IDIFARMA

PHARMACEUTICAL RESEARCH,
DEVELOPMENT AND INNOVATION

Company Introduction

IDIFARMA is an independent, privately-owned pharmaceutical CDMO based in Spain specialized in highly potent drugs.

With an experienced staff of more than 130 people and over 100 international clients, IDIFARMA provides a full range of services covering most of the lifecycle of any pharmaceutical product including all the activities related with formulation of finished product and commercial manufacturing.

Its state-of-the-art facility features a purpose-built high containment plant for GMP manufacturing of oral solid dosage forms, for both highly potent and non-potent drugs.

Relevant Milestones

- **2001** — Foundation
- **2004** — First GMP certification for Quality Control testing
- **2009** — New facilities, GMP certification for manufacturing of IMP (tablets)
- **2014** — GMP certification for commercial manufacturing (tablets)
- **2016** — Manufacturing of first commercial batches for clients and the company exceeds 100 employees
- **2017** — GMP certification for hard capsules
- **2018** — Investment in GMP Spray Drying for highly potent drug intermediates
- **2019** — First FDA inspection

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Main Highlights

Technological solutions

All kind of pharmaceutical development projects, from generic to innovative drugs, including the ability to handle highly potent compounds.

Innovative solutions such as GMP Spray Drying, for value added projects.

Our Team

More than 130 employees with extensive experience in analytical, formulation, manufacturing and regulatory activities in the pharmaceutical field.

High potency capabilities

State of the art GMP-compliant, high containment facility equipped to develop and manufacture highly potent drugs.

Client oriented

Exclusively focused on providing services to its client base, offering agile and flexible services without conflicts of interest, with total alignment with the requirements of the clients.

One-Stop Shop Partner

From initial pre-formulation trials up until commercial manufacturing of niche oral solid drugs.

Experience

We have handled more than 500 different molecules and collaborated in over 100 pharmaceutical development projects.

Contract Development Services

Experience developing a wide range of products, including generic and innovative drugs, as well as OTC and hybrid products. IDIFARMA is able to develop according to ICH Q8 requirements to comply with FDA requirements.

Over 100 products already developed for our clients in a variety of dosage forms: oral solids (IR/MR tablets, hard capsules), injectable (solutions, freeze-dried) and oral liquids (solutions, suspensions).

- Multiple dosage forms
- Highly potent and non-potent drugs
- Excipient compatibility studies
- Formulation and manufacturing process design
- Optional QbD, DoE

- IR/MR tablets and capsules
- Highly potent and non-potent drugs
- Placebo manufacturing
- Organic or water solvents
- Flexible batch sizes up to 60-70 Kg

API Selection

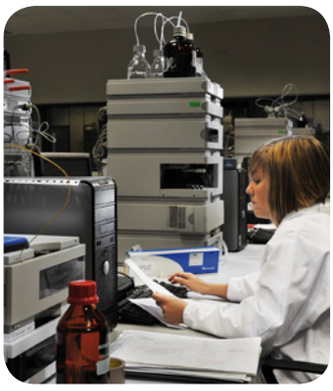
Formulation Development

Analytical Development

Tech Transfer

Process validation and clinical batches

Quality Control and Batch Release



- Development and validation of analytical methods
- Active substance and reference product characterization
- Quality control and validation of the manufacturing process

- Quality control of raw materials, API and finished products
- QP release of finished products
- Analytical Methods Transfer

- ICH Stability studies (Zones I to IV)
- Photostability studies
- In-use stability studies
- Ongoing stability studies

- eCTD dossier preparation
- IMPD and IB for clinical trials
- Orphan drug designation applications (EMA and FDA)
- Regulatory consultancy and support during dossier evaluation
- Product life-cycle management

Stability Studies

Clinical Trial Supply

Clinical Trials

Regulatory Affairs

Marketing Authorisation

Commercial Manufacturing

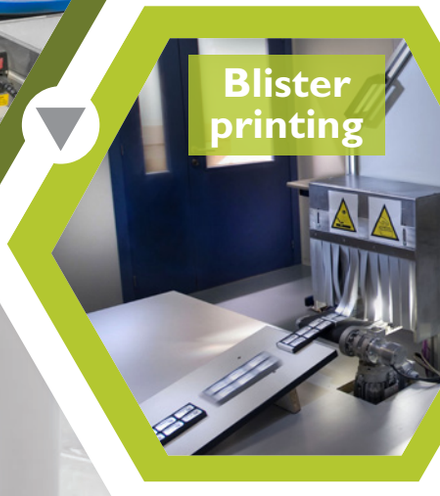
- Sourcing of comparator drugs
- Design of blinding/ masking strategies
- Labeling, primary and secondary packaging
- Storage, shipment and destruction of medication

- CMO for IR/MR tablets and capsules
- High potency up to level 4 OEB/OEL
- Narcotics and low humidity capabilities
- Organic or water solvents
- Small and mid-sized batches
- Late stage packaging customization

Contract Manufacturing Services

IDIFARMA is a certified GMP manufacturer for both IMP and commercial use medicinal products in oral solid dosage forms (IR/MR tablets and hard capsules), as well as drug product intermediates with Spray Drying technology.

