IDIFARMA *is a leading Contract Research and Development Organization for the pharmaceutical and biotechnology industries.*

Based in Spain, and with an increasingly international reach, **IDIFARMA** *provides a full range of services that encompasses: drug formulation, development and validation of analytical methods, quality control and batch release in the EU, Pilot-Scale GMP-compliant manufacturing, ICH stability studies, clinical trial logistics management and regulatory support.*

Our state-of-the-art facility features a purpose-built high containment plant for the manufacturing of GMP-compliant pilot batches in oral solid dosage forms, for both conventional and high potency drugs.

IDIFARMA's *Analytical Laboratory* *has the most advanced technology and a highly qualified and experienced staff, offering* ***a wide range of analytical services*** *for both* ***marketed and investigational products****, ensuring the maximum quality and compliance with deadlines.*

We have dedicated areas specially equipped to handle and analyze ***high potency substances****.*

IDIFARMA*'s expertise, capabilities and proven track record make us the perfect partner for the development of your projects.*

IDIFARMA
PHARMACEUTICAL RESEARCH, DEVELOPMENT AND INNOVATION

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PROYECTO PARA LA PROMOCIÓN DE EMPRESAS INNOVADORAS DE BASE TECNOLÓGICA

Scan to visit our Analytical Laboratory

Cofinanciado por:
UNION EUROPEA
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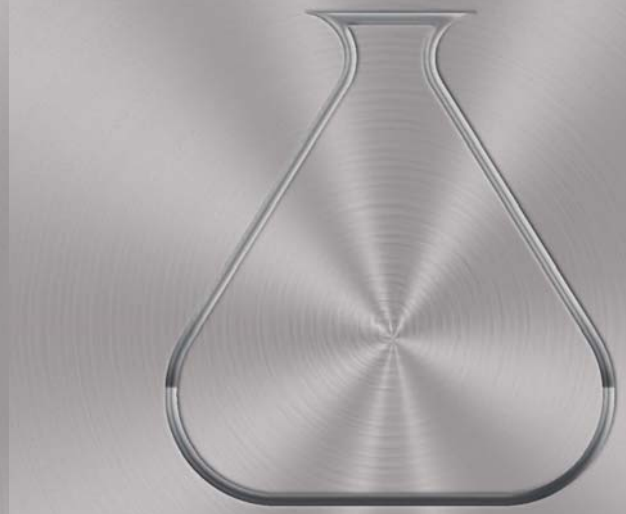


IDIFARMA

PHARMACEUTICAL RESEARCH, DEVELOPMENT AND INNOVATION

Analytical Services

Analytical Methods Development
Quality Control and Batch Release
ICH Stability Studies

Analytical Development

Development and validation of analytical methods

- Assay methods, uniformity of content and preservatives.
- Related substances methods.
- Water content determination methods.
- Residual solvent methods.
- Dissolution methods.
- Methods for active substance determination in "in vitro" permeation studies.
- Enantiomeric purity determination methods.
- Microbiological methods.

Comparative analyses

- "In vitro" dissolution tests.
- "In vitro" permeation studies.

Comprehensive range of assays

- Dissolution profiles.
- Analytical assays.
- Galenical assays.
- Microbiological assays.
- Sterility and endotoxins assays.

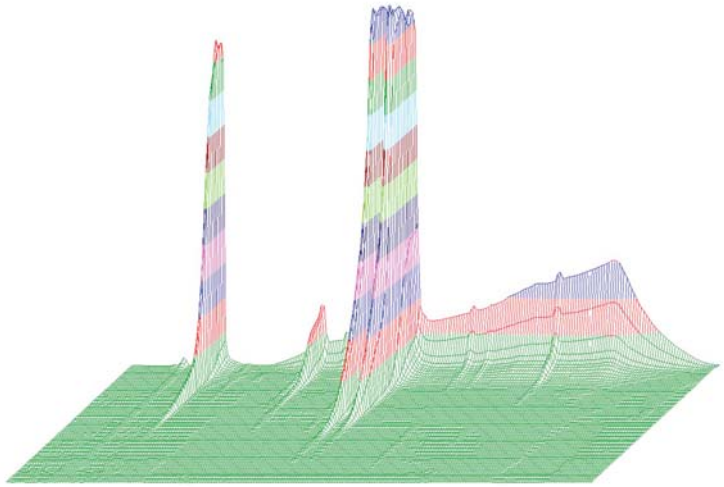
Quality Control and Batch Release

Raw material quality control

- Quality control and issuing of analytical certificates for raw materials and active ingredients.

Quality control and release of finished product

- Quality control and issuing of analytical certificates both for marketed and investigational products.
- Release of final product to be marketed in the European Union.



Stability Studies

ICH stability studies:

- Stability studies in controlled temperature and humidity conditions according to ICH (climatic zones I to IV).

Photostability studies:

- Stability studies to evaluate the resistance to light radiation.

In-use stability studies:

- Stability studies to determine periods of use in multidose or reconstituted drugs.

Ongoing stability studies:

- Stability studies on already marketed products.