Pharma Chemicals

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RECORDATI

Recordati Group at a glance

With its beginnings in a family-run pharmacy in Correggio, Italy, in the 1920s, Recordati is now a global pharmaceutical group listed on the Italian Stock Exchange.

We are a group of like-minded, passionate individuals who go to extraordinary lengths for our partners, customers, investors, and the people we serve across the globe.

We develop and commercialise medicines for people living with common diseases, as well as those living with some of the rarest.

GROUP HIGHLIGHTS

9 manufacturing plants, covering the full production cycle from active pharmaceutical ingredients (APIs) to finished products and packaging, dedicated to our medicines.

Ecovadis 2026

GOLD | Top 5% ecovadis Sustainability Rating JUN 2026

We pursue a sustainable growth model by integrating social and environmental aspects into our corporate strategy.

We work on **reducing our environmental impact** and continuing to fight against climate change, increasing our efforts towards a circular economy and promoting waste reduction initiatives.

100% of electricity purchased for Group plants comes **from renewable sources,** in countries where this was possible.

[This figure excludes Tunisia, where renewable energy is not available]

We have advanced on our roadmap regarding **renewable energy production systems** at our main plants.

Pharma Chemicals milestones

1926

The manufacturing of active ingredients has been closely linked with pharmaceutical activities since the beginning of Recordati's history: as early as 1926, Giovanni Recordati transformed the family-run pharmacy and adjoining chemical laboratory into the **"Laboratorio Farmacologico Reggiano"**, resulting in the birth of Recordati as a Chemical Pharmaceutical Industrial Company.

1952

Pharmaceutical production and research moved from Correggio (RE, Italy) to **Milan**. Since then, innovation and internationalisation have always been Recordati's objectives.

1963

The new pharmaceutical chemicals plant in **Campoverde di Aprilia** is born, replacing the chemical plant in Correggio. Here, Recordati produced and continues to produce **flavoxate**, **the first Italian drug to receive FDA approval in the US.** Under the new name Recordati Industria Chimica e Farmaceutica, the company grew internationally with products such as flavoxate, fenticonazole and lercanidipine and outlined its development strategy.

2005

Recordati establishes the new pharmaceutical chemical plant in **Cork**, Ireland, to guarantee adequate and continuous supplies of active ingredients and in 2007 enters into the Rare Diseases sector.

Today

Our pharmaceutical chemicals business is an important company asset, exporting around **90%** of its production of **APIs** and **intermediates**, selling directly in over **50 countries** and manufacturing intermediates and active ingredients for Recordati pharmaceutical brands. Recordati is also engaged in the exclusive and custom manufacturing business, serving major innovator and big pharma organisations.

01. Plants and facilities

The Campoverde site is focused on supplying high-quality active pharmaceutical ingredients and intermediates to the pharma market and to Recordati's pharmaceutical operations, in the framework of a strong vertical integration.

It was **one of the first Italian chemical pharmaceutical plants authorised to export to the United States**, and it is the manufacturer of flavoxate HCl, the first Italian synthetic drug to be approved by the U.S. Food and Drug Administration. Many different therapeutic areas are covered, in both **Specialty & Primary Care**, with relevant contributions in the field of **Rare Diseases treatment**. An outstanding level of technical expertise, combined with a dynamic and purpose-driven organisation, enables the full management of a reliable production chain, from raw materials supply to finished APIs. The wide range of technologies and the extensive know-how acquired over the years enable the Campoverde plant to maintain the highest quality standards. Located in the green countryside south of Rome, the site operates with a strong commitment to **Environmental, Social and Governance (ESG) principles**, integrating sustainability into our business strategy and supporting positive relationships with the local community.

CAMPOVERDE

KEY FIGURES

- Total Area: 375,000 m^2
- Building Area: 35,000 m^2
- Output: 600 MT/y
- In-process intermediates: more than 4,000 MT/y

MANUFACTURING EQUIPMENT

- Reactors: 800 m^3, glass lined (30%) and stainless steel (70 %), from 0.4 m^3 to 25 m^3 each
- Total storage volume: 2,600 m^3

