Pharma

Active Pharmaceutical
Ingredients and Excipients

Jungbunzlauer

Comprehensive solutions

Jungbunzlauer serves a broad range of industries with its natural and sustainable ingredients, including the pharmaceutical industry.

Committed to rigorous quality standards, our portfolio of active pharmaceutical ingredients (APIs) and excipients meets the highest industry requirements. Jungbunzlauer's products support a wide range of applications, offering comprehensive solutions for the entire pharmaceutical sector.

Highest quality standards

The quality of our products has a profound impact on the quality of our customers' end products. This applies not only to our products, but also to packaging, documentation, and logistics. At Jungbunzlauer, we use state-of-the-art technologies and continuously improve our processes in order to manufacture cost-effective, safe products of exceptional quality.

Jungbunzlauer's internal quality standards are more stringent than international norms, and we continuously invest in research and development to sustain these high standards. Overall, our products meet the requirements of relevant international food and drug regulations, as well as other essential regulations.

Jungbunzlauer offers individualised customer solutions through a combination of premium product quality, specialised technical support, and experienced regulatory affairs—always on time and close to the customer.

Pharma development

Jungbunzlauer began producing APIs in 2000. Since then, our portfolio has grown continuously. Our goal is to provide additional regulatory documents, such as a Type II US Drug Master File (US DMF) and/or a Certificate of Suitability to the Monographs of the European Pharmacopoeia (CEP), to support and facilitate worldwide drug licensing for our customers.

Active Pharmaceutical Ingredients

Jungbunzlauer's manufacturing site in Ladenburg, Germany, is specialised in the manufacture of active pharmaceutical ingredients (APIs).

This site is registered as an API manufacturer according to Section 67 German Drug Law. We have acquired Good Manufacturing Practice (GMP) certificates issued by the District Government Tübingen (Tübingen regional council) as the competent authority for ensuring compliance with GMP-regulations for our range of APIs. Jungbunzlauer's API manufacturing plant in Germany has been confirmed to be compliant with current GMP regulations set out by the U.S. FDA and the EU GMP Guide since 2001.

Our current API portfolio contains four different products, which can be provided with a US DMF and/or CEP to facilitate finished drug registration in the USA, Europe and beyond. All APIs comply with the respective monograph in the United States Pharmacopoeia (USP) and/ or European Pharmacopeia (Ph. Eur.).

Jungbunzlauer regularly expands its API portfolio in response to customer and market needs. Please get in touch with us to request further information or to receive a personalised quote for one of our APIs.

API	Registration status	Potential applications
Citric Acid Anhydrous	US DMF (USP), CEP (Ph.Eur.), GMP certificate	- Bowel and colon cleansing (with magnesium oxide) - Antacid (with sodium bicarbonate) - Acidifier/buffering agent
Tripotassium Citrate Monohydrate	US DMF (USP), CEP (Ph.Eur.), GMP certificate	- Renal tubular acidosis/Kidney stone management - Systemic alkaliser - Hypokalemia/Electrolyte replenishment
Trimagnesium Citrate Anhydrous	CEP (Ph.Eur.), GMP certificate	- Magnesium deficiency/Supplement - Muscle function normalisation - Laxative/Constipation
Trisodium Citrate Dihydrate	US DMF (USP), CEP (Ph.Eur.), GMP certificate	- Anticoagulant - Laxative - Rehydration solution

API portfolio at a glance

Citric Acid Anhydrous (CAA)

Jungbunzlauer offers CAA for pharmaceutical use holding a CEP, a Type II US DMF and a GMP certificate. This unique quality standard helps us to provide optimal product solutions for the pharmaceutical industry.

CAA is used in a variety of applications, mostly as an excipient, acting as an acidulant, pH regulator, or effervescent aid in formulations such as tablets, dry blends, emulsions, and suspensions.

