#### Quality Chemicals Range of API´s

With our extensive expertise in the development and manufacturing of APIs, excipients, and starting materials, we are fully equipped to assist you in achieving your objectives. Moreover, our regulatory team is here to support your registrations across the Middle East, Asia Pacific, Africa, Europe, North and South America, as well as Oceania. We are committed to contributing to a brighter future on an international scale.

API Product List	CAS No.	EUASMF	CEP	USASMF	Other countries
Acetic Acid 80% w/w	64-19-7	•			
Ammonium Chloride	12125-02-9		•		CHINA
Ammonium Metavanadate	7803-55-6	•			
Ammonium Molybdate 4-Hydrate	12054-85-2	•			
Antimony Potassium Tartrate	28300-74-5	٠			TAIWAN
Calcium Acetate Anhydrous	62-54-4	•			CHINA
Calcium Hydrogen Phosphate Anhydrous	7757-93-9	•			
Chromium (III) Chloride 6-Hydrate	10060-12-5	•			
Cobalt (II) Chloride 6-Hydrate	7791-13-1	•			
Copper (II) Chloride 2-Hydrate	10125-13-0	•			
Copper (II) Hydroxicarbonate (Malachite)	12069-69-1	•		•	
Copper (II) Oxide	1317-38-0	•			
Copper (II) Sulphate 5-Hydrate	7758-99-8	•			CHINA
Copper (II) Sulphate Anhydrous	7758-98-7	•			
Di-Sodium Hydrogen Phosphate 12-Hydrate	10039-32-4		•		
Iron (III) Chloride Solution 10-14% w/w	7705-08-0	•			
L(+)- Tartaric Acid	87-69-4	•			
Magnesium Acetate 4-Hydrate	16674-78-5		•		
Magnesium Bromide 6-Hydrate	13446-53-2	•			
Magnesium Fluoride	7783-40-6	•			
Magnesium Hydroxide	1309-42-8	•			
Magnesium L-Lactate 2-Hydrate	18917-93-6	•			
Manganese (II) Chloride 4-Hydrate	13446-34-9	•			
Manganese Carbonate Precipitated	598-62-9	•		•	
Nickel (II) Sulfate 6-Hydrate	10101-97-0	•			
Phenol	108-95-2	•			
Potassium Acetate	127-08-2		•	•	
Potassium Bromide	7758-02-3	•			
Potassium Chlorate	3811-04-9	•			
Potassium lodate	7758-05-6	•			
Sodium Acetate 3-Hydrate	6131-90-4		•		
Sodium Dihydrogen Phosphate 1-Hydrate	10049-21-5	•			
Sodium Dihydrogen Phosphate 2-Hydrate	13472-35-0		•		
Sodium Dihydrogen Phosphate Anhydrous	7558-80-7	•			
Sodium Federetate, EDTA Iron & Sodium Salt 3-Hydrate	18154-32-0	•			
Sodium Fluoride	7681-49-4		•		
Sodium Molybdate 2-Hydrate	10102-40-6	•	-		
Sodium Selenite	10102-18-8	•		•	
Succinic Acid	110-15-6	•		-	
Tri-Sodium Citrate 2-Hydrate	6132-04-3	-		•	
Urea	57-13-6	•		-	
Zinc Acetate 2-Hydrate	5970-45-6	-	•		JAPAN
Zinc Oxide	1314-13-2	•	•	•	
	1014 10-2	•		•	



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## **O** purity chemicals

Purity Chemicals S.L. Av. Tren Expreso 34200 Venta de Baños, Spain +34 979 76 10 97 www.purity-chemicals.com Reshaping Industries

Challenging the boundaries

Working together to improve quality of life



**Reshaping industries** 

#### **Your Trusted Partner** in Pharma and Biopharma

At Quality Chemicals, we simplify the business for pharmaceutical and biopharmaceutical companies. With over 90 years of experience, we're European leaders in manufacturing high-purity mineral salts, ensuring top quality and compliance.