CAMPOVERDE CORE CAPABILITIES

- A wide range of competencies in the field of organic synthesis enables the rapid and effective development of new processes, from research to final industrialisation.
- The Research and Development department is fitted with an extremely versatile pilot plant, equipped for c-GMP compliant scale-up testing and small-scale production of high-value APIs.
- The site has expertise and technical capabilities, enabling the execution of many different types of chemical reactions and purifications, and safely utilising highly dangerous chemicals.
- All operations are carried out in compliance with current Good Manufacturing Practices (cGMP) and to the most stringent international environmental regulations.
- The Plant Environmental Management System is certified by Det Norske Veritas Italy according to the ISO 14001:2015 standard.
- Investments are continuously made to enhance the technological and production capacity of the plant; in recent years, these projects have resulted in the installation of more than 25 new reactors, a latest generation three-stage distillation unit for liquids unstable at high temperatures, two thin film evaporators, four filters for the isolation of solid products and an anti-acid dryer.
- Specific sustainability projects are implemented to continuously reduce the environmental footprint of the site, by reducing emissions and resource utilisation.
- Recordati has started a three-year project aimed at the installation of a 10 MWp photovoltaic power generation facility and the downsizing of the methane-based co-generation unit currently in use. These measures will provide a significant reduction in Recordati's carbon footprint.

CORK

KEY FIGURES

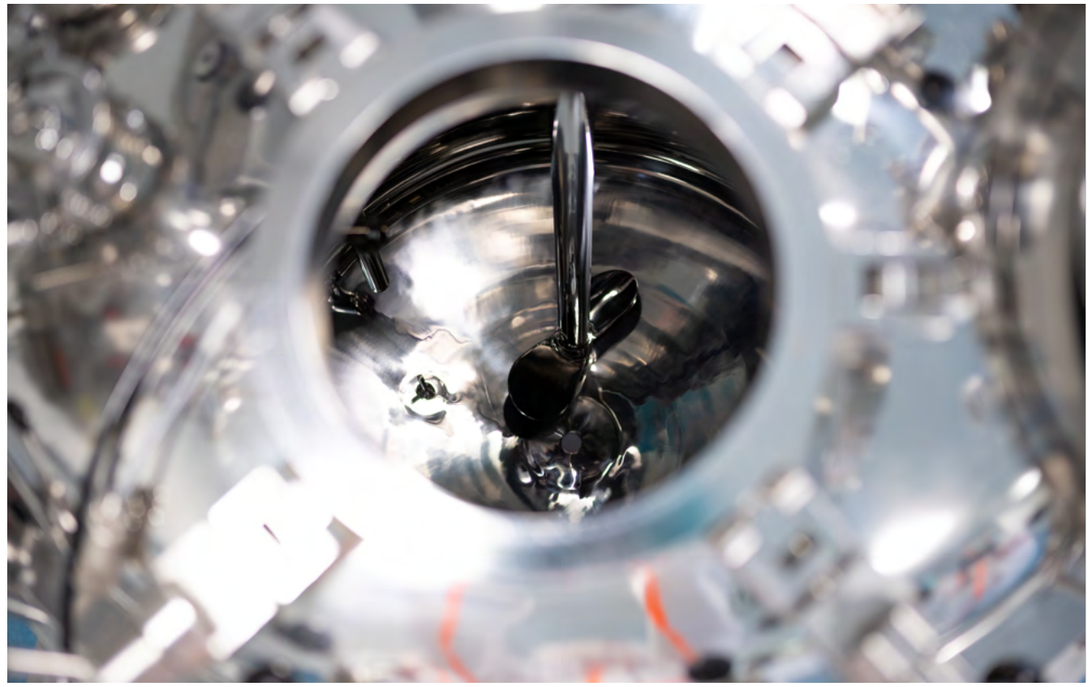
- Total area: 43,400 m^2
- Production Area: 2,100 m^2
- Production: Lercanidipine API

MANUFACTURING EQUIPMENT

- Reactors: 17 m^3 (35% glass lined; 65% stainless steel)
- Storage vessels: 395 m^3 (60% solvents; 40% utilities)

CORK CORE CAPABILITIES

- Our plant in Cork is dedicated to the continuous supply of a single active ingredient, Lercanidipine HCl, fully researched and developed by Recordati.
- The manufacturing process is controlled through an automated system, maintaining the highest Safety and Quality standards.
- The site operates in accordance with GMP (Good Manufacturing Practices).
- It received the 2012 National Energy Efficiency Award promoted by the Sustainable Energy Authority of Ireland (SEAI) and in 2013 received the European Energy Efficiency Award promoted by the Chemical European Federation Industry Council (CEFIC).
- An extension completed in 2016 allowed for additional space in the Quality Control Laboratory and the Administration Building.
- Photovoltaic panels for the generation of electricity were installed in 2022 for a total area of 1,100 sq.m., providing 10% of the site's electricity demand.



