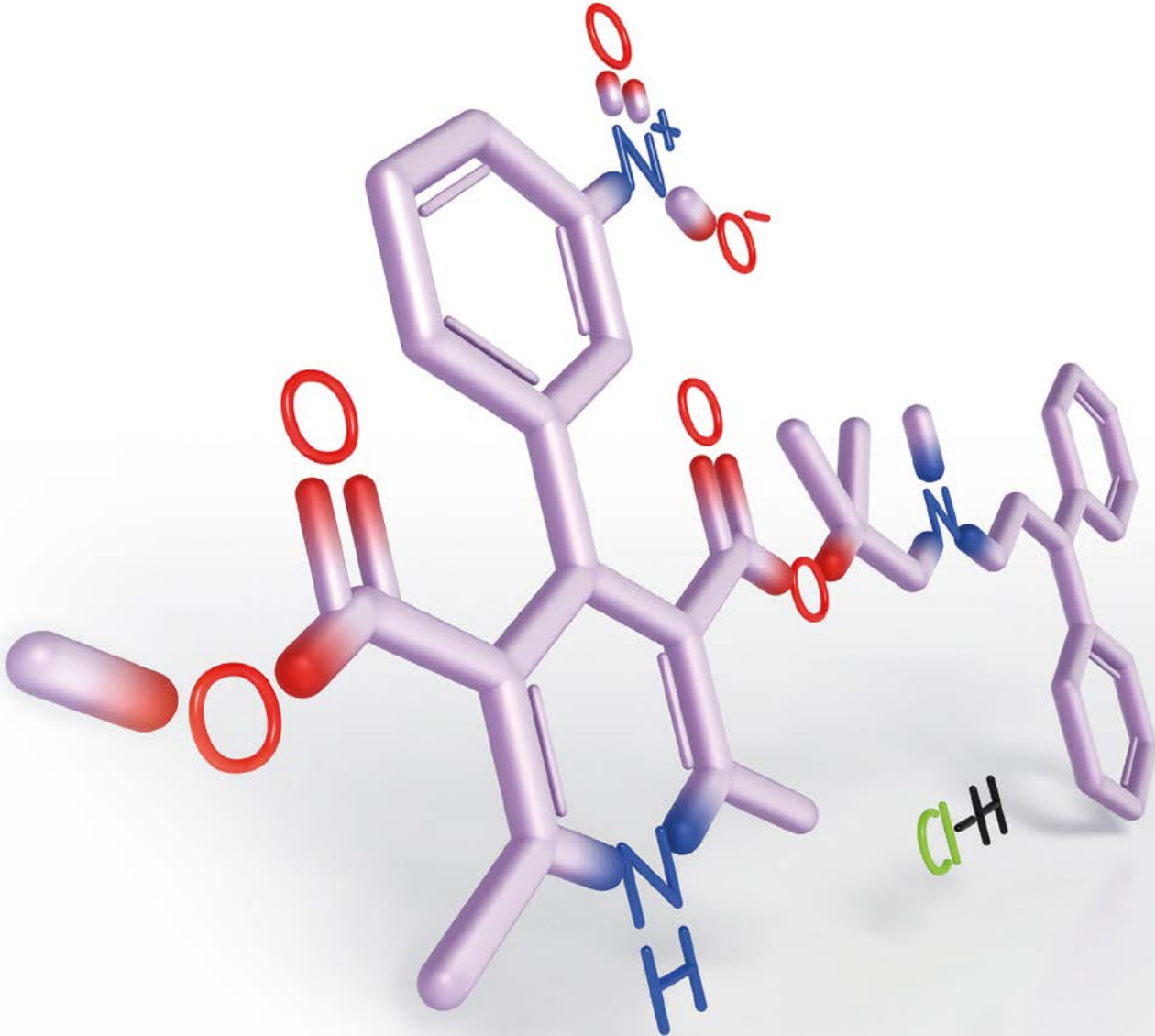


PHARMA CHEMICALS

for the last ninety years



OUR HISTORY



Under the guidance of **Arrigo Recordati**, representing the second Recordati generation, Pharmaceutical production and research moved from Correggio to Milan. While **innovation** and **internationalization** have been Recordati's goals, they have also been among the crucial aspects for the company's growth through the execution of a focused strategy.



