

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.

Comprehensive Management of Change Control System	Supplier Auditing and Integrity
Multi-compendial Products Individual Pharmacopoeias, a combination of several of them or even a monograph	Process Deviation and Complaint Investigations
Customized solutions and tailored packaging Product Repack	We promptly address CAPAs and ensure compliance with SOPs

Bioburden Standards (microbial limit, TAMC, TYMC)	Compliance to IPEC-PQG GMP Guide
Strict working conditions following ICH Guideline Q7	Availability of ICH Q3D elemental impurities data
Stability Test Data (following ICH Q1)	Transparent Supply Chain Information

Quality Chemicals: Ensuring Quality, Traceability & Compliance in every Product

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		We have our own water production plant and we can reach WFI Water Quality
Endotoxin limit <0.25EU/ml	Total microbial count <100CFU/ml	
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.

Regulatory Expertise: Fast-Track Your Product to Market

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
Transparent Supply Chain Information	Deficiency Letters Management

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**.



GMP Solutions for Cleaning In Place

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	High Efficacy Proven to effectively remove proteins, nucleic acids, and other organic residues.
Endotoxins Level	<0.2 guaranteed	Broad Antimicrobial Action Inactivates most viruses, bacteria, yeasts, fungi, and endotoxins, making it a powerful cleaning agent.
Microfiltered	by 0.2 on request	Cost-Effectiveness Economical in terms of procurement, usage, and waste management.
		Ease of Handling Simplifies detection, removal, and disposal processes.

CAS	PRODUCT
64-19-7	Acetic Acid Solutions
1336-21-6	Ammonia Solutions
1310-73-2	Sodium Hydroxide Solutions

We can manufacture any required concentration of Sodium Hydroxide and any other product on demand.

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	CAS	PRODUCT
64-19-7	Acetic Acid Glacial	6131-90-4	Sodium Acetate 3-Hydrate
6381-92-6	EDTA Disodium Salt 2-Hydrate	7647-14-5	Sodium Chloride
56-40-6	Glycine (Aminoacetic Acid)	1310-73-2	Sodium Hydroxide Pellets
7647-01-0	Hydrochloric Acid Solution	6132-04-3	Tri-Sodium Citrate 2-Hydrate
7778-77-0	Potassium di-Hydrogen Phosphate	10049-21-5	Sodium di-Hydrogen Phosphate 1-Hydrate
7758-11-4	di-Potassium Hydrogen Phosphate Anhydrous	7558-79-4	di-Sodium Hydrogen Phosphate Anhydrous

Trace Elements: Purity for Your Formulations

Trace Elements for Injection are indicated as part of intravenous solutions for **parenteral nutrition**. Our high-purity trace elements ensure consistency, safety, and compliance with stringent industry regulations.

CAS	PRODUCT	CAS	PRODUCT
10060-12-5	Chromium (III) Chloride 6-Hydrate	13446-34-9	Manganese (II) Chloride 4-Hydrate
10125-13-0	Copper (II) Chloride 2-Hydrate	7681-49-4	Sodium Fluoride
13478-10-9	Iron (II) Chloride 4-Hydrate	10102-18-8	Sodium Selenite

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	CAS	PRODUCT
64-19-7	Acetic Acid	7778-77-0	Potassium di-Hydrogen Phosphate
5949-29-1	Citric Acid 1-Hydrate	127-09-3	Sodium Acetate
7758-11-4	di-Potassium Hydrogen Phosphate Anhydrous	10049-21-5	Sodium di-Hydrogen Phosphate 1-Hydrate
7558-79-4	di-Sodium Hydrogen Phosphate Anhydrous	1310-73-2	Sodium Hydroxide 1N
7647-01-0	Hydrochloric Acid 1N	6132-04-3	Trisodium Citrate 2-Hydrate

High-Quality Raw Materials for Pharma and Biopharma

We are a GMP-certified European manufacturer of high-purity mineral salts, specializing in 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 international 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.
In-House Lab	Our in-house laboratory facilities provide quick and reliable analysis, ensuring the highest quality control standards.
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.
Kilo-lab	Our Kilo-Lab provides a controlled environment for small-scale manufacturing.



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Reshaping Industries

Challenging the boundaries

Working together to improve quality of life



Where Purity Makes the Difference