BASEL

KEY FIGURES

- Total area: 1,500 m^2
- Production Area: 250 m^2
- Production: pasireotide microparticles for Signifor® LAR

MANUFACTURING EQUIPMENT

- Manufacturing Vessels, stainless steel (100%), from 0.02 to 05m^3
- Storage Vessels, stainless steel (100%), from 0.02 – 1.5 m^3
- Manufacturing & Storage of Water for Injection, 1.5m^3

BASEL CORE CAPABILITIES

- Located on the Novartis Campus, the facility operates under an advanced automated process control system, ensuring high reproducibility, safety and consistent product quality. The site specialises in the technologically advanced manufacturing of biodegradable microparticles, an innovative dosage form for long-acting injectables.
- Since its successful qualification and GMP certification by Swissmedic in 2012, the plant has been regularly inspected by both national and international regulatory authorities, including the Swissmedic (Swiss Agency for Therapeutic Products), the FDA (US Food and Drug Administration), and ANVISA (Brazilian Health Regulatory Agency).
- The site combines flexible manufacturing capabilities, scalable infrastructure and a highly-skilled workforce with a continuous investment programme in process technologies, facility upgrades and digital solutions, enabling it to efficiently adapt to evolving product and business needs.
- Designed with sustainability in mind, the facility minimises energy consumption and prevents process-related emissions, safeguarding environmental protection.

02. Manufacturing

A wide range of vertically integrated operations ensures the production of top-quality products, transforming simple raw materials through highly complex chemical processes.

One of Recordati's key areas of manufacturing expertise is the utilisation of substances requiring special risk management measures and the execution of reactions under extreme conditions, such as high temperatures and pressures. Continuous efforts are made to keep all production lines and areas at the forefront of technology, with relevant investments aimed to continuously improve **QHSE management** and to **develop production capacity, efficiency and flexibility**.

MANUFACTURING FACILITIES AND UTILITIES

- 4 Synthesis Departments, producing intermediates and APIs wet cakes
- 1 Finishing Department, in charge of drying, milling, micronising and packaging intermediates and products
- Multipurpose Equipment, with a high level of flexibility
- Waste Water Treatment Plant, performing chemical-physical and biological processes
- Thermo-electrical Power Station, able to supply the entire energy requirements of the site
- Reverse Osmosis System for Purified Water
- Internal nitrogen production, for blanketing equipment with no significant risks of operations interruption
- A large variety of cooling and heating fluids, covering a wide range of operating conditions

PROCESS CAPABILITY

- Oxidations
- Chloromethylations
- Friedel-Crafts and Fries reactions
- High temperature condensations
- High and low pressure catalytic reductions
- Alkylations and dealkylations
- Cryoreactions
- Halogenations
- Phase-transfer catalytic reactions
- Esterifications
- Amidations
- Hydrogenations and dehydrogenations
- High OEB chemicals in small scale
- Medium to high vacuum distillations for thermally sensitive compounds

03. Quality

Recordati's pharmaceutical chemicals business unit is committed to establishing and maintaining a quality system that meets international guidelines.

The Quality System established by the business unit is committed to meet international guidelines, including (but not limited to):–ICH Q7 **"Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients"**, Eudralex Volume 4 Good Manufacturing Practice (GMP) Guidelines: Part II - **"Basic Requirements for Active Substances used as Starting Materials", Part III "GMP - related document"**, Annex 11 "Computerized systems", CFR 21 part 11 and ANVISA Resolution RDC 654/2022.

Recordati is recognised as a leader in several high purity APIs and a reliable provider of compendial reference standards. The company's cooperation with European and United States pharmacopoeia expert committees began more than 20 years ago with the proposal for compendial monographs for APIs developed by Recordati. More recently, the company cooperated in the revision of several compendial monographs to introduce highly selective methods for related substances determination.

GMP AND EHS COMPLIANCE

- Approved by the Italian Ministry of Health since 1964
- Last AIFA inspection was held in September 2025
- FDA inspected since 1969
- Last FDA Inspection was held in June 2018
- Approved by Korean Ministry of Health since 2006
- Accredited by Japanese Ministry of Health since 2009
- Last renewal of the PMDA accreditation in September 2024
- Approved by the Brazilian Ministry of Health since 2011
- Last ANVISA inspection in 2015
- UNI EN ISO 14001 Certification by DNV since 2003
- Integrated Pollution Prevention and Control Authorisation (AIA) according to European Directive 2010/75/UE
- Compliant to Directive 2012/18/UE on the control of major-accident hazards involving dangerous substances

AIFA AGENZIA ITALIANA DEL FARMACO

Pharmaceuticals and Medical Devices Agency, Japan

FDA U.S. FOOD & DRUG ADMINISTRATION

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

edqm European Directorate for the Quality of Medicines & HealthCare

ICH Member

ANVISA Agência Nacional de Vigilância Sanitária

KFDA Korea Food & Drug Administration 식품의약품안전청

04. Small scale API manufacturing & Tech Transfer

The R&D department's main role is to support Recordati's business development through the fine-tuning of new products and the manufacturing of APIs for both Recordati and other pharmaceutical companies.

