

# Archimica

## Corporate Presentation

Strong. Steady.  
Focused on Technology.



# Archimica at a Glance - Strengths

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Vast Experience with the Most Challenging Reagents, Reactions and Substance Classes Known.



Made in Europe



Premium Client  
Attention



Agile  
Capacity  
Availability



Experienced, flexible  
Technology Transfer,  
Development and  
Engineering Team



Highly Flexible  
Manufacturing  
and Development

# Profile

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APIs/GMP Building Blocks - Process Development and Manufacturing.  
From Clinical to Large Commercial Scale for the Innovative and Generic Industry.

## Products

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**APIs.**  
Active Pharmaceutical Ingredients.

**GMP/non-GMP Building Blocks.  
Reagents.**

## Capacities

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Typically:  
**1 to 600 mt annually.**  
Batch Size 25-2500 kg.  
synthesis steps 1-8.

Specifically:  
**2 to 300 mt annually.**  
Batch Size 50-1500 kg.  
Synthesis Steps 2-5.

## Portfolio

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**Products.**  
Generic API Portfolio.  
**Services.**  
Custom Development and Manufacturing.

**Broad Range of  
Substance/Therapeutic Classes.**

## Regulatory/Quality

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**Track Record of Successful  
Agency Inspections.**  
FDA (2017), AIFA (2021).

**Broad Scope.**  
Highly Flexible Permit.  
State-of-the-Art Environmental Protection.

## Technology/Differentiators

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**Small Molecules.**  
Up to OEB4 Potency Level.

**Vast Range of the Most  
Challenging Reagents and  
Reactions on Industrial Scale.**

## Company

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**Global Supply.**  
More than 50 Countries Actively Supplied.

**Backed by Prime Independent  
Investor.**

# Market Presence

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Customers are relying on Archimica's Products and Services for Quality Medicine Worldwide.

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All Therapeutic Classes  
All Substance Classes (including Anticancer APIs)

11 Active Products  
24 Active Drug Master Files in 39 Countries  
200 Active Customers  
Supplying more than 50 Countries Worldwide

SAP™-ERP System

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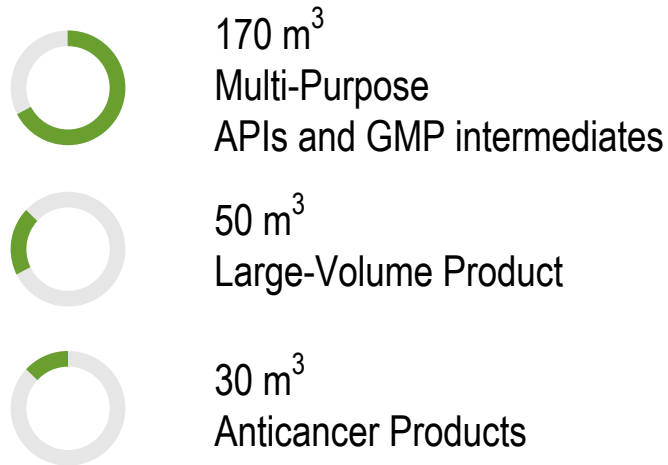
# Site Overview

Highly Flexible, Efficient, Experienced GMP Site - Located in Lodi, Italy, close to Milano

## Plant



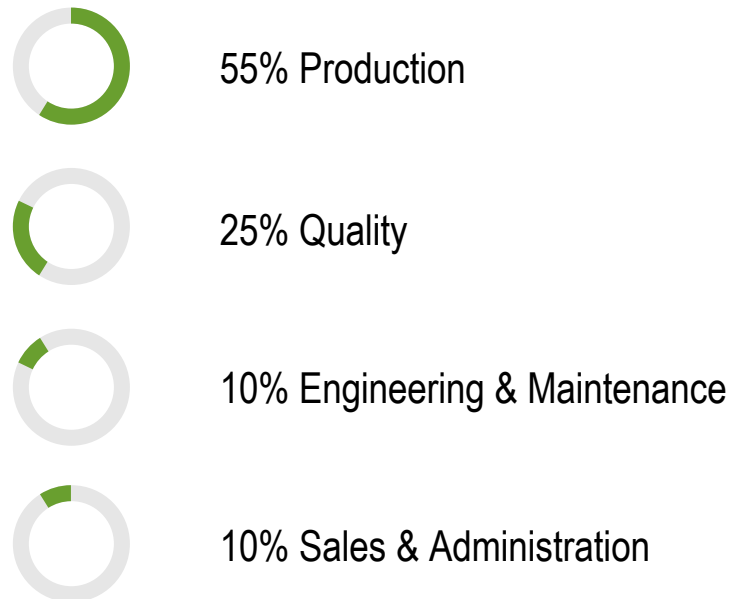
Total Reactor Volume: 250 m<sup>3</sup>



## Staff



Total Staff Number: 130



# Manufacturing Overview

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Reactor Capacity Supported by a Vast Range of Sophisticated Ancillary Technology

## Reactor Capacity



Highly Flexible Multi-Purpose Capacity.  
Various Materials of Construction.

Stainless Steel - Glass Line - Glass - Hastelloy - Monel - Various.

Temperature Range: -20 to 160°C.

Pressure Range: 10 mbar to 6 bar.

Reactor Volume Range: 50 to 10.000 liters.