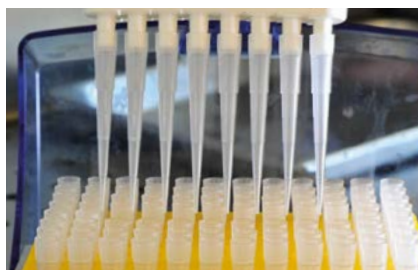
Under the new name "**Recordati Industria Chimica e Farmaceutica**" the company grew internationally to become renowned in the industry not only as a chemical manufacturer, but as a pharmaceutical company as well, with products such as Flavoxate, Fenticonazole and Lercanidipine, leading up to the most advanced products in the orphan drug line.



Recordati is engaged in the exclusive and custom manufacturing business, serving major innovator and big pharma organizations as well.

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 Pharmacy and adjoined Chemical Laboratory into the "**Laboratorio Farmacologico Reggiano**", resulting in the birth of Recordati as a Chemical Pharmaceutical Industrial Company.



In **1963**, Arrigo took the decision to replace the old and outdated chemical plant in Correggio with a new facility that was more suited to the times: **the new plant in Campoverde di Aprilia is born.**



Today Recordati's Chemical Division is still an important company asset, exporting around 90% of its production of API's and intermediates, selling directly in over 50 Countries and manufacturing intermediates and active ingredients for the Recordati pharmaceutical brands.

Selling directly in over
50 Countries



RECORDATI GROUP

Recordati is listed on the Italian Stock Exchange since 1984. It has grown constantly since 1926 thanks to the quality of its products and to the implementation of a decisive internationalization policy through a focused strategy of acquisitions and license agreements. Recordati produces and promotes innovative medicines worldwide including both products for specialty and primary care therapies as well as treatments for rare diseases. In addition to the marketing of specialties generated by its original research, the Recordati group is the European partner of leading international pharmaceutical companies. Headquartered in Milan, Italy, Recordati is present in about 150 Countries and it has operations in Europe, Russia and the other C.I.S. countries, in Ukraine, Turkey, North Africa, the United States of America, Canada, Mexico, some South American countries, Japan and Australia and it continues to strengthen its geographical presence. In 2021 it established a new subsidiary in China. Recordati constantly enhances its therapeutic offering through the development of its product pipeline with a focus on rare diseases. In July 2023, EcoVadis confirmed the Recordati group's "Platinum" rating, falling within the top 1% of companies with the highest score globally. This recognition represents a further sign of the importance of sustainability in the company's corporate strategy. The score assigned to Recordati is based on the policies, actions and results achieved by the company in 4 key areas for sustainability assessed by EcoVadis: Environment, Labor and Human Rights, Ethics, and Sustainable Procurement.

Employees exceed 4,300



PLANTS AND FACILITIES

The Campoverde site is focused on supplying **high quality active principles** 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 authorized 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 primary and specialty care, with relevant contributions in the field of rare diseases treatment. An outstanding level of technical expertise, combined with a dynamic and purpose-oriented organization, makes the full management of a reliable production chain, from raw materials supply to finished API. The wide range of technologies and the extensive know-how acquired over the years allow the Campoverde plant to produce with high quality standards. All operations are carried out with **special attention to sustainability**, with reference to global issues and to the relationship with the local community, located in the beautiful green plain south of Rome.