Mastering Industry Excellence	We bring deep knowledge and tailored solutions to each sector we serve, leveraging our track record of success.		
Our Evolution and Expansion	Our state-of-the-art facilities and flexible manufacturing capabilities allow us to customize products to meet specifications, aligned with regulatory requirements.		
Unyielding Quality Unit	Quality is the bedrock of our commitment at Quality Chemicals; we are not just the stewards of quality but also the architects of trust.		
End-to-End Comprehensive Services	Our aim revolves around simplifying raw material purchasing from initial development to final delivery.		
Global Reach and Seamless Distribution	We take immense pride in our extensive global reach, rooted in a network of approvals, registrations, and strategically located facilities that contri- bute to ease distribution and delivery to clients worldwide.		
Building Lasting Partnerships	Our focus extends far beyond delivering produc <mark>ts; it cente</mark> rs on nurturing enduring partnerships.		
	While our expertise spans various industries, our true passion lies in phar- maceuticals and biopharma. Thanks to our 2 state-of-the-art facilities		

strategically located in Europe, we have the capability to develop products tailored precisely to your specifications and quantity requirements while ensuring full compliance.

### Essential **Mineral Salts**

Continuous

Support

Improvement

and Regulatory

Mineral salts are essential in pharmaceuticals and biopharma, supporting bioproduction processes for top-tier quality. In the pharmaceutical industry, adherence to international pharmacopoeias (EP, USP, JP, CP, etc.) and regulatory standards such as GMP, IPEC, and ISO, in accordance with the ICH Guidelines, is paramount. This ensures the safe and reliable use of APIs, excipients, starting materials, and products.

ring the highest quality of your products.

For biopharmaceutical manufacturing lines that utilize biological sources, we recommend our sodium hydroxide solution of customisable concentrations. These solutions have been specifically designed to effectively remove proteins, nucleic acids, and inactivate a wide range of harmful elements, including viruses, bacteria, yeasts, fungi, and endotoxins. They are commonly used for facility and equipment sanitation, resin cleaning for chromatography columns, and pH adjustment.

Our products are ideal for critical and sensitive manufacturing, thanks to our advance water purification plant. We provide purified water with controlled levels of endotoxins and bioburdens, ensuring the highest standards of quality and safety for the use in formulations dedicated to injectables and parenteral applications.

In addition to our unrivalled expertise in product development, our team of experts continuously research and develop products to ensure they meet your specific needs. We evaluate synthetic routes, raw materials, and methods of analysis to guarantee excellence.

And when it comes to registering APIs, our in-house experienced regulatory team can efficiently handle requests from health authorities to ensure successful product registrations. We offer and submit:

- DMF (drug master file)

In the upstream process, our mineral salts act as versatile catalysts. They function as vital nutrients, processing aids, and the secret ingredient that excels in buffering and promoting cell growth. These salts are the driving force behind the success of your biopharma upstream operations.

While downstream processes become effortless with our salts by your side. They serve as reliable buffers, maintaining the robustness and ensu-

 CEP (Certificate of Suitability of the European Pharmacopeia) - EU-ASMF (EU-active substance master file) - Special dossiers for non-API products

# Quality That Shines

Our certifications from AEMPS, FDA, and PMDA ensure global compliance combined with our commitment to quality is unwavering. As a certified manufacturer operating under GMP, we uphold the highest standards across all our operations.

This dedication is the cornerstone of our promise to deliver products of impeccable quality to offer a specialized portfolio of APIs and excipients, adhering to stringent quality assurance standards.

#### Our Key Advantages:

Scalability	From kilo-lab to large scale production, we have the capacity to match your demand, ensuring growth for your projects.
Made to Order	Our products are crafted to your specifications, ensuring they align perfectly with your project requirements.
Sustainability and Ethics	We're deeply committed to sustainability and ethical practices, prioritizing responsible production every step of the way.
Quality Systems	Our commitment to excellence is backed by our EU-GMP as well as, ISO 9001 & 14001 & 45001 certifications, reflecting our dedication to quality and safety.
Expert Advice	Our team of chemists and industrial experts are always at your service, ready to offer guidance and support to help you make adequate decisions.
In-House Lab	Our in-house laboratory facilities provide quick and reliable analysis, ensuring the highest quality control standards.
Customization	We excel in providing tailored solutions that precisely match your unique needs and goals.
Stability	Our products undergo rigorous ICH 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.
Product	We offer a comprehensive range of product statements, providing you with peace of mind and confidence in our products.
Open to Audits	We welcome on-site audits and provide detailed audit reports, demonstrating our commitment to transparency and accountability.