In addition to its role as an excipient, CAA is also used as an active pharmaceutical ingredient (API) in finished drug products. When combined with sodium bicarbonate, it acts as an antacid to relieve heartburn and gastric discomfort. Furthermore, CAA reacts with magnesium oxide to form magnesium citrate, which is used as a laxative in bowel cleansing protocols prior to colonoscopy procedures.

Tripotassium Citrate Monohydrate (TPC)

TPC serves as a highly bioavailable potassium source in a broad range of nutritional and pharmaceutical applications. As an API, TPC is primarily used as a urinary and systemic alkaliser in the treatment of renal tubular acidosis (RTA, Butler-Albright-Lightwood Syndrome). Its citrate-based chelating properties help prevent the crystallisation of urates and support kidney stone management by forming soluble complexes with stone-forming cations, which are then excreted naturally.

In addition, TPC is used in electrolyte replenishment therapies for hypokalemia and contributes to restoring physiological balance. Its alkalising effect also provides symptomatic relief in cases of cystitis, making TPC a multifunctional agent in renal and urological care.

Trimagnesium Citrate Anhydrous (TMC)

GMP certificate and a CEP can be provided for TMC. Jungbunzlauer is prepared to expand its regulatory documents according to the customer needs.

TMC supports essential physiological functions by contributing to the maintenance of healthy bones and teeth, normal muscle function, and a well-regulated nervous system. It also helps reduce tiredness and fatigue by supporting energy metabolism and electrolyte balance. Due to its high bioavailability and gentle effect on the gastrointestinal tract, TMC is widely used in dietary supplements to correct magnesium deficiency. In clinical settings, it is commonly administered as a laxative prior to colonoscopy procedures, offering a well-tolerated and effective solution for bowel preparation.

Trisodium Citrate Dihydrate (TSC)

Jungbunzlauer provides TSC with a GMP certificate, Type II US DMF and a CEP for drug product registrations.

TSC, predominantly used in its dihydrate form, offers excellent pH regulation and buffering capacity, making it a valuable excipient in various formulations. As an active pharmaceutical ingredient (API), TSC is widely employed as an anticoagulant in blood preservation and dialysis solutions, in oral rehydration therapies, and as a gentle laxative. Its high solubility and physiological compatibility support its use in both clinical and nutritional contexts, contributing to the stabilization of formulations and the normalization of electrolyte balance.

API	US DMF	CEP
Citric Acid Anhydrous	#23078	CEP 2016-005
Tripotassium Citrate Monohydrate	#14847	CEP 2011-388
Trimagnesium Citrate Anhydrous	-	CEP 2015-129
Trisodium Citrate Dihydrate	#32842	CEP 2018-273

Excipients

Jungbunzlauer's products support the development of drugs and supplements in the pharmaceutical industry and play an important role in the composition of a variety of prescription medicines and over-the-counter products.

Our pharmaceutical products cover APIs as well as excipients, whose functionalities—along with those of mineral salts—are wide-ranging. We support our customers by providing the required documents and data statements on residual solvents, nitrosamines, BSE/TSE, GMO, allergens, contaminants, ISO/FSSC certificates, and more.

Functionalities of Jungbunzlauers excipients and mineral salts

	Citric Acid Anhydrous	Trisodium Citrate Anhydrous	Trisodium Citrate Dihydrate	Glucono-delta-Lactone	Sodium Gluconate	Calcium Lactate Gluconate	Monosodium Citrate	Potassium Gluconate	Tricalcium Citrate	Trimagnesium Citrate	Tripotassium Citrate	Zinc Citrate	CITROFOL® AI	CITROFOL® AII	Functional Acids	ERYLITE®	Xanthan Gum
Acidifying agent	■			■			■								■		
Bitterness masking agent					■											■	
Buffering agent	■	■	■	■	■		■		■		■				■		
Bulking agent or carrier																■	
Chelating agent	■	■	■	■	■			■	■		■				■		
Desiccant		■								■							
Emollient													■	■			
Mineral source			■			■		■	■	■	■	■					
Plasticiser													■	■			
Release control agent																	■
Stabiliser of emulsions, syrups, suspensions									■								■
Sweetener																■	
Tablet binder									■						■		■
Tablet disintegrant	■						■								■	■	
Tablet or capsule diluent									■							■	

Quality standards

The quality of our ingredients has a profound impact on the quality of your end products.

