



API

Active Pharmaceutical Ingredients



company

products

History page

"... founded in 1932 ..."

The company was founded in 1932 and its activity was to produce generic preparations. During Second World War the facility was heavily damaged and, after the end of the war, was reconstructed and started the manufacture of organ extracts and enzymes for human use.

The preparation of enzymes from animal organs still continues. In the sixties a new chemical facility was established with the intention to support the Production of Pharmaceutical Specialities.

the activities of the company are:

- Production of large volume I.V. Solutions
- Production of Generics
- Manufacturing and marketing of bulk active ingredients for the pharmaceutical industry

The manufacturing of API is carried out at the state of the art

plant in Fresonara near Novi Ligure.

Established with the intention to support its own pharmaceutical activities, the Fresonara plant has in a very short time, improved the efficiency of the overall organisation by increasing its production capacity.

At present time, Bioindustria L.I.M. is able to offer both a large range of Active Pharmaceutical Ingredients in bulk for pharmaceutical industry and also to develop specialist custom synthesis for 'highly demanding' customers.



Research & Development page

**"... the importance of the
ever changing
needs ..."**

Bioindustria L.I.M. recognises the importance of the ever changing needs of customer and has accordingly structured and expanded its Research and Development department to comply with these requirements.



our R&D laboratories are in charge of:

- Developing new synthetic methods for Production Department
- Pilot synthesis up to 30 litres
- Synthesizing process and degradation impurities for Analytical Department and to support customers in developing their generics.

Bioindustria has a long-term collaboration agreement with important University institutes (Milan, Rome and Pavia) for its researches in Organic Chemistry and Biochemistry.

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Production page

"... 'high technology' processes ..."

Production plant is located in Fresonara. The plant facilities and buildings enclose an area of 2,300 square metres and occupy a site with a total area of about 17,000 square metres. Production capacity, based on total reactor volume is 60,000 litres (this includes steel, enamelled reactors and autoclaves) that makes Bioindustria L.I.M. competitive in the field of A.P.I. synthesis requiring 'high technology' processes.



equipment:

- S/S Reactors: 21, tot. Vol.: 44m³
- EN Reactors: 12, tot. Vol.: 16m³
- Centrifuges: 5
- Nutsche Filters: 3
- Rotating Dryers: 2
- Static Dryers: 5
- Mills: 3
- Micronizers: 2





Production page

"... We list here under some examples of reactions carried out at our plant: ..."

Temperature capabilities from -100°C to +170°C

special techniques

- DIAZOTISATIONS
- HYDROGENATIONS (USE OF CATALYSTS)
- HOFFMAN DEGRADATIONS
- FRIEDEL-CRAFTS REACTION
- GRIGNARD REACTION
- CHLORINATIONS WITH CHLORINE GAS
- REACTIONS WITH HYDRIDES
- REACTIONS WITH BUTYL LITHIUM AT - 78°C



general reactions:

- Amidations
- Dealkylations
- Esterifications
- Oxidations
- Mannich reaction
- Chromatographic purification
- Optical and cis-trans resolutions
- Transesterifications
- Halogenations

Production page

"... the production ..."

The production is on three shifts starting at 6 a.m. on Monday to 12 p.m. on Friday

[key personnel]

- Technical Manager
- Production Manager
- Chief Warehouseman
- Chief of Maintenance Service



[staff personnel]

- Production: 3 Chief Workshift, 15 Operators
- Warehouse: 2 operators
- Maintenance: Contract Workers





Quality control page

"... performed 'on line' with modern instrumentation ..."

Central Quality Control Laboratory is located in Novi Ligure where finished products analysis are performed. A satellite unit is located in Fresonara in support to the production performing in process controls, intermediates and starting materials analysis. Analytical control is performed 'on line' with modern instrumentation and all results are stored directly on our computer system.

[Instruments]

- HPLCs
- GASCHROMATOGRAPHS
- UV-VIS
- TOC ANALYZER
- POLARIMETER
- AUTOMATIC TITRATORS/K.F.
- NEAR INFRARED SPECTROMETER (NIRS)
- ATOMIC ABSORPTION SPECTROMETER (AAS)
- IONIC CROMATOGRAPHS
- FT-I.R.



[key personnel]

- Chemical Quality Control Responsible
- Microbiological Quality Control Responsible

[staff personnel]

- Operators: 14
- Employees: 3

Quality system page

"... guarantee that production follows the correct procedures..."

The Quality Assurance Department together with Quality Control, guarantee that production follows the correct procedures of current Good Manufacturing Practices (cGMP) to assure the highest possible quality standards.

Our Quality System is based on written SOP's, validations, equipment qualification, change controls, deviations management, quality annual reviews, scheduled training and self audits

[validation on]

- Cleaning
- Purified Water Production
- Processes
- Equipment Qualifications
- Analytical Methods
- Suppliers

[sop's]

- General System Management
- Analytical Laboratory
- Warehouse
- Production
- Maintenance
- Safety
- Technical Instructions



Q.

System

Quality system page

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[sop's]

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Q.

