Jungbunzlauer

From nature to ingredients®

Pharma

Active Pharmaceutical Ingredients and Excipients

Pharma

Jungbunzlauer's comprehensive solutions

Jungbunzlauer serves a broad range of industries with its natural and sustainable ingredients, including the pharmaceutical industry. Committed to our rigorous quality standards, our active pharmaceutical ingredients and excipient portfolio meet the highest quality standards. Jungbunzlauer's products can be used in various applications and provide a comprehensive solution for the entire pharmaceutical industry.

Highest quality standards

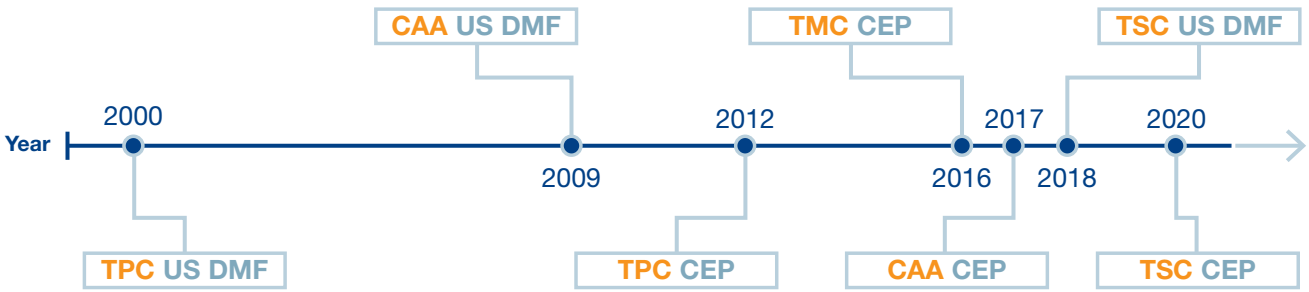
The quality of our products has a profound impact on the quality of our customers' end products. This applies not only to our products, but also to packaging, documents and logistics. At Jungbunzlauer, we use state-of-the-art technologies and continuously improve our processes in order to manufacture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

With a combination of top product quality, specialised technical service and experienced regulatory affairs, always in time and close to the customer, Jungbunzlauer is able to offer individualised customer solutions.

Pharma development at Jungbunzlauer

Jungbunzlauer began producing active pharmaceutical ingredients in 2000. Since then our portfolio has grown continuously. Our goal is to provide additional regulatory documents like a Type II US drug master file (DMF) and/or certificate of suitability to the monographs of the European Pharmacopeia (CEP) to support and facilitate worldwide drug licensing of 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 with the responsible German authorities (§67 German Drug Law) as an API manufacturer. According to ICHQ7 we have acquired and maintained Good Manufacturing Practice (GMP) certificates from the legal authority (Regierungspräsidium Tübingen) for our range of APIs. Jungbunzlauer's API manufacturing plant in Germany has been confirmed compliant with cGMP regulations set out in the FDA and EU GMP Guide since 2001.

Our current API portfolio covers four different products, which can be provided with a DMF and/or CEP to facilitate finished drug registrations in USA, Europe and beyond.

API	Registration status	Applications
Citric Acid Anhydrous	US DMF, USP CEP, Ph. Eur. GMP certificate	Bowel and colon cleansing (with Magnesium Oxide) Antacid (with Sodium Bicarbonate) Citrate source Acidifying agent Blood treatment
Tripotassium Citrate Monohydrate	US DMF, USP CEP, Ph. Eur. GMP certificate	Renal tubular acidosis Kidney-stone management Electrolyte replenishment Potassium deficiency (Hypocalemia) Cystitis Systemic alkaliser
Trimagnesium Citrate Anhydrous	CEP, Ph. Eur. GMP certificate	Constipation Magnesium deficiency Muscle function normalisation Laxative Magnesium supplement
Trisodium Citrate Dihydrate	US DMF, USP CEP, Ph. Eur. GMP certificate	Rehydration solution Electrolyte replenishment Laxative Anticoagulant Acidifier

Jungbunzlauer regularly expands the API portfolio according to customer and market needs. Please get in touch with us to acquire further information or to receive a personal quote for one of our APIs.

API portfolio at a glance

Citric Acid Anhydrous

Jungbunzlauer offers citric acid anhydrous (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.

Citric acid is used in a variety of applications, mostly as excipient, acting as acidulant, pH regulator or effervescent aid in applications like tablets, dry blends, emulsions and suspensions.

In addition, citric acid anhydrous is widely used as API in finished drug formulations. It is applied in combination with sodium bicarbonate as antacid to treat heartburn or stomach upset. CAA is reacting with magnesium oxide to magnesium citrate which acts as laxative and is taken prior to colonoscopy.