Consistent high quality and purity of our products minimise the risk of deficiencies in your finished drug products and minimise the risk of product liabilities as well as of brand and image damages. Jungbunzlauer guarantees to fulfil required product and quality standards for the pharmaceutical industry.

GMP

Jungbunzlauer's APIs are manufactured at our production site in Ladenburg, Germany. This manufacturing site is compliant with current GMP requirements as set out in the guidelines of the US FDA and EU GMP Guide Part II. GMP certificates are available for all four APIs.

GDP

According to EU guidelines, it is mandatory to transport medicinal products and APIs according to Good Distribution Practice (GDP) within the European Economic Area (EEA). EU GDP guidelines ensure high transport quality standards and integrity of medicinal products and APIs. At Jungbunzlauer, GDP guidelines are followed for all APIs as an integral part of our GMP system in the production plant in Ladenburg, Germany.

IPEC

The International Pharmaceutical Excipients Council Europe (IPEC) guarantees an appropriate quality of our excipients to improve patient safety. IPEC standards for excipients are followed in our plants in Pernhofen, Austria, and Ladenburg, Germany.

ISO 9001

Fulfilment of the requirements of the ISO 9001 Quality Management Standards is the logical result of Jungbunzlauer's comprehensive quality commitment and all company's plants have been certified according to the ISO 9001 criteria. Furthermore, all Jungbunzlauer production sites have completed their Food Safety System Certification (FSSC) 22000. In this context HACCP – risk assessment concepts are established in all our plants (Austria, France, Germany, and Canada).

Pharma Customer Service

Along with our APIs we can provide a documentation and service package for your specific regulatory needs, including a letter of authorisation for our US type II DMFs or our CEPs, stability data or other documents required for the licensing of your finished product.

Our regulatory affairs and technical support experts will accompany you when qualifying our products for manufacture, during the preparation of your licensing application in the course of the licensing procedure and along the lifecycle of your finished product.

Regulatory support

Our experts in regulatory affairs are experienced in the application and maintenance of API registrations at the EDQM and the US-FDA. In addition, we offer regulatory support during the preparation of the respective API section in the finished drug dossier and during the licensing procedure in countries within or outside Europe and the USA.

Technical support

With their expert knowledge, Jungbunzlauer's Technical Support team accompanies our customers in resolving their commercial and technical challenges with tailor-made solutions to their individual requirements and with up-to-date technical information on our products. The Technical Support team guarantees reliable and competent handling of any quality-related customer inquiry, as well as detailed information on the high quality standards in the production sites and of our products.

Audits

Customers can perform on site audits at our plant in Ladenburg and third party audit reports are also available. Our business partners can easily verify the high standards adherent to in our manufacturing processes and in our quality standards.

Application development

The application development centre in Ladenburg, Germany, provides professional service and experienced-based consulting regarding the application of Jungbunzlauer's products to customers.

Pharma dedicated sales

Jungbunzlauer provides an international sales structure to cover global needs for all products. A sales team with focus on pharmaceutical ingredients was established at Jungbunzlauer to enable a fast, reliable and professional support of our pharma customers with national or international drug registrations.

Jungbunzlauer Group

Jungbunzlauer is represented in all major markets. Our regionalised setup of the sales organisations and respective local distribution partners enable us to provide optimal and efficient service to customers in more than 130 countries.

Jungbunzlauer is one of the world's leading producers of biodegradable ingredients of natural origin. The Swiss-based, international company's roots date back to 1867. Today, Jungbunzlauer specialises in acidulants, sweetners, texturants, minerals. and tailored solutions for the food and beverage, nutrition, home and personal care, and pharmaceutical sectors, as well as for various other industrial applications.

