quality chemicals

European Manufacturer of
High-Purity Mineral Salts

WHERE PURITY MAKES THE DIFFERENCE

High-Purity Mineral Solutions for Pharma & Biopharma

Your Trusted Partner in Pharma

High-Quality Mineral Salts for Pharma and Biopharma

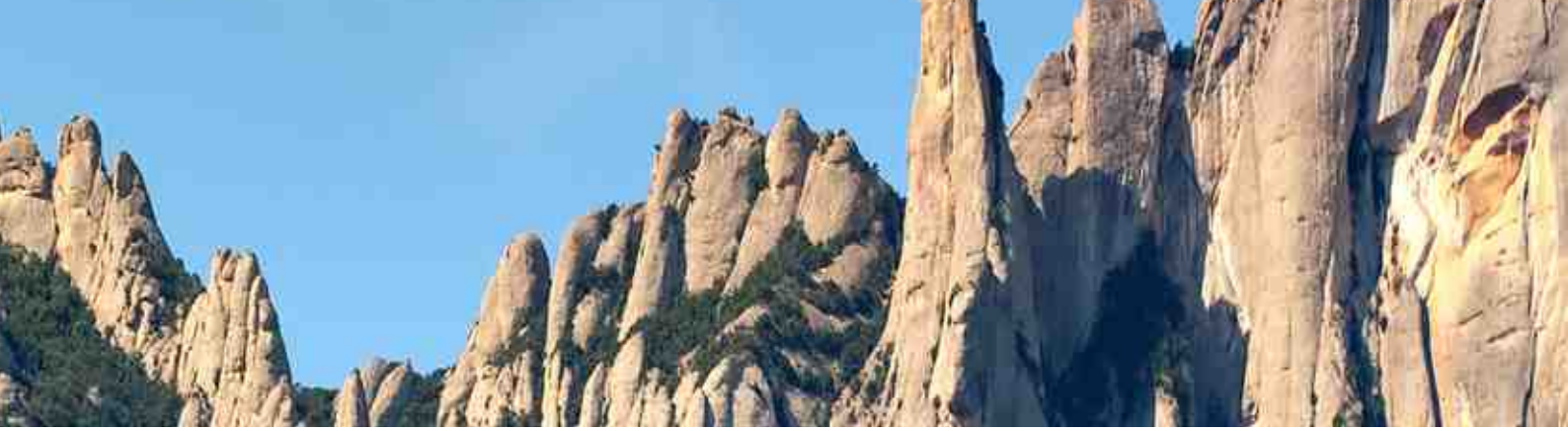
We are a GMP-certified European manufacturer of high-purity inorganic salts, specializing in raw and starting materials, API and excipient grades for the pharmaceutical and biopharmaceutical industries. With more than 30 years of experience, we have developed an in-depth understanding of i**nternational regulations**, establishing us as a trusted partner for companies worldwide.
Our expanding API portfolio includes **over 45 internationally registered APIs in the last ten years**, compliant with ICH guidelines, and we continuously invest in new product development.

Excellence in GMP Development & Manufacturing

Quality Chemicals is a trusted partner for the pharmaceutical and biopharmaceutical industries, specialized in the contract development of **Raw and Starting Materials, Excipients and APIs according to GMP regulations**. Our core competence lies in the **production of tailor-made inorganic mineral salts**, as we can **adapt to the specifications and needs** of our customers. Headquartered in Barcelona, we have **two GMP production sites** and **two dedicated laboratories**.

Our experience in both complex R&D projects and structured and controlled GMP production makes us **the best choice to develop new APIs**. With our **in-house Quality Assurance department,** we guarantee to work in accordance with the most recent ICH Q7 guidelines.

