

**75**  
years  
Since 1949

 **Dipharma**

# EXPERIENCE YOU CAN TRUST

Achieving your goals more  
easily, safely and rapidly.



**APIs**

for Generic  
Market

# With you every step of the way, bringing innovation

## What we offer

We develop **proprietary chemical processes and alternative solutions** to support the generic API industry.

You can rely on a true turnkey service where **commercially competitive products** are promptly conceived and manufactured in full compliance with third-party intellectual property rights.

Along with **quality, confidentiality, safety** and the ability to meet deadlines, **we ensure a well-established and reliable supply chain for your peace of mind.**

## Our talent

Our collaboration extends beyond technical skills with **more than 70 years of experience** in the field. We realise how valuable it is for you **to rely on a trusted partner** to propose the right solution and support your formulation team for a **successful launch that respects the timeline.**

This talent is, for us, a matter of pride. **We are with you every step of the way**, from the first gram in the Lab until the commercial launch.



## Why you can trust us

As part of the global pharmaceutical industry, we serve human health and, therefore, operate under **the highest standards of safety and quality.** This is confirmed by an extensive list of **successful inspections run by EU and US Health Authorities** certifying the cGMP level of our production sites.

We have the right dimensions and several scale capabilities **to manage processes efficiently:** sizable and experienced enough to be solid, but flexible and agile enough **to promptly solve any challenge** in the life of the project.

# Taking the API supply further



**More than 40** commercially APIs



A history of **75 years** of constant reliability



**All four sites** governed by the strictest **cGMP Quality System**



**Extensive positive** track record of **inspections** by the main **Regulatory Agencies**



**Experience** in **filing DMF** worldwide



**More than 250 patents** filed to protect our innovation rights



Specializing in the **handling of hazardous process**



**Customizing particle size** to match your formulation requirements



**Providing pre-formulation and solubility data** to enhance the API proposal



## Core Technologies

✓ High-pressure hydrogenation\*

✓ Nitration\*

✓ Nitroesterification\*

✓ Azide chemistry

✓ Borane reductions

✓ Carbohydrate chemistry

✓ Cross-coupling reactions

✓ Curtius reaction reduction

✓ Dissolving metal

✓ Enantioselective reactions

✓ Enzymatic chemistry

✓ Epichlorohydrin chemistry

✓ Hoffman reaction

✓ Hydrogen peroxide oxidations

✓ Use of nitroalkanes (Henry reaction)

✓ Wolff-Kishner reduction

\* Strategic cooperation with Biazzi SA, engineering sister company specializing in hazardous chemistry



# Our products

## Commercial products

- ◇ AMINOCAPROIC ACID
- ◇ AMITRIPTYLINE HCl
- ◇ BUPROPION HCl
- ◇ CHENODEOXYCHOLIC ACID\*
- ◇ CYCLOBENZAPRINE HCl
- ◇ DAPSONE
- ◇ DEXLANSOPRAZOLE ANHYDROUS CRYSTALLINE
- ◇ DICLOFENAC POTASSIUM
- ◇ DICLOFENAC SODIUM
- ◇ DOTHIEPIN HCl (DOSULEPIN HCl)
- ◇ DOXEPIN HCl
- ◇ ENTACAPONE
- ◇ FESOTERODINE FUMARATE
- ◇ FEXOFENADINE HCl
- ◇ GLIBENCLAMIDE (GLYBURIDE)
- ◇ GLYCOCHOLIC ACID
- ◇ IBUPROFEN LYSINE SALT
- ◇ ISOSORBIDE DINITRATE
- ◇ ISOSORBIDE-5-MONONITRATE
- ◇ METARAMINOL\*
- ◇ MINODRONIC ACID
- ◇ MODAFINIL
- ◇ NIFEDIPINE
- ◇ NITROGLYCERINE
- ◇ NORTRIPTYLINE HCl
- ◇ PIRFENIDONE
- ◇ PIROXICAM
- ◇ RUFINAMIDE
- ◇ SELEGILINE BASE\*
- ◇ SELEGILINE HCl
- ◇ TAUROURSODEOXYCHOLIC ACID
- ◇ TOLBUTAMIDE
- ◇ TRIAMTERENE
- ◇ URSODEOXYCHOLIC ACID
- ◇ ZONISAMIDE

## New products

Already validated/under validation

- ◇ BENSERAZIDE HCl
- ◇ BIPERIDEN HCl
- ◇ CHOLIC ACID
- ◇ CRISABOROLE
- ◇ DICLOFENAC EPOLAMINE
- ◇ EFINACONAZOLE
- ◇ SODIUM PHENYLBUTYRATE
- ◇ VARENICLINE TARTRATE
- ◇ VORTIOXETINE HBr



\* only for specific markets

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# Our team in action

How to develop an innovative, successful and cost-competitive API for Generic



### PROCESS RESEARCH

Selecting a non-infringing and cost-effective process by **combining technological innovation with our experience.**



### PROCESS DEVELOPMENT

Defining and investigating key process parameters including a **complete safety** and **calorimetric assessment**. Securing the **protection of IP rights.**



### SUPPLY CHAIN EVALUATION

Suppliers for the main raw materials are identified and selected based on **reliability, quality, geographical risk mitigation and cost competitiveness.**



### ANALYTICAL RESEARCH

In order to guarantee the highest quality, **dedicated analytical methods are developed in-house** to characterize products and intermediates.



### PROCESS INDUSTRIALIZATION

R&D coordinates process scaling-up to commercial scale batch validation, **ensuring a complete and smooth transfer** to the production teams.



### REGULATORY SUPPORT

**Full regulatory support** is available, including CEP or DMF filing in almost all countries worldwide.



### A STEP FORWARD

**Pre-formulation trial** with excipient, solubility studies in different solvents and particle size adjustment, move our API a step forward.





## APIs

for Generic  
Market

75  
years  
Since 1949

 **Dipharma**

## Where we are

### Sales Department:

#### Headquarters

**Dipharma Francis S.r.l.**

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20021 Baranzate (MI) - Italy  
Tel. + 39 02 38228.241

#### Contact us:

##### Europe

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##### North America

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##### Other countries

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### Branch Offices:

#### USA

**Dipharma Inc.**

4502 Campus Drive  
Kalamazoo, MI 49008

#### CHINA

**Beijing Repr. Office**

**Dipharma Francis**  
Room 527 Building 6  
No. 9 in FangYuan NanLi  
Chaoyang District  
100016, Beijing

### Manufacturing Sites:

#### ITALY

**Dipharma Francis S.r.l.**

- Via Bissone, 5  
20021 Baranzate (MI)
- Via Origgio, 23  
21042 Caronno  
Pertusella (VA)
- Via XXIV Maggio, 40  
33036 Mereto di Tomba  
(UD)

#### USA

**Dipharma Inc.**

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### R&D Centers:

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