CAMPOVERDE FIGURES

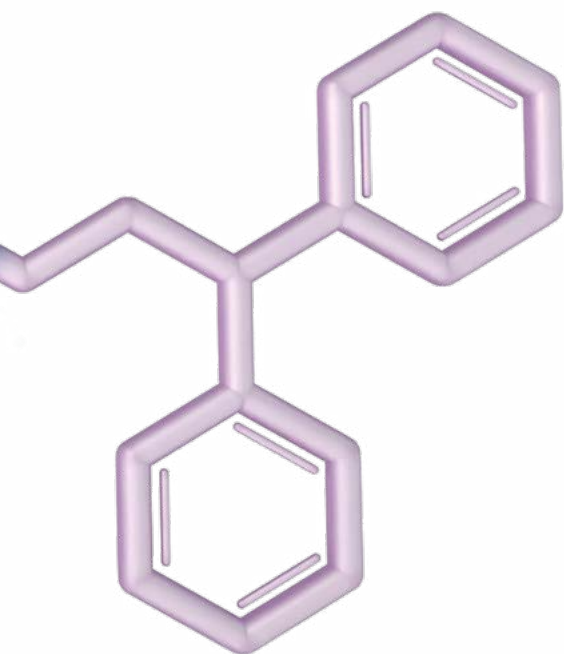
- Total Area: 335,000 m²
- Building Area: 35,000 m²
- Output: 650 MT/y
- In-process intermediates: more than 5,000 MT/y

THE MANUFACTURING EQUIPMENT

- Reactors: 820 m³, glass lined (30%) and stainless steel AISI 316/304 (70%), from 0.4 m³ to 25 m³ each
- Total storage volume: 2,600 m³

CORE CAPABILITIES

- A wide range of competencies in the field of organic synthesis allows to **quickly and effectively study new processes** from research to final industrialization.
- The Research and Development Department is fitted with an extremely versatile pilot plant equipped for c-GMP compliant scale-up tests and small scale productions.
- The site has **expertise and technical capabilities** enabling execution of many different types of chemical reactions and purifications, safely utilizing highly dangerous chemicals.
- All operations are carried out in compliance with current **Good Manufacturing Practices (cGMP)** and with 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; over the last decade, these projects have resulted in the installation of **more than 20 new reactors, a latest generation three stage distillation unit for liquids unstable at high temperatures, 2 thin film evaporators, 2 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 pursuing reduction of emissions and resources utilization reduction.



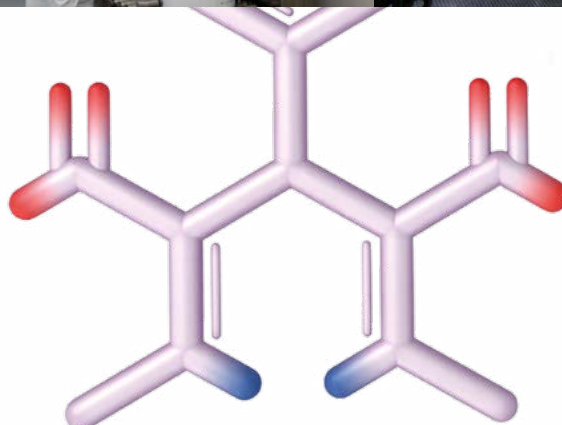
MANUFACTURING

A huge variety of vertically integrated operations allow to obtain **top quality products** starting from very simple raw materials, by managing extremely complex chemical processes. The capabilities related to the utilization of substances requiring special risk management measures and the possibility to carry out reactions in extreme conditions, such as high temperatures and pressures, are one of the most important components of the manufacturing expertise. A permanent effort is made to keep 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 API's wet cakes
- 1 Finishing Department, in charge of drying, milling, micronizing and packaging 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
- Cyanations
- 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



QUALITY ASSURANCE

Recordati's Pharmaceutical Chemical Division is committed to establish and maintain a **Quality System** which meets the 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" and Annex 11 "Computerized systems" and CFR 21 part 11. Recordati is recognized as a leader in the market of several high purity APIs and a reliable provider for compendial reference standards. Recordati's cooperation with the pharmacopoeia expert committees started **more than 20 years ago** for the proposal of the compendial monographs for the APIs developed by Recordati and more recently Recordati cooperated in the revision of several compendial monographs to introduce high 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 June 2019
- 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 2019
- Approved by the Brazilian Ministry of Health since 2011
- Last ANVISA inspection in 2015
- UNI EN ISO 14001 Certification by DNV since 2003
- Integrated Environmental Certification (AIA)
- Compliant to Directive 2012/18/UE "on the control of major-accident hazards involving dangerous substances"



SMALL SCALE API'S MANUFACTURING & TECH TRANSFER OF NEW API'S

The R&D Department main duty is supporting the **Recordati Business Development** through the fine-tuning of new products and the manufacturing of API's both for Recordati and other pharmaceutical companies. To this end, a complete set of manufacturing facilities is available both at lab and pilot plant scale, combined with the use of **suitable softwares for the process development** and **tech transfer from the lab to the production plant**.