To this end, a complete set of manufacturing facilities is available both at laboratory and pilot plant scale, combined with the use of **suitable software for process development and tech transfer from the lab to the production plant**.

SMALL SCALE CGMP MANUFACTURING FACILITIES: KG-LAB

- Small scale production in cGMP compliance
- GMP Kg-Lab
- GMP isolator for API manufacturing: handling of Toxic, air/moisture sensitive compounds and HPAPI (OEL< 1 µg/ m^3)
- Isolator Total Capacity: 25 L
- API batch size: from 200 gr up to 1 Kg
- Kg-lab Glass reactors: 0,5 to 10 L
- Operative conditions: -90°C to 220°C
- GMP kg-lab Vacuum-Filter/Dryer (100 mL to 1000 mL capacity)
- GMP glovebox for packaging under inert atmosphere (argon, nitrogen)

PILOT FACILITY

- Pilot Reactors: 100- 1400 L (Glass lined, AISI 316, Hastelloy reactor with Cryogenic capability)
- Pilot equipment under SCADA control, equipped with mass flow controllers and load cells
- Hydrogenation Autoclaves: 200 L (100 bar) - AISI 316
- Operative conditions:-90°C to 140°C
- Equipment for batch Distillation
- Pilot Total Capacity: 7500 L
- Isolating Equipment: Pressure Filter-Dryer, Centrifuges
- Tray Dryer; Crusher; Sieving Mill
- Controlled areas for APIs isolation and finishing
- High containment for HPAPI handling (OEL< 1 µg/ m^3)

ANALYTICAL R&D CAPABILITIES

- Bruker AvanceNeo 400MHz NMR with H, C and other nuclei
- LC-MS-iontrap detector, equipped with ESI and APCI sources
- SCIEX QTRAP 6500+ SYSTEM for nitrosamine and genotoxic impurities identification
- GC-MS with head-space capability
- Polarimeter
- FT-IR with NIR capability, UV-Vis spectroscopy
- HPLC with ELS detector
- DSC and Mettler melting point
- GMPcertified GCs with-head space capability
- GMPcertified HPLCs
- GMPcertified UPLC with multiple columns comparison
- Classic titration equipment
- KF titrators
- Other equipment available at QC: Malvern for particle size, microscope for crystal studies, muffle for ashes

PROCESS R&D CAPABILITIES

- Hel Multi-reactor for process development, optimisation and critical parameters studies
- Multi-reactor Capability for Calorimetric Study
- Crystal 16 for solubility and crystallisation studies
- Lab. Hydrogenation Autoclaves with dosing system up to 60 bars
- Flasks and Lab Reactors from 100 mL up to 10 L, with operative range from-90°C to 220°C
- VisiMix software for mixing simulation to study scale-up parameters
- Flow reactor for flow chemistry studies
- Isolator for handling toxic reagents and air/ moisture-sensitive products
- Standard distillation and kilo-scale Short Path Distillation Equipment
- Laboratory Pressure-Filter/Dryers and Ovens

05. R&D

The R&D department is composed of a team of highly specialised researchers and technicians, who have mastered organic chemistry reactions and production technologies as well as short path distillation, high pressure hydrogenation and flow chemistry.

Thanks to highly efficient discovery programmes, as well as alliances with other pharmaceutical and research institutes, **Recordati has always been able to successfully introduce new products into its portfolio**. Commitment, scientific rigour and technological capability in the R&D department allow Recordati to develop new treatments and to build an innovative product pipeline. To constantly ensure high API quality and robustness of production, the R&D group is involved in a continuous performance improvement cycle; however, the main research and development activities are mainly focused on generating innovative treatments with special attention to rare diseases.

R&D EXPERTISE

EXPERTISE IN HAZARDOUS AND HIGHLY TOXIC CHEMICALS HANDLING:
Na2 S, NaCN (not gaseous HCN), POCl3, SOCl2, formaldehyde, methylbromide, dimethylsulfate, other H350, liquid ammonia, peroxyacids.

