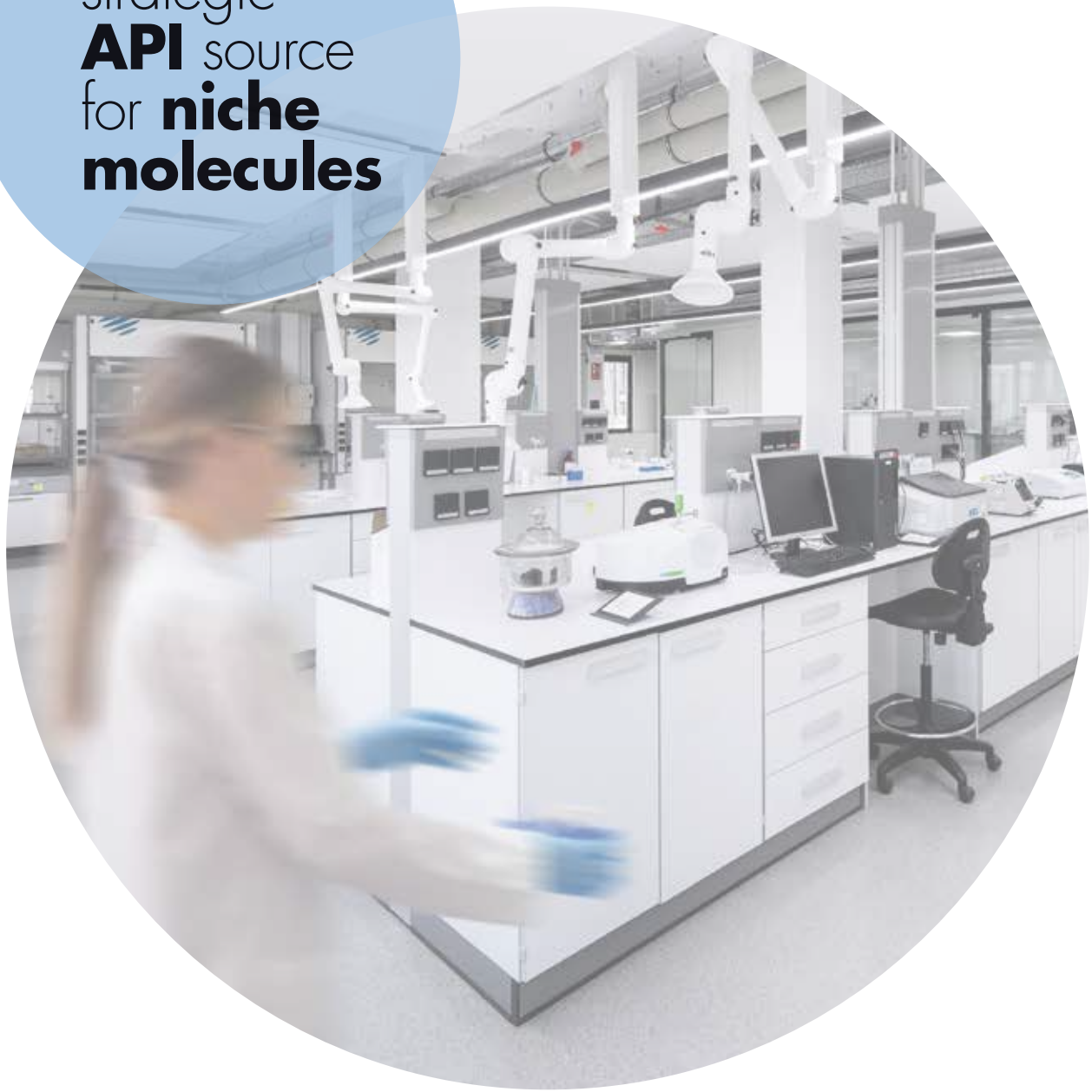
CERTIFICATE GMP Nº NCF-II/1914/001/CAT

Your strategic **API** source for **niche molecules**



Lebsa

Your Partner in API's Manufacturing

70 ANIVERSARY

Lebsa is an innovative European laboratory dedicated to the development, manufacture and distribution of **Active Pharmaceutical Ingredients** (API) with **70 years of experience.**

Based in Barcelona, Spain, Lebsa is a trusted partner. **We are flexible, customer-centred, committed to successful long-term business relationship and continuously** seeking out new challenges, focusing on niche molecules, R&D development and up to date flow-chemistry processes.

Lebsa has always had high standards:
in innovation, engineering, supply-chain management, regulatory support, quality control and customer service.

The challenging API industry

Pharmaceutical companies are facing new and more complex challenges every day. From stronger regulatory boundaries to the urgent need for new developments.