SMALL SCALE CGMP MANUFACTURING FACILITIES: KG-LAB & PLANT

- 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 $\mu\text{m}/\text{m}^3$)
- Isolator Total Capacity: 25 lt
- API batch size: from 200 gr up to 1 Kg
- Kg-lab Glass reactors: 0,5 to 10 lt
- GMP kg-lab Pressure-Filter/Dryer (100 ml to 1000 ml capacity)
- GMP glove-box for packaging in inert atmosphere (Argon, Nitrogen)
- Pilot Plant Reactors: 100 - 1400 lt (Glass lined, AISI 316, Hastelloy Cryogenic)
- Hydrogenation Autoclaves: 250 lt (100 bar); 600 lt (5 bar) - AISI 316
- Operative conditions: -90°C to 250°C
- Pilot Plant Equipment for batch Distillation
- Pilot Plant Total Capacity: 7500 lt
- Isolating Equipment: Pressure Filter-Dryer, Centrifuges
- Tray Dryer; Crusher; Seaving Mill
- Controlled areas for APIs isolation and finishing
- High containment for HPAPI handling (OEL < 1 $\mu\text{m}/\text{m}^3$)

ANALYTICAL R&D CAPABILITIES

- Bruker AvanceNeo 400MHz NMR with H, C and other nuclei
- LC-MS - ion trap detector, equipped with ESI and APCI sources
- GC-MS with head-space capability

- Polarimeter
- FT-IR with NIR capability, UV-Vis spectroscopy
- HPLC with ELS detector
- DSC and Mettler melting point
- GMP certified GCs with-head space capability
- GMP certified HPLCs
- GMP certified UPLC with multiple columns comparison
- Classic titration equipment
- KF titrators
- Other equipments available at QC: Malvern for particle size, microscope for crystal studies, muffle for ashes

PROCESS R&D CAPABILITIES

- Hel Multireactor for process development, optimization and critical parameters studies
- Multireactor Capability for Calorimetric Study
- Crystal 16 for solubility and crystallization studies
- Lab. Hydrogenation Autoclaves for low and high pressure up to 60 bar
- Flasks and Lab Reactors 100 ml up to 10 lt
- Micro-flow reactor for flow chemistry studies
- Isolator for toxic reagents handling
- Distillation Equipment and kilo-scale Short Path Distillation Equipment
- Puriflash Chromatography for products and impurities isolation
- Laboratory Pressure-Filter/Dryer
- Lab. Ovens for drying

R&D PROCESS DEVELOPMENT

The R&D Department is composed by a **team of highly specialized researchers and technicians** (5 PhD's in Chemistry, 5 Master Degree in Chemistry, 1 Process Engineer, 4 high school graduates) who master most of organic chemistry reactions and production technologies as well as short path distillation, high pressure hydrogenation, flow chemistry. Thanks to highly efficient discovery programs, as well as wise alliances with other pharmaceutical and research institutes, **Recordati has always been able to successfully implement new products in its portfolio**. Commitment, scientific rigor and availability of technological capability in the R&D Department, allow Recordati to develop new treatments and to count on an always innovative product pipeline. In order to constantly ensure high API quality and robustness of the production, the R&D group is involved in a neverending performance improvement cycle; however, the main research and development activities are mainly focused on generating innovative treatments with special care on rare diseases.



