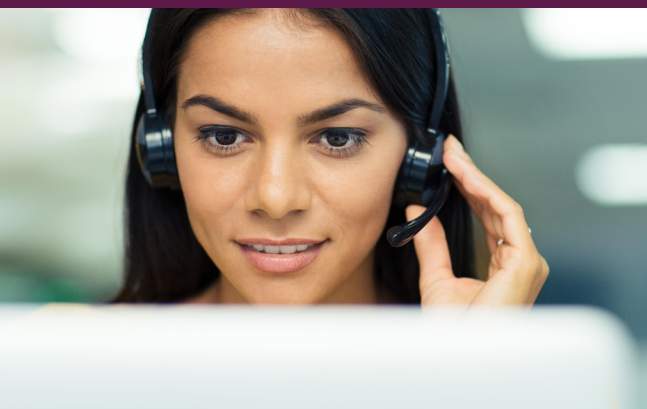


Partner Service Organization

At Actylis we 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.



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.

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



Actylis Injectable Grade Ingredient Portfolio

Product	Grade	CAS No.	End use
2-phenoxyethanol	Multi-compendial, Ph. Eur	122-99-6	a p
Acetic Acid (Glacial)	Multi-compendial	64-19-7	ba ph
Acetic acid glacial	USP, Ph.Eur, BP, IP, JP	64-19-7	ba ph
Acetone	USP-NF, Ph.Eur, BP, CDMF	67-64-1	s co
Acetonitrile	USDMF, CDMF	75-05-8	s co
Ammonium acetate	Excipient grade	631-61-8	
Benzalkonium chloride 50% Solution	USP-NF, Ph.Eur, IP, BP	8001-54-5	a p
Benzene sulphonic acid	USDMF, CDMF	98-11-3	ba ph
Benzethonium Chloride	USP-NF	121-54-0	a p
Benzoic acid	USP, Ph.Eur, IP	65-85-0	a p
Benzyl alcohol	USP-NF, Ph.Eur, BP, IP, CDMF	100-51-6	a p
Benzyl benzoate	USP, Ph.Eur, BP, IP, CDMF	120-51-4	s co
Butylated Hydroxytoluene	USP-NF, Ph.Eur, IP, CDMF	128-37-0	ara
Calcium Chloride Dihydrate	Multi-compendial	10035-04-8	a p
Calcium saccharate	USP, CDMF	5793-89-5	s s
Cetrimonium Bromide	USP-NF	57-09-0	a p
Citric Acid Anhydrous	Multi-compendial	77-92-9	ba ph
Citric Acid Anhydrous	USP, Ph.Eur, IP	77-92-9	ba ph
Citric Acid Monohydrate	Multi-compendial	5949-29-1	ba ph
Creatinine	USP-NF	60-27-5	ba d f
D-Maltitol	USP-NF, Multi-compendial	585-88-6	ba d f
Di-sodium hydrogen o-phosphate anhydrous	USP, Ph.Eur, BP	7558-79-4	ba ph
Di-sodium hydrogen o-phosphate heptahydrate	USP	7782-85-6	ba ph
Di-sodium hydrogen o-phosphate dodecahydrate	IP, BP, USP, Ph.Eur	10039-32-4	ba ph
Di-sodium succinate hexahydrate	USDMF, USP-NF, CDMF	6106-21-4	ba ph
Diisopropanolamine	USP	110-97-4	ba ph
Diethanolamine	USP-NF, IP	111-42-2	ba ph
Dimethyl sulphoxide	USP-NF, IP	67-68-5	s co
EDTA di-sodium salt dihydrate	USP, Ph.Eur, IP	6381-92-6	ca
Ethylenediamine	USP-NF	107-15-3	ba ph
Formaldehyde 37%	USP-NF	50-00-0	a p
Glycerin	USP, Ph.Eur, IP, BP, JP, CDMF	56-40-6	ba ph & s co
Glycerol	USP-NF, Multi-compendial	56-81-5	hu
Glycine	IP, Excipient grade	56-40-6	sw
Hydrochloric Acid solution (10% w/v)	USP-NF	7647-01-0	ba ph
Isopropyl Alcohol (2 Propranolol)	Multi-compendial	67-63-0	so & a p

a p	Antimicrobial Preservative	ca	Chelating Agents	s co	Solvents Co-solvents
ara	Antioxidants & Reducing Agents	hu	Humectants	s s	Stabilizer Surfactants
bi	Binders	lu	Lubricants	sw	Sweeteners
ba ph	Buffering Agents Ph Monitors	pl	Plasticizer	taa	Tonicity Adjusting Agents
ba d f	Bulking Agents Diluents Filler	so	Solvents		