System



Quality system page

All our products are supported by DMF that is filed in house by Bioindustria L.I.M. staff and managed by the Regulatory Affairs Unit.

Our Quality System has been recognised by the FDA approval (Last Italian Ministry of Health inspection Aug 2013), following an inspection of the plant and of the analytical laboratories; as well as many successful audits by major Italian and foreign pharmaceutical companies and their respective countries' Health Authority. Bioindustria L.I.M. is always accessible to customers audits.

[controls on]

- Batch Production records
- Product Specifications
- Analytical Methods
- SOP's
- Validation Documentation



[training on]

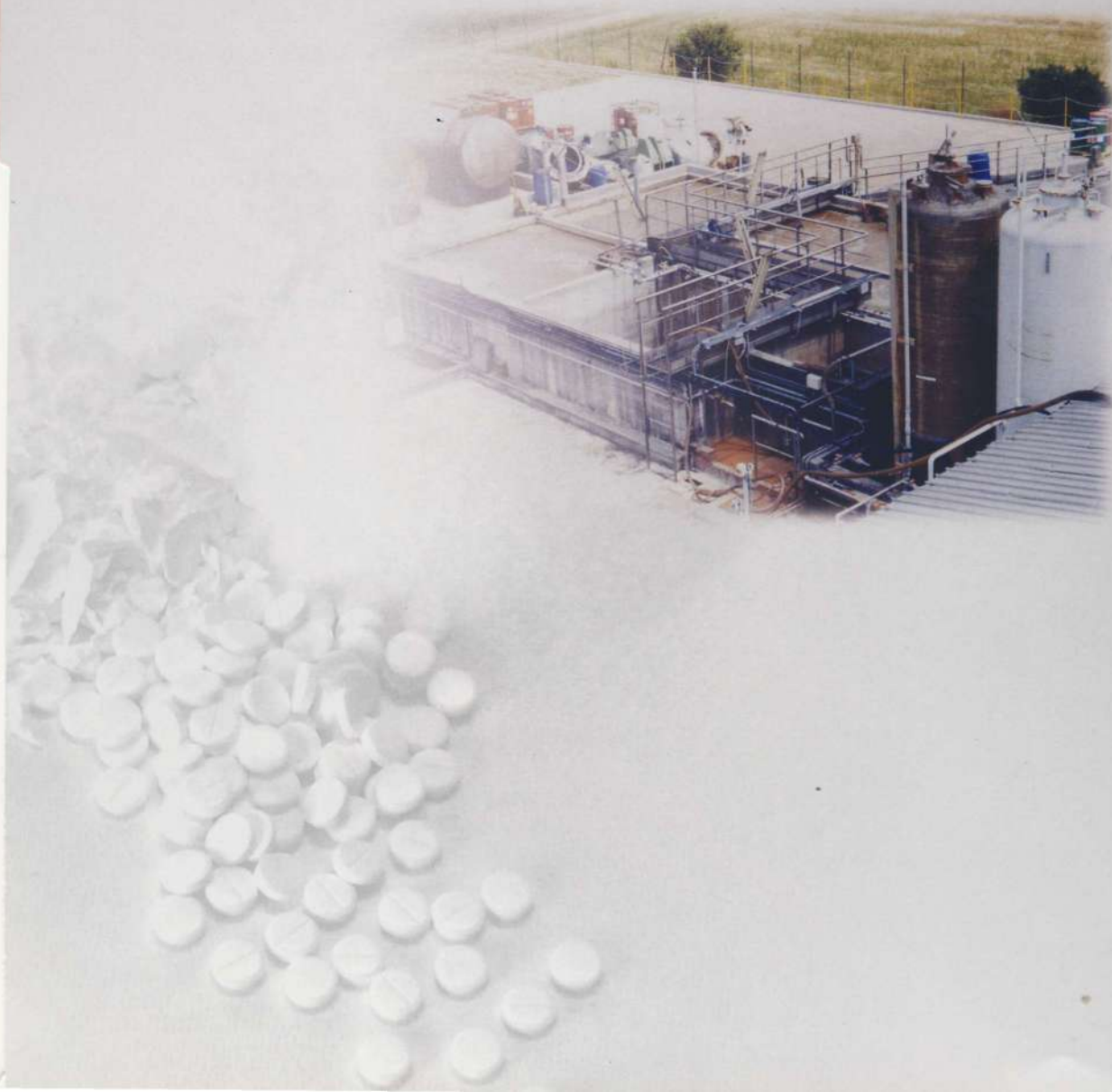
- cGMP
- Safety
- Processes
- Internal Procedures
- Technical Issues

Environmental page

"... our waste water is biologically pre-processed..."

The plant comprises of modern buildings and equipment and has all the necessary operating approvals required by law. The factory is regularly inspected by the Health and Safety inspectorate.

All our waste water is biologically pre-processed by our own internal treatment plant before being returned to the local water purification.



Where we are



[Km. distances]

from Genoa: 50 km
from Milan: 85 km
from Turin: 100 km



BIOINDUSTRIA L.I.M. S.p.A.
dal 1935 Laboratorio Italiano Medicinali

[Bioindustria L.I.M. S.p.A.]

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