R&D EXPERTISE

EXPERTISE IN HAZARDOUS AND HIGHLY TOXIC CHEMICALS HANDLING:

Na₂S, NaCN (not gaseous HCN), POCl₃, SOCl₂, formaldehyde, methylbromide, dimethylsulfate, other R45, liquid ammonia, peroxyacids.

ORGANOMETALLIC REACTIONS:

Grignard reagents, Raney Ni in liquid NH₃.

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

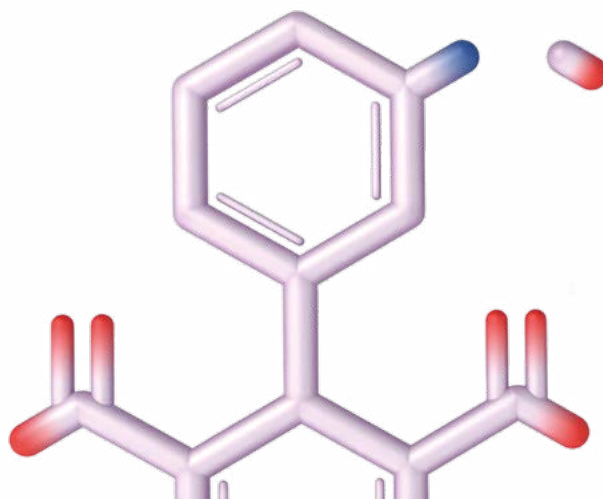
ANALYTICAL R&D:

Specification set-up, Method development and validation, Solubility & Crystallization studies, Operative stability and Material Compatibility studies.

SOLID STATE MANAGEMENT:

Polymorphism studies: detection, characterization and interconversion mapping.

Particle size studies



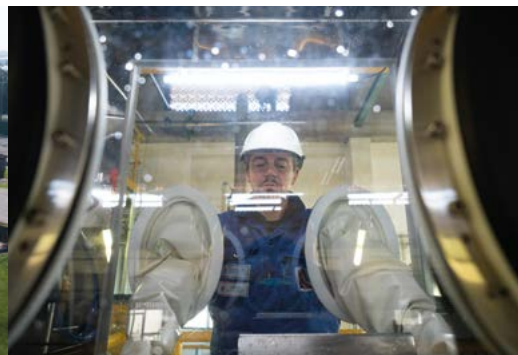
PRODUCT LIST

Alongside Recordati's Chemical division, Recordati's International Pharma Sales division manages out-licensing and supply agreements in over 120 countries. The range of partnerships varies: API trading with a Trademark license; selling finished products under the Trademark with local partners being also Recordati's regulatory representative and taking care of distribution and promotion; as well as, in some cases, local manufacturing. The products available for out-licensing are as follows:

MOLECULE	TRADEMARK	INDICATION
Lercanidipine	ZANIDIP	Indicated in adults for the treatment of mild to moderate essential hypertension
Lercanidipine/Enalapril	ZANIPRESS/ZANEXTRA	Indicated for the treatment of essential hypertension in patients whose blood pressure is not adequately controlled by Lercanidipine or Enalapril alone
Pitavastatin	LIVAZO/ALIPZA	Indicated for the reduction of elevated total cholesterol (TC) and LDL-C, in adults, adolescents and children aged 6 years or older with primary hypercholesterolaemia
Leuporelin acetate	ELIGARD	Indicated for the treatment of hormone dependent advanced prostate cancer and for the treatment of high-risk localized and locally advanced hormone dependent prostate cancer in combination with radiotherapy
Fenticonazole	LOMEXIN/GYNOXIN	Indicated for the treatment of vulvovaginal candidiasis, Trichomoniasis and mixed infections
Flavoxate	URISPAS/GENURIN	Indicated for the symptomatic relief of urinary tract symptoms, such as dysuria, urgency, nocturia, vesical supra-pubic pain, frequency, and incontinence, as may occur in different urological conditions
Silodosin	UROREC/SILODYX	Treatment of the signs and symptoms of BPH in adult men
Beta-alanine	ABUFENE	Used in menopausal hot flashes
Cetylpyridinium, Chlorobutanol, Eugenol	ALODONT	Local adjunctive treatment of oral cavity infections, and post-operative care in stomatology
Calcium	CALPEROS	Calcium deficiencies during growth, pregnancy and lactation. Adjunctive treatment of osteoporosis
Erythromycin	ERY	Treatment of infections due to germs defined as sensitive
N-acetylcystein	EXOMUC	Treatment of bronchial secretion disorders, especially during acute bronchial affections: acute bronchitis and acute episode of chronic broncho-pneumopathy
Ginkgo Biloba extract, Troxérutin, Heptaminol	GINKGO BILOBA	Treatment of symptoms related to veno-lymphatic insufficiency (heavy legs, pain, impatience of the primodecubitus...). Treatment of functional signs related to the hemorrhoidal crisis
Biclotymol, Lysozym, Enoxolone	HEXALYSE	Local adjunctive treatment of mild sore throat without fever
Biclotymol	HEXASPRAY	Local symptomatic treatment of acute disorders of the oropharynx
Framycetin	ISOFRA	Treatment of bacterial rhinitis and rhinopharyngitis
Codeine, Sulfogaïacol, Grindelia	NEO-CODION	Symptomatic treatment of troublesome non-productive coughs
Metronidazol, Neomycin, Nystatine	NEO-TERGYNAN	Local treatment of sensitive germ vaginitis and non-specific vaginitis
Rifamycin	OTOFA	Local treatment of certain purulent otorrhea: with a transtympanic aerator, with a draining cavity, and chronic non-osteitic otitis with an open tympanic membrane
Neomycin, Polymyxin B, Dexamethason	POLYDEXA	Local treatment of otitis externa due to bacterial infection (in particular infectious eczema of the external auditory canal) as long as the tympanic membrane is intact
Ternidazole, Neomycin, Nystatine, Prednisolon	TERGYNAN	Local treatment of sensitive germ vaginitis and non-specific vaginitis
Cholecalciferol	VITAMINE D3	Prophylaxis and/or treatment of vitamin D deficiency
Glycerol	ADULAX	Local symptomatic relief of transitory and occasional constipation in adults