ORGANOMETALLIC REACTIONS:
Grignard reagents, organolithium and lithium derivatives.

REDUCTIONS:
Catalytic hydrogenation (homogeneous and heterogeneous), metal hydrides (NaBH4, LiAlH4), Raney-Nickel, hydrogen transfer.

ASYMMETRIC REACTIONS:
Transition metal catalysts (hydrogenation, oxidation), biocatalysts, racemate resolution, use of chiral building blocks.

OXIDATIONS:
Peroxyacids, bichromate, inorganic salts, dehydrogenations.

REACTIONS UNDER SPECIAL CONDITIONS:
high-temperature reactions (+250°C) high-pressure reactions (10–100 bar) Flow-chemistry

ANALYTICAL R&D:
Specification set-up, Method development and validation, Solubility & Crystallisation studies, Operative stability and Material Compatibility studies.

SOLID STATE MANAGEMENT:
Polymorphism studies: detection, characterisation and interconversion mapping. Particle size studies.

06.
Our responsible growth

Recordati has a long history of entrepreneurial passion, a strong reputation and a desire to continue growing and creating value in an ethical, enduring and sustainable way.

We pursue these goals in accordance with the laws and regulations in each of the countries in which we operate, protecting people and the environment and supplying safe, high-quality products.

Recordati integrates ESG activities into corporate strategy.

GROUP CLIMATE COMMITMENT BY 2030:

-20% **Group CO_2 emissions (Scope 1 and 2 market-based vs 2022)**

Specifically, Campoverde plant is supporting this commitment by ambitious sustainability investments:

PHOTOVOLTAIC INSTALLATION (UPON PROJECT COMPLETION)

- Approximately **17,000 solar panels** installed across **100,000 m²**.
- Total installed capacity of **up to 10 MWp**, expected to cover approximately **40% of the plant's electricity demand**.

  - **4 MWp** already operational.

  - **6 MWp** is currently in progress.
  Once completed, it will be among the largest industrial photovoltaic installations in Italy in terms of both scale and technology and will contribute to reducing the Group's carbon footprint.

FOSSIL FUEL REDUCTION

- **30% reduction** in on-site methane consumption (mc), thanks to the downsizing of the cogeneration turbine, scheduled by 2027.

Product list

RECORDATI PHARMACEUTICAL ACTIVE PRODUCTS

PRODUCT	THERAPEUTIC CATEGORY
Acyclovir	Antiviral
Dimenhydrinate	Antiemetic
Diphenhydramine HCl	Antihistaminic
Diphenhydramine Citrate	Antihistaminic
Dobutamine HCl	ß-Adrenergic Agonist
Dopamine HCl	ß-Adrenergic Agonist
Ketorolac	Anti-inflammatory
Manidipine 2HCl	Calcium channel blocker
Mebeverine HCl	Antispasmodic
Methenamine Hippurate	Antibacterial (synthetic)
Papaverine HCl	Antispasmodic
Phenytoin	Anticonvulsant
Phenytoin Sodium	Anticonvulsant
Pyridoxal-5-phosphate	Enzyme co-factor vitamin B6
Sertraline HCl	Antidepressant
Tribenoside	Vasoprotective
Verapamil HCl	Calcium channel blocker

RECORDATI INTERMEDIATES

PRODUCT
(R)-Tetrahydropapaverine HCl
Tetrahydropapaverine HCl
Homoveratric Acid

PHARMACEUTICAL CHEMICALS
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Our first 100 years

In the 19th century, the Recordati family ran a small pharmacy in Correggio, Northern Italy, serving their local community. In 1926, at the age of 28, Giovanni Recordati moved from experimenting in the back of that same pharmacy to founding a company: the “Laboratorio Farmacologico Reggiano.”

One hundred years later, in 2026, we stand as a global pharmaceutical group with a presence in over 150 countries, committed to unlocking the full potential of life. Our centenary is not just a celebration of longevity, it is a confirmation of our purpose, values, continuity, and care.

At Recordati, we have always believed that health, and the opportunity to live life to the fullest, is a right, not a privilege. Whether addressing common conditions or the rarest diseases, we are committed to giving everyone the opportunity to be the best version of themselves. This commitment will not waver.

Recordati has a long history of entrepreneurial passion, a strong reputation, and a clear ambition to continue growing, innovating, and creating value in an ethical, enduring, and sustainable way—protecting people and the environment, and providing safe, high-quality products.

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RECORDATI

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