Product	Grade	CAS No.	End use
L-(+)-Lactic acid	USP-NF, BP, IP, JP, Ph.Eur	79-33-4	ba ph
Liquefied Phenol	USP	108-95-2	a p
Levulinic Acid	PHARMA	123-76-2	
Magnesium chloride hexahydrate	USP, Ph.Eur, BP, IP	7791-18-6	taa
Meglumine	USP, Ph.Eur, BP, CDMF	6284-40-8	ba ph
meta-Cresol	USP, Ph.Eur, BP, CDMF	108-39-4	a p
Methane sulphonic acid	USDMF, CDMF	75-75-2	s co
Monothioglycerol	USP-NF, IP, CDMF	96-27-5	a p
N,N-Dimethyl acetamide	USDMF, Ph.Eur, CDMF	127-19-5	s co
N-Methyl 2-pyrrolidone	USP-NF, Ph.Eur	872-50-4	s co
Phenol	USP, Ph.Eur, IP	108-95-2	a p
Phenyl Ethyl Alcohol	USP-NF, Multi-compendial	60-12-8	a p
Phenol Red Sodium Salt GMP manufactured	PHARMA	143-74-8	
Phenylmethylsulfonyl Fluoride (PMSF)	PHARMA	329-98-6	
Polyethylene Glycol 200	USP-NF	25322-68-3	s s
Polyethylene Glycol 300	USP-NF	25322-68-3	s s
Polyethylene Glycol 400	USP-NF	25322-68-3	s s
Polyethylene Glycol 400	USP-NF, Ph.Eur	25322-68-3	taa
Polysorbate 20	USP-NF	9005-64-5	s s
Polysorbate 80	Multi-compendial, USP-NF	9005-65-6	s s
Potassium chloride	Multi-compendial	7447-40-7	taa
Potassium chloride	USP, Ph.Eur, BP, IP	7447-40-7	ba ph
Potassium di-hydrogen ortho-phosphate	USP-NF, Ph.Eur	7778-77-0	a p & s co
Propylene glycol	USP, Ph.Eur, BP, IP, CDMF	57-55-6	ba ph
Potassium Phosphate Monobasic	Multi-compendial, USP-NF	7778-77-0	ba ph
Sodium Acetate Anhydrous	USP-NF	127-09-3	ba ph
Sodium Acetate Trihydrate	Multi-compendial	6131-90-4	ba ph
Sodium benzoate	USP-NF, Ph.Eur, BP, IP	532-32-1	a p
Sodium bisulfite	JP, CDMF	7631-90-5	taa
Sodium chloride	USP, Ph.Eur, BP, IP, CDMF	7647-14-5	ba ph
Sodium Chloride	Multi-compendial (Low Endotoxin)	7647-14-5	taa
Sodium Chloride	USP-NF	7647-14-5	taa
Sodium Citrate Dihydrate	Multi-compendial, USP-NF	6132-04-3	ba ph
Sodium di-hydrogen o-phosphate anhydrous	USP, BP, IP	7558-80-7	a p & ara
Sodium Hydroxide 50% (w/w)	USP-NF	1310-73-2	ba ph
Sodium Hypochlorite 5%	USP-NF	7681-52-9	a p

a | p Antimicrobial | Preservative
ara Antioxidants & Reducing Agents
bi Binders
ba | ph Buffering Agents | Ph Monitors
ba | d | f Bulking Agents | Diluents | Filler

ca Chelating Agents
hu Humectants
lu Lubricants
pl Plasticizer
so Solvents

s | co Solvents | Co-solvents
s | s Stabilizer | Surfactants
sw Sweeteners
taa Tonicity Adjusting Agents