Small and flexible manufacturing plant, with a maximum batch size of approx. 60 Kg, making IDIFARMA a suitable partner for manufacturing niche medicinal products, including highly potent drugs and controlled substances.




Spray drying


Wet granulation

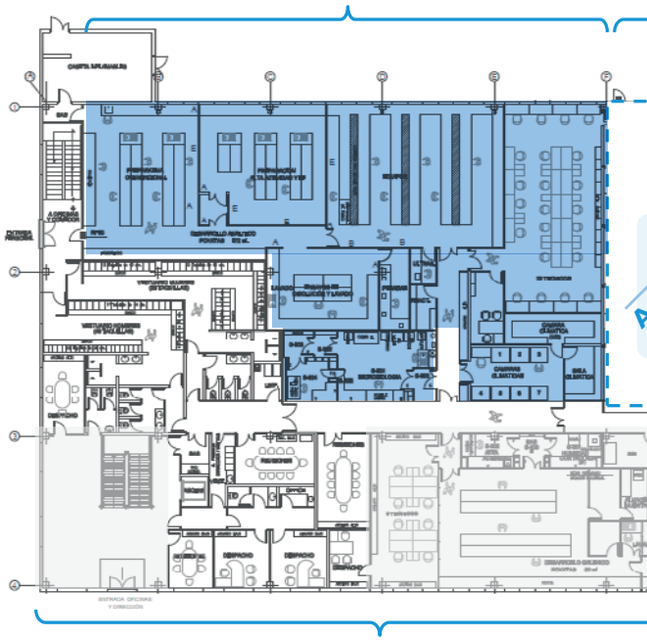

Tabletting


Tablet coating


Capsule filling


Blister packaging
IMA
CLINIPACK

ANALYTICAL LABORATORY



FORMULATION LABORATORY

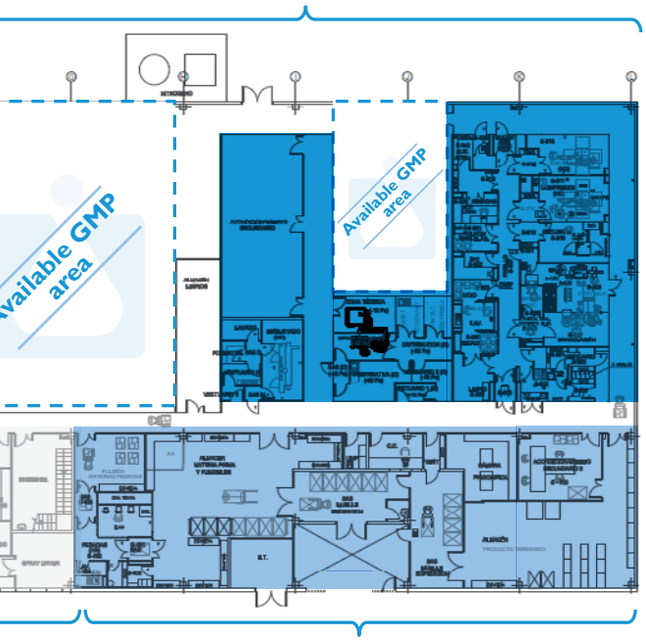
Our Facilities

Our state-of-the-art, 3,500 m2 facilities have all the services and equipment necessary to meet the growing demand for pharmaceutical development and manufacturing.

It consists of three major areas: analytical laboratory, formulation laboratory and the GMP plant, with relevant available space for future growth.

Updated lists of equipment can be found at our website: **www.idifarma.com/facilities**

GMP MANUFACTURING AREA



WAREHOUSE

Key Capabilities

High Potency

Facilities built in 2008 specifically designed for the handling of highly potent substances such as cytotoxics and cytostatics.

We have dedicated rooms for these compounds in our formulation and analytical development laboratories.

Our GMP plant was designed as a high containment area, so we are also fully capable of manufacturing highly potent drugs.

As a general rule, Idifarma is able to work with substances in categories 1 to 4 (up to OEL of 0.1 µg/m3), which comprises the overwhelming majority of pharmaceutical active substances.

Spray Drying

Spray Drying suite (lab-scale Buchi B290 in our formulation lab and Gea Niro Mobile Minor in the GMP manufacturing plant), capable for working with highly potent active substances.

Applications

- Solid dispersions
- Modification of particle size and morphology
- Particle coating
- Manufacturing of microcapsules and microparticles
- Controlled release
- Taste masking

Development and Niche Manufacturing Integration

IDIFARMA's unique value proposition is the ability to combine our experience as contract development partner for over 18 years with our niche manufacturing capabilities, and our specialization in highly potent drugs.

Additionally, IDIFARMA is able to provide niche spray drying services from development to clinical and commercial manufacturing.

IDIFARMA is a 100% client-oriented CDMO partner, without conflicts of interest and respecting the client property and confidentiality in each project.

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