We are on the brink of a revolution in human healthcare, and **the opportunities will be immense.** API manufacturers must rise to meet the challenge.

Lebsa provides solutions for these challenges.

European quality API manufacturing

Following the **highest standards**, Lebsa offers a product range of **niche, small-molecule APIs** while actively researching and innovating in order to bring new products to the market.

Besides, Lebsa facilities and expertise allow us to accept **API CDMO** (Contract Development and Manufacturing Organization) requests, in addition to our existing product catalogue.

Lebsa also provides the API regulatory support you need to get your products to market on time **overcoming barriers** and **speed up time-to-market** processes.

Lebsa has outstanding expertise in **registering APIs in Europe, Canada, Taiwan, China, Russia, Brazil and Japan, among others.**

Facilities

Lebsa's European facilities feature cutting-edge technology, equipment and automated processes, as well as state-of-the-art validated IT systems, including SAP®, Opentext® and SCADA Intouch®.

Lebsa doesn't outsource production. Everything is done within their facilities, with **complete control** over operations and production management. Lebsa's own secure IT systems for supply-chain and quality control management assures **total data integrity.**

Our **highly trained technical team** is ready to work closely with you at every stage, offering total confidentiality, rapid responses and full regulatory support.

Technical details

Reactors:		
All fitted with distillation units		
Glass lined:	1,6 m^3	4
With rectification column		
Stainless steel:	2,5 m^3	1
Centrifuges:		
Stainless steel AISI 904	850 mm	4
Dryers:		
Vacuum Tray Dryer	2,5 m^3	1
Vacuum Bicone Dryer	1,5 m^3	1
Reaction conditions:		
Temperature	-20 °C to 160	°C
Pressure	Up to 5	bar
Vacuum	Up to 1	mbar
Utility services:		
Water steam boiler	2.000 kg/h	1
Chiller	500 kW	2
Scrubber	1.500 m^3/h	2
Vacuum pump	300 m^3/h	3

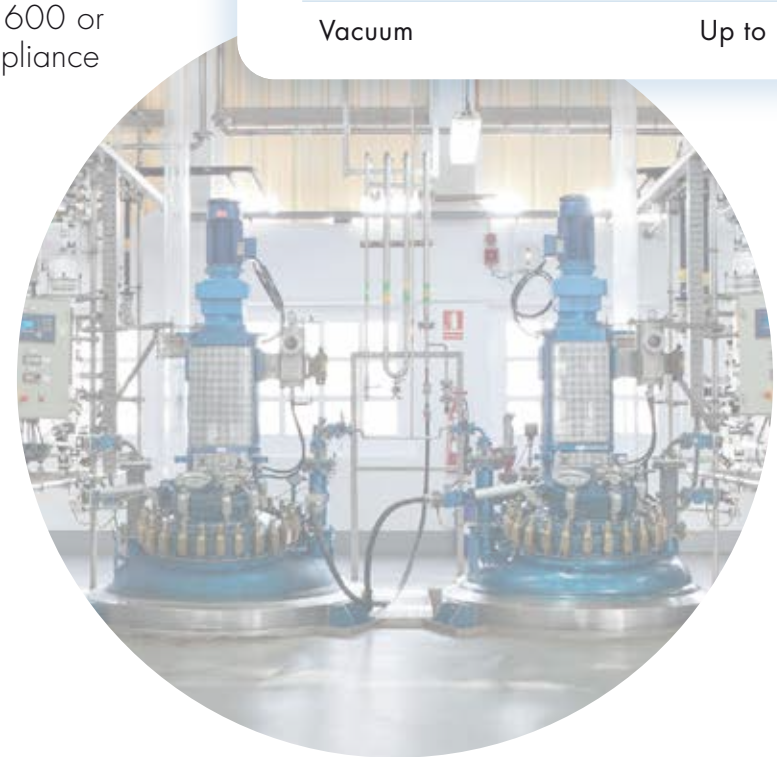
cGMP Pilot Plant

Lebsa's cGMP pilot plant is fully automated and develops API in a scalable, secure and environmentally friendly way. Open to third parties, it also offers analytical services and full regulatory support.

Lebsa's **experience and flexibility** allows us to manufacture from a laboratory scale of just a few grams to some kilograms in our GMP pilot plant (10, 63 and 250 litres reactors) or to industrial quantities (1600 or 2500 litres reactors). Compliance with the highest cGMP standards is always assured.

Technical features

Kilolab	
Triple Wall glass reactor and distillation unit	10 litres
Vacuum oven	2 trays
Operation Conditions	
Temperature	-85 °C to 200 °C
Pressure	Up to 0,5 bar
Vacuum	Up to 1mbar
Reactors	
All fitted with distillation units	
Glass lined	250 litres
With rectification column	
Hastelloy C-22	63 litres
Filter Dryers	
Hastelloy C-22	0,1m² / 60 litres
Operation Conditions	
Temperature	-20°C to 160 °C
Pressure	Up to 3nbar
Vacuum	Up to 1mbar



API Research & Development with purpose

Our active R&D department is constantly focusing on **improving our molecular-synthesis processes**, shortening times and improving the final quality and stability of the molecules.