Product	Grade	CAS No.	End use
Sodium metabisulphite	USP-NF, Ph.Eur, IP, CDMF	7681-57-4	a p
Sodium Phosphate Dibasic Anhydrous	Multi-compendial (Low Endotoxin)	7558-79-4	ba ph
Sodium Phosphate Dibasic Anhydrous	USP-NF	7558-79-4	ba ph
Sodium Phosphate Dibasic Heptahydrate	Multi-compendial (Low Endotoxin)	7782-85-6	ba ph
Sodium Phosphate Dibasic Heptahydrate	USP-NF	7782-85-6	ba ph
Sodium Phosphate Monobasic Anhydrous	USP-NF	7558-80-7	ba ph
Sodium Phosphate Monobasic Dihydrate	Multi-compendial, USP-NF	13472-35-0	ba ph
Sodium Phosphate Monobasic Monohydrate	Multi-compendial, USP-NF	10049-21-5	ba ph
Sodium Saccharin	Multi-compendial	128-44-9	
Sodium sulfite anhydrous	USP-NF, Ph.Eur, BP	7757-83-7	a p
Sodium Tartrate	USP-NF	6106-24-7	ba ph
Sorbitan Trioleate	PHARMA	26266-58-0	sw
Squalane	USP-NF	111-01-3	s s
Succinic acid	USP-NF, CDMF	110-15-6	ba ph
Sucrose	Multi-compendial	57-50-1	
tert - Butanol	USDMF, CDMF	75-65-0	s co
Thimerosal 10% (w/v)	USP-NF	54-64-8	a p
Thimerosal USP 2% (W/v) Aqueous solution	USP	54-64-9	a p
Tri-Sodium citrate dihydrate	USP, Ph.Eur, IP	6132-04-3	ba ph
Trolamine (Triethanolamine)	USP-NF, Ph.Eur, CDMF	102-71-6	ba ph
Tromethamine (Tris)	Multi-compendial	77-86-1	ba d f
Urea	Multi-compendial	57-13-6	ba ph
Xylitol	Multi-compendial	87-99-0	ba ph
Zinc Stearate	USP-NF	557-05-1	ba d f

a p	Antimicrobial Preservative	ca	Chelating Agents	s co	Solvents Co-solvents
ara	Antioxidants & Reducing Agents	hu	Humectants	s s	Stabilizer Surfactants
bi	Binders	lu	Lubricants	sw	Sweeteners
ba ph	Buffering Agents Ph Monitors	pl	Plasticizer	taa	Tonicity Adjusting Agents
ba d f	Bulking Agents Diluents Filler	so	Solvents		

Actylis Cell Culture Ingredients

Product	Grade	CAS No.
Amino Acids		
Glycine	USP-EP, for cell culture	56-40-6
L-Alanine	USP-EP, for cell culture	56-41-7
L-Arginine	USP-EP, for cell culture	74-79-3
L-Arginine Monohydrochloride	USP-EP, for cell culture	1119-34-2
L-Asparagine Monohydrate	USP-EP, for cell culture	5794-13-8
L-Aspartic Acid	USP-EP, for cell culture	56-84-8
L-Cysteine	USP-EP, for cell culture	52-90-4
L-Cysteine Hydrochloride Monohydrate	USP-EP, for cell culture	7048-04-6
L-Cystine	USP-EP, for cell culture	56-89-3
L-Glutamic Acid	USP-EP, for cell culture	56-86-0
L-Glutamic Acid Monosodium Salt	USP-EP, for cell culture	6106-04-3
L-Glutamine	USP-EP, for cell culture	56-85-9
L-Histidine	USP-EP, for cell culture	71-00-1
L-Histidine Hydrochloride Monohydrate	USP-EP, for cell culture	5934-29-2
L-Isoleucine	USP-EP, for cell culture	73-32-5
L-Leucine	USP-EP, for cell culture	61-90-5
L-Lysine Hydrochloride	USP-EP, for cell culture	657-27-2
L-Methionine	USP-EP, for cell culture	63-68-3
L-Phenylalanine	USP-EP, for cell culture	63-91-2
L-Proline	USP-EP, for cell culture	147-85-3
L-Serine	USP-EP, for cell culture	56-45-1
L-Threonine	USP-EP, for cell culture	72-19-5
L-Tryptophan	USP-EP, for cell culture	73-22-3
L-Tyrosine	USP-EP, for cell culture	60-18-4
L-Valine	USP-EP, for cell culture	72-18-4
N-Acetyl-DL-tryptophan	USP-EP, for cell culture	87-32-1
N-Acetyl-L-tyrosine	USP-EP, for cell culture	537-55-3

Product	Grade	CAS No.
Cofactors		
Flavin Adenine Dinucleotide (FAD) Disodium Salt	USP-EP, for cell culture	84366-81-4
Glutathione, reduced	USP-EP, for cell culture	70-18-8
Nicotinamide Adenine Dinucleotide (NADH), reduced Disodium Salt	USP-EP, for cell culture	606-68-8