We offer **GMP-certified micronization and milling**. Our advanced facilities ensure precise particle size reduction and uniform distribution for pharmaceutical applications. With our Malvern instrument, **we can guarantee the particle size and distribution PSD.**



Our Key Advantages

Customization	Our products are crafted to your specification.
European Manufacturing	Two production plants and in-house laboratories, including our Kilo Lab, ensure consistent quality and reliable supply.
Sustainability and Ethics	We prioritize responsible production every step of the way with practices such as decarbonization and solar panels.
Quality Systems	Our commitment to excellence is backed by our EU-GMP as well as ISO 9001 & 14001 & 45001 and FSSC 22000 certifications, reflecting our dedication to quality and safety.
Open to Audits	We welcome on-site audits and provide detailed Audit reports, demonstrating our commitment to transparency and accountability.
Stability	Our products undergo rigorous ICH Q1 guideline-compliant stability studies, guaranteeing consistency and reliability
Regulatory Support	Navigating regulatory matters can be complex. Our experts are here to guide you through the regulatory landscape, making the process smoother for you.

Sedex ecovadis

Quality Control & Quality Assurance

We perform the **quality controls in our two labs** and **release of the lots by our quality assurance team**. Moreover, our analytical experts are ready to develop and validate the optimal analytical methods for each product, guaranteeing its quality and compliance before release.

Change Control System Management

Comprehensive review, approval, and documentation of changes affecting GMP products, with controlled assessment of selected changes for ISO products.

Supplier Auditing & Qualification

Continuous evaluation of supplier integrity, GMP compliance, and operational performance. Customers are welcome to perform on-site audits at our facilities.

CAPA Process & Deviation Management

Structured investigations, root-cause analysis, and implementation of corrective & preventive actions.

Document Control & SOP Compliance

Controlled procedures and records aligned with regulatory and internal standards.

Strict Operations under ICH Q7 Global Guidance

Controlled environments, validated processes, and robust documentation aligned with API-grade requirements.

EU-GMP Part II

Legal European implementation of ICH Q7, legally binding for API manufacturers supplying the EU market.

Stability Test Data for APIs per ICH Q1 Guidelines

Full stability studies ensuring API quality throughout the re-test period and defining appropriate storage conditions.

Transparent Supply Chain Information

Full traceability, batch documentation, CoAs, and proactive change notifications.

Availability of ICH Q3D Elemental Impurities Data

Assessment and control of elemental impurities according to global pharmaceutical limits for APIs.

Compliance to IPEC-PQG GMP Guide

Good Manufacturing Practices applied to GMP grade excipients in line with global standards.

Our expertise ensures customized

High-quality products, comprehensive documentation and superior **customer support** facilitate your efforts in **qualification**, **risk assessment** and **registration process optimization.**

Shorter Registration Phase

Compliance with International Standards

products that meet global standards

Our specialized regulatory team provides comprehensive support to ensure **product registration compliance across global markets.** For APIs we offer **CEP and ASMF.**
All these documents can be provided in **e-CTD Format.**

Transparent Supply Chain Information

Deficiency Letters Management

Parenteral Grade & Low Endotoxins

A **special grade of water** must be used when manufacturing APIs and excipients intended **to be used in sterile, parenteral drug products.**
The production of parenteral API ingredients requires absolute **control over water purity and endotoxin levels**. High-purity salts for parenteral use are manufactured at our GMP plant in Palencia under ICH Q7-compliant conditions.

Manufacturing with Purified Water

Endotoxin limit	Total microbial count
<0.25EU/ml	<100CFU/ml

We have our own water production plant and we can reach WFI Water Quality

We can produce any of our salts in low-endotoxin grade on demand

Key Applications

Parenteral Nutrition (TPN)	Essential elements like Zn, Cu, Mn and Se
Dialysis Solutions	Strict control of heavy metals in hemodialysis and peritoneal dialysis.
Bioprocesses & Cell culture	Trace elements supporting cell growth in biologics manufacturing.
Vaccines & Gene Therapies	High-purity buffers and excipients for critical formulations.

