

GMP manufactured



For years **Quality Chemicals S.L.** has supplied products to the pharmaceutical industry featuring guaranteed compliance with pharmacopoeia monographs. Using our experience and following regulatory changes in the pharmaceutical sector, we are proud to offer a wide range of products manufactured under GMP conditions.

These products are supplied under the **Farmaqemical** brand.

These products ensure both quality and the necessary documentation. We comply with the requirements of the most complex API and excipient regulations.

These products are manufactured in our facilities which have been adapted to meet the requirements of the various pharmacopoeias using inspected, audited and validated GMP processes. With the guarantee of our GMP certification and our experience in these types of processes, we can provide the documentation needed to comply with regulations and product protection.

We have passed API inspection by the health authorities (Spanish Agency of Medicines) and customers audits.

Since nowadays almost all products used in the pharmaceutical industry need to meet GMP requirements, our range for this sector has several GMP compliance levels for the products we supply:

Products manufactured or purified in GMP conditions

- The product is synthesised in GMP processes and facilities.
- Traceability of raw materials is guaranteed.
- Authorised equipment.
- Traceability of the production process is guaranteed.
- They are packaged in a controlled environment.
- The product can be supplied in compliance with the quality standards of individual pharmacopoeias, a combination of several of them or even without a monograph in any pharmacopoeia.
- A technical package could be supplied in accordance with regulatory requirements: “Guideline Module 3 CTD Format”.

DMF documentation

- We can supply the documents required to present the DMF for products synthesised or purified in GMP procedures.
- **Quality Chemicals S.L.** can do the paperwork and provide the support needed to submit the DMF to the European health authorities if the customer wishes

Purity Chemicals facilities in Venta de Baños and Quality Chemicals facilities in Esparraguera are both authorised to manufacture products according to GMP standards and our authorised equipment includes the following:

- Reactors, distillers, centrifuges, fluidised bed drier and static dryers, standardised in a conical screw dryer and packaging room.

The equipment is sited in a number of cleanrooms.