Product	Grade	CAS No.
Nucleotides		
2'-Deoxyadenosine Monohydrate	USP-EP, for cell culture	16373-93-6
2'-Deoxycytidine Hydrochloride	USP-EP, for cell culture	3992-42-5
2'-Deoxyguanosine	USP-EP, for cell culture	961-07-9
2'-Deoxythymidine	USP-EP, for cell culture	50-89-5

Product	Grade	CAS No.
Nucleotides (Cont.)		
Adenine	USP-EP, for cell culture	73-24-5
Adenosine	USP-EP, for cell culture	58-61-7
Adenosine-5'-triphosphoric Acid Disodium Salt	USP-EP, for cell culture	987-65-5
Cytidine	USP-EP, for cell culture	65-46-3
Guanosine	USP-EP, for cell culture	118-00-3
Hypoxanthine	USP-EP, for cell culture	68-94-0

Product	Grade	CAS No.
Other Cell Culture Ingredients		
Ammonium Chloride	In-house, for cell culture	12125-02-9
Ammonium Sulfate	USP-NF-CP, for cell culture	7783-20-2
Benzalkonium Chloride Solution	USP-NF-Ph.Eur, for cell culture	
Calcium Chloride Dihydrate	USP-Ph.Eur, for cell culture	10035-04-8
Calcium Nitrate Tetrahydrate	In-house, for cell culture	13477-34-4
Dextrose Anhydrous	USP-NF-BP, for cell culture	50-99-7
Dibasic Potassium Phosphate Anhydrous	USP-Ph.Eur-BP, for cell culture	7758-11-4
Dibasic Sodium Phosphate Dihydrate	USP-Ph.Eur-BP, for cell culture	10028-24-7
Dibasic Sodium Phosphate Heptahydrate	USP, for cell culture	7782-85-6
Dimethyl Sulphoxide	In-house, for cell culture	67-68-5
Disodium Phosphate Anhydrous	USP-Ph.Eur-BP-JP, for cell culture	7558-79-4
Glycerine	In-house, for cell culture	56-81-5
Imidazole	In-house, for cell culture	288-32-4
L(+)-Ascorbic Acid	Ph.Eur, for cell culture	50-81-7
Lithium Chloride	In-house, for cell culture	7447-41-8
Magnesium Chloride Hexahydrate	USP-Ph.Eur-BP, for cell culture	7791-18-6
Magnesium Sulfate Heptahydrate	USP-Ph.Eur-BP-JP, for cell culture	10034-99-8
Manganese Sulfate Monohydrate	USP-Ph.Eur, for cell culture	10034-96-5
Monobasic Potassium Phosphate	USP-NF-Ph.Eur-BP-CP, for cell culture	7778-77-0
Monobasic Sodium Phosphate Monohydrate	USP-BP, for cell culture	10049-21-5
Nickel Sulphate Hexahydrate	In-house, for cell culture	10101-97-0
Polysorbate 20	In-house, for cell culture	9005-64-5
Polysorbate 80	In-house, for cell culture	9005-65-6
Potassium Chloride	USP-Ph.Eur-BP-JP, for cell culture	7447-40-7
Potassium Iodide	In-house, for cell culture	7681-11-0
Potassium Sulphate	Ph.Eur-BP-JP, for cell culture	7778-80-5
Sodium Bicarbonate	USP-Ph.Eur-BP-JP, for cell culture	144-55-8
Sodium Ascorbate	In-house, for cell culture	134-03-2
Sodium Chloride	USP-Ph.Eur-BP-JP, for cell culture	7647-14-5
Sodium Dihydrogen Phosphate Anhydrous	BP, for cell culture	7558-80-7
Sodium Dihydrogen Phosphate Dihydrate	USP-Ph.Eur-BP, for cell culture	13472-35-0
Sodium Selenite Anhydrous	In-house, for cell culture	10102-18-8
Succinic Acid	USP-NF-CP-JP, for cell culture	110-15-6
Sucrose	USP-NF-Ph.Eur-BP-CP-JP, for cell culture	57-50-1
Triethanolamine	In-house, for cell culture	102-71-6
Urea	In-house, for cell culture	57-13-6
Zinc Sulphate Heptahydrate	USP-Ph.Eur-BP-JP, for cell culture	7446-20-0

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