Sodium Citrate Potassium Chloride Sodium Chloride Glucose <i>Lactobacillus Reuteri</i> Protectis	Bi-ORALSUERO BABY	Oral Rehydration Salt for the treatment of acute gastroenteritis. Replenish the body water and salts, helping to maintain an optimal fluid balance and repopulate the intestinal flora
Glucose Monohydrate Sodium Citrate Potassium Chloride Sodium Sulfate <i>Lactobacillus Reuteri</i> Protectis	Bi-ORALSUERO	Treatment of acute gastroenteritis, dehydration (vomiting and diarrhoea) Restores mineral salts by reducing the duration of diarrhoea while contributing to repopulate the intestinal flora
Glucose Sodium Citrate Potassium Chloride Sodium Sulfate <i>Lactobacillus Reuteri</i> Protectis	Bi-ORALSUERO PLUS	Treatment of acute gastroenteritis, dehydration (vomiting and diarrhoea) Restores mineral salts by reducing the duration of diarrhoea while contributing to repopulate the intestinal flora
Resistant maltodextrine Fructooligosacharides	CASENFIBRA	Regulatory effect of intestinal transit
Chicory inulin (Orafti®) Resistant maltodextrine	CASENFIBRA DIGEST	Contribute to maintain a regular intestinal transit by improving the frequency of bowel movements
Sodium Sulfate Anhydrous Potassium Chloride Sodium Chloride Sodium Bicarbonate PEG 4000 Sodium Biphosphate	CASENGLICOL	Bowel evacuation prior to colonoscopy, surgery, radiology, and other colorectal and genitourinary examinations. Treatment of chronic constipation of non-organic cause that has previously been treated, without satisfactory results, with a diet high in water content and an increase in daily physical exercise
Macrogol 4000	CASENLAX	Symptomatic treatment of constipation in adults and children aged from 6 months and above
Disodium Phosphate Dodecahydrate Sodium Dihydrogen Phosphate Dihydrate	CLEEN ENEMA	Cleansing of the rectum, sigmoideum and lower part of the colon descendente in acute constipation and preparation of medical and diagnostic procedures
Sodium Picosulfate Magnesium Oxide, Ligth Citric Acid Anhydrous	CITRAFLEET	Bowel cleansing prior to any diagnostic procedures requiring a clean bowel e.g. colonoscopy or x-ray examination
Saline Solution	FISIOENEMA	Mechanic rectal laxative when bowel cleansing is required: fecal impaction, surgery, Intestinal explorations, before delivery, gynecological examinations, post partum, radiological tests, evacuation disorders
Soy Isoflavones Trifolium Pratense L.	FITOGYN	Relief of menopausal hot flushes as a consequence of estrogen deprivation
Sodium Hyaluronate	MUVAGYN HYALURONIC GEL	Promote recovery of flexibility and elasticity of the vaginal mucosa when dryness exists, especially in the perimenopausal and menopausal periods, during the last period of the menstrual cycle, or occurring as the consequence of use of oral contraceptives
Sodium Hyaluronate Centella Asiatica Cell Lysate	MUVAGYN CENTELLA ASIATICA	Significantly improves natural regeneration specially developed promoting regeneration, flexibility and elasticity of the vaginal mucosa when dryness is present
Glycerol	PAIDOLAX	Local symptomatic relief of transitory and occasional constipation in children
Disodium Phosphate Dodecahydrate Sodium Dihydrogen Phosphate Dihydrate	PHOSPHOSODA	Bowel cleansing prior to any diagnostic procedures requiring a clean bowel e.g.colon surgery, x-ray or endoscopic examination. Laxative for severe constipation only allowed in certain countries
Glucose Sodium chloride Potassium chloride Sodium citrate	SUERO ORAL	Oral replacement of electrolytes and fluids in patients with dehydration particularly associated with acute diarrhoea of various origins
Glucose Sodium chloride Potassium chloride Sodium citrate	SUERO ORAL HYPOSODIC	Oral replacement of electrolytes and fluids in patients with dehydration particularly associated with acute diarrhoea of various origins

PRODUCT LIST



GMP
Fine Chemicals

Organic
Synthesis

Contract
Manufacturing



Manufacturing site: Campoverde di Aprilia (Latina) - Italy

PRODUCT LIST

PHARMACEUTICAL ACTIVES

PRODUCT	THERAPEUTIC CATEGORY
Acyclovir	Antiviral
Benidipine HCl	Antihypertensive
Dimenhydrinate	Antiemetic
Diphenhydramine HCl	Antihistaminic
Diphenhydramine Citrate	Antihistaminic
Dobutamine HCl	Cardiotonic
Dopamine HCl	Cardiotonic
Ketorolac	Anti-inflammatory
Lansoprazole	Antiulcer
Manidipine	Antihypertensive
Mebeverine HCl	Antispasmodic
Methenamine Hyppurate	Antibacterial (Synthetic)
Papaverine HCl	Antispasmodic
Phenytoin	Antiepileptic
Phenytoin Sodium	Antiepileptic
Pyridoxal-5-phosphate	Enzyme co-factor vitamin B6
Sertraline HCl	Antidepressant
Tetrabenazine	Antidyskinetic; antipsychotic
Tribenoside	Sclerosing agent
Verapamil HCl	Coronary vasodilator

INTERMEDIATES

PRODUCT
(R)-Tetrahydropapaverine
Tetrahydropapaverine
Homoveratric Acid
Homoveratronic nitrile
Homoveratrylamine

Sales & Marketing

Email: pharmaceuticals@recordati.it

Ph +39 02 48787336

<https://recordati.com/our-business-chemical-business/our-business-chemical-business-products/>



HEADQUARTER

Via Matteo Civitali,1 - 20148 Milano, Italy
Ph +39 02 48 787.1 - Fax +39 02 40 073 747
www.recordati.com

SALES&MARKETING

pharmaceuticals@recordati.it
Ph +39 02 48787336