At the same time, we are incorporating **new green manufacturing technologies**, such as **flow chemistry.**

LABORATORY: R&D

Reactor

Microwave Synthesizer	
Operation Conditions	
Temperature	40 - 300 °C
Pressure	0 - 30 bar

Analytical equipment

HPLC/UHPLC with mass detector

Reactor Low Flow – Corning

Temperature	-60 - 200 °C
Pressure	Up to 18 bar
5 liquid pumps	0.001 - 25 mL/min
Gas mass flow controller *(Bronkhorst)*	N2, O2, H2, CO2, CO, C2H2, air, Ar

LABORATORY: ANALYTICAL EQUIPMENT

- High pressure liquid chromatography
- Gas chromatography instrument with Head Space
- UV/Vis Spectrophotometer 160
- Infra Red Spectrophotometer FT-IR 8400S
- Titrator (Potentiometer) DL 25
- Karl Fischer Apparatus DL 31
- Melting Point Apparatus FP 61
- Muffle furnaces
- Vacuum furnace V0400
- Polarimeter Carl Zeiss
- Refractometer

Quality and compliance

Lebsa's concept of quality goes beyond certification. It extends to everything we do - and how we do it.

Our dedicated Quality Assurance (QA) and Regulatory Affairs department ensures complete compliance with regulations and manages the documentation for pharmaceutical registration records.

Our own QMS (Quality Management System) is based on the GMP ICH Q7A guide and the ISO 9001:2015 standard. Its objective is continuous improvement in all areas of the company.

IQNet CERTIFIED QUALITY SYSTEM

AENOR QUALITY MANAGEMENT SYSTEMS ISO 9001 ER-0098/1999

AENOR ENVIRONMENTAL MANAGEMENT SYSTEMS ISO 14001 GA-2018/0183

AENOR OCCUPATIONAL HEALTH AND SAFETY ISO 45001 SST-0138/2018

All standard Lebsa products have EU DMF and/or CEP, which guarantee a robust manufacturing process, data integrity and traceability.

Transparency is total: Lebsa is regularly audited and inspected by clients and healthcare regulatory agencies. We work only with approved and trusted providers to assure full supply chain control.

Sustainability

We adhere to the highest standards of **health and safety in the pharmaceutical industry.** We work tirelessly to prevent risks, ensuring that industrial safety is paramount and fully incorporated into all operations.

Our respect for the environment drives us to follow best practices and achieve full certification in managing solid and liquid waste.

Standard APIs

Main Therapeutic Application	Product Name	CAS-RN	Specification	Documentation
ANTIPSYCHOTICS	Amisulpride	71675-85-9	Ph. Eur.	EDMF / CEP
	Sulpiride	15676-16-1	Ph. Eur.	EDMF
	Tiapride hydrochloride	51012-33-0	Ph. Eur.	EDMF / CEP
ANTIVERTIGO	Betahistine dihydrochloride	5579-84-0	Ph. Eur. / USP	EDMF / CEP / KDMF
	Betahistine dimesilate	54856-23-4	Ph. Eur.	EDMF
ANTIEMETIC	Bromopride	4093-35-0	Ph. Brazil	EDMF
ANTISEPTICS	Dequalinium chloride	522-51-0	Ph. Eur.	EDMF / JDMF / CEP
	Dibrompropamidine isetionate	614-87-9	Ph. Eur.	EDMF
	Picloxydine dihydrochloride	19803-62-4	In-house	EDMF
	Propamidine isetionate	140-63-6	In-house	EDMF
DIAGNOSTIC AGENT	Histamine dihydrochloride	56-92-8	Ph. Eur.	EDMF / CEP
	Histamine diphosphate monohydrate	51-74-1	In-house	EDMF
ANTIHYPERTENSIVE	Lacidipine	103890-78-4	B.P.	EDMF / KDMF
ANTIDEPRESSANT	Mianserin hydrochloride	21535-47-7	Ph. Eur	CEP EDMF

APIs Pipeline

ANTINEOPLASTIC AGENT	Venetoclax	1257044-40-8	In-House	Technical pack
ANTISEPTIC	Octenidine dihydrochloride	70775-75-6	In-House	Technical pack
ANTIVIRAL	Letermovir	917389-32-3	In-House	Under development

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MADE IN EUROPE

Are you looking for other molecules?

For more information about our R&D pipeline and CDMO services

CONTACT US

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