Tripotassium Citrate Monohydrate

Jungbunzlauer is the worldwide leading supplier of tripotassium citrate monohydrate (TPC) as an API with GMP quality and documentation, including Type II US DMF and CEP.

TPC serves as potassium source in a widespread range of nutritional and pharmaceutical applications. As an API, TPC is mainly used as urinary and systemic alkaliser to treat renal tubular acidosis (RTA, Butler-Albright-Lightwood-Syndrome). In addition, TPC prevents crystallisation of urates due to its citrate-based chelating properties and is used during kidney stone management therapy. Citrates react with stone forming cations to a soluble form and are subsequently excreted by the body. TPC is as well used as an API for electrolyte replenishment therapies in hypokalemia and its alkalizing properties can be used to treat the symptoms of cystitis.

Trimagnesium Citrate Anhydrous

Trimagnesium citrate anhydrous (TMC) has a GMP certificate and a CEP. Jungbunzlauer is prepared to expand its regulatory documents according to the customer needs.

TMC helps to maintain bones and teeth, normalises muscle function, influences the nervous system, and reduces fatigue. TMC is often used as laxative taken prior to a colonoscopy and in supplements to treat magnesium deficiency to normalise physiological body functions.

Trisodium Citrate Dihydrate

Jungbunzlauer provides trisodium citrate dihydrate (TSC) with a GMP certificate, Type II US DMF and a CEP for drug product registrations.

TSC, mostly used in its dihydrate form, has excellent pH regulation and buffering properties. As an API, TSC is widely used in oral rehydration solutions, laxatives or alkalising products.

To facilitate your licensing activities, Jungbunzlauer strives for high-quality regulatory support and provides four APIs with an US Type II DMF and/or CEP.

API	US DMF	CEP
Citric Acid Anhydrous	#23078	R0-CEP 2016-005-Rev 02
Trimagnesium Citrate Anhydrous	-	R0-CEP 2015-129-Rev 01
Tripotassium Citrate Monohydrate	#14847	R1-CEP 2011-388-Rev 01
Trisodium Citrate Dihydrate	#32842	R0-CEP 2018-273-Rev 00

Excipients

Jungbunzlauer's products support the life science efforts of the pharmaceutical industry and play an important role in the composition of a variety of prescription drugs and over-the-counter products. Our pharmaceutical products cover APIs as well as excipients of which the functionalities of the excipients and mineral salts are widespread. We support our customers by providing required documents and data like elemental impurities according to ICH Q3D, statements on residual solvents, BSE/TSE, GMO, allergens and others.

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									■							■	

*anhydrous form

Quality standards for the safety of your products

The quality of our ingredients has a profound impact on the quality of your end product. Consistent high quality and purity of our products minimise the risk of deficiencies in your finished drug product 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 produced at our production site in Ladenburg, Germany, which is registered with German authorities as an API manufacturer (§67 German Drug Law). This manufacturing site is compliant with current GMP as set out in the guidelines by the FDA and EU GMP Guide Part II. GMP certificates are available for all four APIs.

GDP

According to EU guidelines, it is obligatory 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 and 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.

ISO9001

Fulfilment of the requirements of the ISO9001 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 our plants in Pernhofen, Austria and Ladenburg, Germany.

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 service experts will support you when qualifying our APIs for production, during the preparation of your filing and in the course of the licensing procedure. This includes the option to perform on site audits at our Ladenburg plant.

Regulatory Support

Our experts in Regulatory Affairs are experienced in applying for and maintaining API registrations at the EDQM and the US-FDA and are currently expanding the API registrations outside Europe and the USA. In addition, we can 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 Service

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

Audits

Customer audits or third-party-audits can be arranged upon request. Our business partners can easily verify the high standards adherent to in our manufacturing processes and in our quality standards.

Application Technology

The application technology center (AppliTech) in Ladenburg, Germany, provides professional service and experienced-based consulting regarding the application of Jungbunzlauer products to customers.

API Sales

Jungbunzlauer provides an international sales structure to cover global needs for all products. A sales team with focus on pharmaceutical ingredients is 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 global network of sales companies and distributors covers more than 130 countries.

North America

Europe
(incl. Russia, Africa and Middle East)

Latin America

Asia & Pacific

- SALES OFFICE
- PRODUCTION SITE
- PRODUCTION SITE / SALES OFFICE
- APPLICATION TECHNOLOGY CENTER

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 citric acid, xanthan gum, gluconates, lactics, specialties, special salts and sweeteners for the food, beverage, pharmaceutical and cosmetic industry as well as for various other industrial applications.

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

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.

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