All its products can be used, transported and disposed of in a secure and ecologically safe way. The Group operates manufacturing plants in Austria, Canada, France and Germany.

A worldwide network of sales companies and distributors with a thorough understanding of target markets and client requirements underlies Jungbunzlauer's strong market and customer focus. Committed to its rigorous quality standards, Jungbunzlauer guarantees for the excellence and sustainability of its products and services.

Jungbunzlauer's products are manufactured utilising natural fermentation processes based on renewable raw materials.

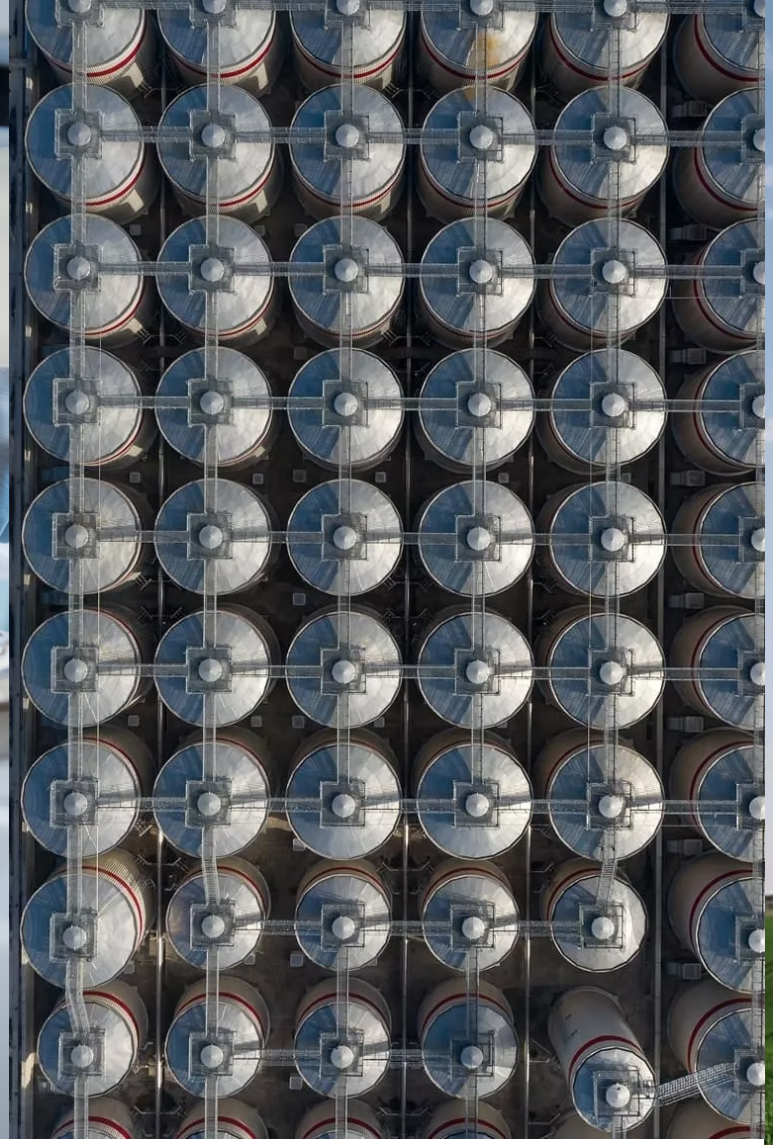
Americas

Europe

(incl. Africa and Middle East)

Asia & Pacific

■ Sales office ☐ Production site ● Production site / Sales office ○ Application development centre



Jungbunzlauer

Headquarters **Jungbunzlauer Suisse AG**

4051 Basel · Switzerland · Phone +41 61 295 51 00 · headquarters@jungbunzlauer.com · www.jungbunzlauer.com