quality chemicals

Sodium hydroxide solutions for Biopharma

Biopharma companies manufacture pharmaceutical drugs extracted or semi-synthesised from biological sources.

They are different from totally synthesised pharmaceuticals: they include vaccines, blood, blood components, allergenics, somatic cells, gene therapies, tissues, recombinant therapeutic proteins and living cells used in cell therapy. Biological components are isolated from living sources—human, animal, plant, fungal, or microbial.

Sodium hydroxide is widely accepted for the following applications:

- Facility and equipment sanitisation
- Chromatography column resin **cleaning, sanitisation and storage** and pH adjustment of process streams

The benefits of its use include efficacy, low cost and ease of detection, removal, and disposal. Sodium hydroxide has been shown to be effective in removing proteins and nucleic acids as well as in inactivating most viruses, bacteria, yeasts, fungi, and endotoxins. It is common practice in industrial manufacturing to save time by adding a salt, such as **sodium chloride**, to the sodium hydroxide solution to combine cleaning with sanitisation.

We offer **sodium hydroxide solutions produced under cGMP**. Currently we provide a range of concentrations of sodium hydroxide but we can manufacture any required concentration.

Product	Code
Sodium hydroxide 30% GMP	3813
Sodium hydroxide 32% GMP	3840
Sodium hydroxide 50% GMP	3843
Sodium hydroxide 2M / Sodium chloride 2M GMP	3849
Sodium hydroxide 3M GMP	3848
Sodium hydroxide 5N GMP	

Different presentations are available: 1l, 25l, 200l, IBC 1000l
Endotoxins level < 0.2 can be guaranteed

Microfiltered by 0.2 on request is available

Headquaters & Production Plant

quality chemicals

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GMP Production Plant

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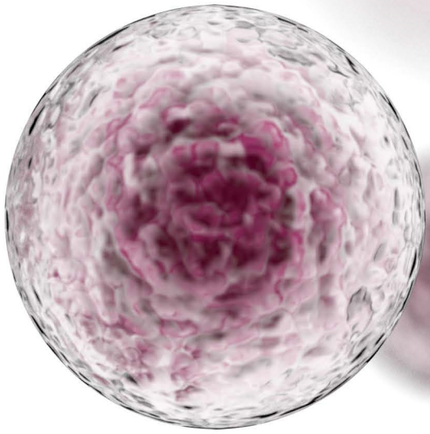
APIs and excipients
of inorganic and organic salts



quality chemicals

Quality Chemicals offers a comprehensive portfolio of essential pharma ingredients. These include APIs, intermediates, excipients, starting material, solvents and reagents. One of our two plants, our GMP plant in Venta de Baños, has been operating since 2004 and complies with **European GMP guidelines ICH Q7-part II**. It mainly produces raw material for the pharma, veterinary and biopharmaceuticals industries.

GMP Products

- Strict working conditions following ICH guideline Q7-part II
- Customised solutions and tailored packaging to meet your needs
- Change control
- Full traceability
- Supplier audits
- Dedicated regulatory support
- Comprehensive dossiers in the international **e-CTD format, acc. to ICH Module 3**

Low endotoxins / Parenteral grade

We manufacture "Parenteral grade" products using **purified water** with an **endotoxins** limit lower than 0.25 EU/ml and a total aerobic count limit lower than 100 cfu/ml.

Most of the time mineral salts for **injectable use** need to have low endotoxin content. Pharmacopoeias would indicate the maximum level of endotoxins allowed depending on the product. In other cases the level of endotoxins is specified by our customers.

Custom Development & Manufacturing

One of the many services we have been offering for the past 23 years with our agile and innovative regulatory expertise in inorganic and organic salts.

We harness this experience and a state-of-the-art facility that includes diverse teams of highly experienced scientists and regulatory technicians to collaborate with you on a tailored project.

With commitment to executing projects seamlessly through maintaining optimized and cost-effective manufacturing processes that do not compromise transparency nor quality.

Quality Systems

Both facilities are certified with WHO-GMP, ISO 9000, ISO 14000, ISO 22000, ISO 45000, GMP Plus, and FDA Approved. These allow us to foster production dedicated to regulation restricted industries for Active Pharmaceutical Ingredients (APIs), excipients, intermediates, starting material, and industrial products suitable for the pharma, biotech, oral & personal care, cosmetics, and industrial sectors.

Regulatory Support

Recognized by worldwide health authorities such as the FDA, AEMPS, MHRA, EU, PMDA, CDE, and TW-FDA. Our dedication has allowed us to successfully register more than 35 APIs and obtain CEPs, ASMFs, JP-DMFs, and US-DMFs. When documents do not need to be submitted, we can offer other documentation (SDS, BSE/TSE, Stability, etc.) with an informative summary of our data verification protocol.

Dossier Library

The pharma and biopharmaceutical industry calls for increasing transparency along the supply chain. There is growing demand to have complete documentation about the raw materials supplied in this sector.

All our products suitable for use as excipients are produced under GMP conditions and meet the requirements for excipients according to the joint **IPEC-PQG GMP Guide for pharmaceutical excipients.**

Our regulatory team offers you dedicated regulatory support for all our GMP products. For our products suitable for use as API, we offer access to:

- CEP Certificate of Suitability of the European Pharmacopeia
- ASMF Active Substance Master Files

Ctd Module 3 Index	Description	ASMF	Technical Package	Basic
	Product Quality Self Assesment	N/A	✓	N/A
	Supply Chain Information	N/A	✓ (Only If GMP Condition: CDA)	N/A
3.2.S.1	General Information			
3.2.S.1.1	Nomenclature	✓	✓	✓
3.2.S.1.2	Structure	✓	✓	✓
3.2.S.1.3	General Properties	✓	✓	✓
3.2.S.2	Manufacture			
3.2.S.2.1	Manufacturer	✓	✓	✓
3.2.S.2.2	Description of Manufacturing Process	✓	✓	Flow Chart Simple
3.2.S.2.3	Control of Materials	✓	N/A	N/A
3.2.S.2.4	Control of Critical Steps		N/A	N/A
3.2.S.2.5	Process Validation and/or Evaluation	✓	N/A	N/A
3.2.S.2.6	Manufacturing Process Development	✓	N/A	N/A
3.2.S.3	Characterisation			
3.2.S.3.1	Elucidation of Structure and Other Characteristics	✓	N/A	N/A
3.2.S.3.2	Impurities	✓	ICH Q3D	TSE/BSE+ Allergens+ Halal+ Kosher+ Etc.
3.2.S.4	Control of Drug Substance			
3.2.S.4.1	Specification	✓	✓	✓
3.2.S.4.2	Analytical Procedures	✓	✓	✓
3.2.S.4.3	Validation of Analytical Procedures	✓	N/A	N/A
3.2.S.4.4	Batch Analysis	✓	✓	✓
3.2.S.4.5	Justification of Specification	✓	✓	✓
3.2.S.5	Reference Standards of Materials	✓	✓	N/A
3.2.S.6	Container Closure System	✓	✓	✓
3.2.S.7	Stability			
3.2.S.7.1	Stability Summary and Conclusions	✓	If Available	Retest Date Justification
3.2.S.7.2	Post-Approval Stability Protocol and Stability Commitment	✓	N/A	N/A
3.2.S.7.3	Stability Data	✓	N/A	N/A