BioPharma - CIP & SIP

Cleaning is a **key operation in biopharmaceutical manufacturing for removal** of product residues and microbial contamination. **These processes, require GMP manufactured, low bioburden CIP solutions for cleaning of equipment, chromatography resins and filters.**

Different Presentations Available	1l, 25l, 200l IBC, 1000l, Isotank
Endotoxins Level	<0.2 guaranteed
Microfiltered	by 0.2 on request

We can manufacture any required concentration, molarity, normality of any of the solutions

Cleaning and sanitisation (CIP SYSTEMS)

Buffer production and PH adjustments

Water tratment and neutralisaation processes

Chromatography and protein purification

Resin cleaning and storage

CAS	SOLUTIONS
64-19-7	ACETIC ACID
1336-21-6	AMMONIA
1310-73-2	SODIUM HYDROXIDE
1310-73-2	POTASSIUM HYDROXIDE

“Reliable quality driven by strict standards, supporting critical pharmaceutical applications worldwide”

Raw Material for Plasma Fractionation

We provide raw materials for plasma fractionation to ensure the **safe and efficient purification of plasma proteins** like albumin, clotting factors and immunoglobulins. With strict quality standards, we support the production of **high-purity, pathogen-free therapies** for healthcare applications.

CAS	PRODUCT LIST
64-19-7	ACETIC ACID GLACIAL
6381-92-6	EDTA DISODIUM SALT 2-HYDRATE
56-40-6	GLYCINE (AMINOACETIC ACID)
7647-01-0	HYDROCHLORIC ACID SOLUTION
7778-77-0	POTASSIUM DI-HYDROGEN PHOSPHATE
7758-11-4	DI-POTASSIUM HYDROGEN PHOSPHATE ANHYDROUS

CAS	PRODUCT LIST
6131-90-4	SODIUM ACETATE 3-HYDRATE
7647-14-5	SODIUM CHLORIDE
1310-73-2	SODIUM HYDROXIDE PELLETS
6132-04-3	TRI-SODIUM CITRATE 2-HYDRATE
10049-21-5	SODIUM DI-HYDROGEN PHOSPHATE 1-HYDRATE
7558-79-4	DI-SODIUM HYDROGEN PHOSPHATE ANHYDROUS

Trace Elements: Parenteral Nutrition

Trace Elements for Injection are used in intravenous solutions for **parenteral nutrition**, ensuring high purity, safety, and regulatory compliance.

CAS	PRODUCT LIST
10060-12-5	CHROMIUM (III) CHLORIDE 6-HYDRATE
10125-13-0	COPPER (II) CHLORIDE 2-HYDRATE
13478-10-9	IRON (II) CHLORIDE 4-HYDRATE
7631-95-0	SODIUM MOLYBDATE

CAS	PRODUCT LIST
13446-34-9	MANGANESE (II) CHLORIDE 4-HYDRATE
7681-49-4	SODIUM FLUORIDE
10102-18-8	SODIUM SELENITE
7758-05-6	POTASSIUM IODATE

Buffers for Cell Culture Media Production

Buffer quality is key in biopharma, ensuring **optimal pH and protein stability throughout production**. Our GMP-grade buffers are low in endotoxins, DNases, RNases and proteases free, and support all major buffering systems for upstream and downstream processes.

CAS	PRODUCT LIST
64-19-7	ACETIC ACID
5949-29-1	CITRIC ACID 1-HYDRATE
7758-11-4	DI-POTASSIUM HYDROGEN PHOSPHATE ANHYDROUS
7558-79-4	DI-SODIUM HYDROGEN PHOSPHATE ANYHDROUS
7647-01-0	HYDROCHLORIC ACID SOLUTIONS

CAS	PRODUCT LIST
7778-77-0	POTASSIUM DI-HYDROGEN PHOSPHATE
127-09-3	SODIUM ACETATE
10049-21-5	SODIUM DI-HYDROGEN PHOSPHATE 1-HYDRATE
1310-73-2	SODIUM HYDROXIDE SOLUTIONS
6132-04-3	TRISODIUM CITRATE 2-HYDRATE

“Precision and purity are at the core of every solution we develop, ensuring consistent performance across all applications”

quality chemicals

Barcelona
Fornal 35, Pol.Ind.Can Comellas Sud
08292 Esparreguera, Spain
+34 93 770 97 30

Palencia
Av. Tren Expreso
34200 Venta de Baños, Spain
+34 97 976 10 97

customer-service@qualitychemicals.com
www.qualitychemicals.com