## Centrifuges/Filters



Filters:

Filter Presses - Filter Dryers - Pressure Filters

Centrifuges:

Vertical Axis Top Discharge - Vertical Axis Bottom Discharge - Horizontal Axis Peeler

## Dryers



Fluid Bed - Agitated Vacuum Pan -  
Vacuum Horizontal Agitated -  
Vacuum Double Cone - Planex™ - Tray

## Ancillary Equipment



Sieves - Ultra Filters -  
Ion Exchange Chromatography Columns

# Multi-Purpose Capabilities - Broad and Flexible

Seamless from 1 kg to 100 mt-Scale - APIs and GMP Intermediates.

Scale	1-10 kg	10-250 kg	1-5 mt	5-20 mt	5-100 mt	10-100 mt	0,1-100 mt
Plant	F5	F2B	F5B	F6B	F7	F2A	F3B Drying
Reactor Size	0,05-0,1 m <sup>3</sup>	0,2-0,8 m <sup>3</sup>	3,0-4,9 m <sup>3</sup>	3,4-10 m <sup>3</sup>	0,7-6,6 m <sup>3</sup>	0,8-9,7 m <sup>3</sup>	0,1-1 m <sup>3</sup>
Temperature Range	-20/120°C	-20/160°C					-10/145°C
Equipment	Reactors Distillation Pressure Filters	Reactors Distillation Columns Centrifuges, Filters, Ancillary Equipment					Fluid Bed, Double Cone Various
Construction Materials	Stainless Steel Glass Line	Stainless Steel Hastelloy Monel	Stainless Steel Glass Line				Stainless Steel Glass Line
Volume Total: 170 m <sup>3</sup>	0,25 m <sup>3</sup>	2,75 m <sup>3</sup>	15 m <sup>3</sup>	20 m <sup>3</sup>	60 m <sup>3</sup>	72 m <sup>3</sup>	Volume Total 5,5 m <sup>3</sup>

# Therapeutic Areas and Substance Classes

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Supporting Active Pharmaceutical Ingredient Supply for All Applications.

## Therapeutic Areas

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Anthrachinones

Benzodiazepinones

Benzophenones

Dibenzazepines

Fluorouracils

Heterocyclic Acidic Acids

Heterotricyclics

Nitroimidazoles

Nucleoside Analogues

Organometallic Complexes

Phospholipids, deacylated

Phtalazines

Purine Analogues

Pyrrole Derivates

Sucrose Sulfates/Complexes

Sulfanilamides

Sulfonamides

Tetrazoles, Mono/Bicyclic

Ureas

## Substance Classes

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Anti-Alzheimer, Cognition Enhancers

Antiacidics, Antiulcers

Antiarrhythmics

Anticancers, Cytostatics

Anticonvulsants

Antidepressives/Anti-Epileptics

Anti-Bipolar Disorders

Antihistaminics, Antiallergics

Antihypertensives/Vasodilators

Antiinfectives

Antiinflammatories

Antiobesities

Immunosuppressives



# Reactions, Reagents and Solvents

Practically unlimited capability to perform/use the most challenging reactions, reagents and solvents on small, medium and large industrial scale under GMP - a few examples.

## Reagents/Reactions



1-500 mt/a

SO<sub>3</sub>·Py (sulfur trioxide/pyridine)

ClSO<sub>3</sub>H (chlorosulfonic acid)

CrO<sub>3</sub> (chromium trioxide)

Ac<sub>2</sub>O (acetic anhydride)

HOAc (acetic acid)

Py (pyridine)

AlCl<sub>3</sub> (aluminium chloride)

POCl<sub>3</sub> (phosphorous oxychloride)

1-100 mt/a

NH<sub>2</sub>OH (hydroxylamine)

NaOCN (sodium cyanate)

Natural source materials (lecithin, aloine)

1-20 mt/a

N<sub>2</sub>H<sub>4</sub> (hydrazine)

NH<sub>3</sub> (ammonia)

HCHO (acetaldehyde)

HCOOH (formic acid)

HF/HCl/HBr (hydrogen halides)

KCN (potassium cyanide)

CH<sub>3</sub>N (trimethylamine)

F<sub>2</sub>/Cl<sub>2</sub>/Br<sub>2</sub> (halogen gases)

H<sub>2</sub> (hydrogen)

CH<sub>2</sub>O (ethylene oxide)

Styrene oxide

Dess-Martin Periodinane

R-SO<sub>2</sub>Cl (sulfonyl chlorides)

Ag/Au/Cu-salts (precious metals)

## Solvents



1-500 mt/a

Dimethylacetamide

Ethanol

Acetone

Cyclohexane

Isopropanol

Methanol

1-100 mt/a

Methylene chloride

1,2-Dichloropropane

Tetrachloromethane

Dimethylformamide

# Generic API Portfolio

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Archimica Continuous API Supply Worldwide.

## Active Pharmaceutical Ingredients (APIs)

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Anticancer

Cytarabine (nucleoside analogue)

Hydroxyurea (modified urea)

Antirheumatic

Diacerein (anthraquinone)

Anti-Alzheimer/Cognition Enhancer

Glycerophosphoryl-choline (GPC) (deacetylated phospholipid)

Glycerophosphoryl-ethanolamine (GPE) (deacetylated phospholipid)

Antipsychotic

Mianserin (tetracyclic)

Oxcarbazepine (dibenzazepine)

Antiacidic/Antiulcer

Sucralfate (saccharose sulfate)

Antiinfective

Sulfathiazole (sulfonamide)

# Generic API Portfolio

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Archimica Continuous API Supply Worldwide.

## Products on Request - Active Pharmaceutical Ingredients (APIs)

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More than additional 20 Active Pharmaceutical Ingredients (APIs) available from Archimica's Experience - including Customer-Specific Development - a selection

Amtolmetin Guacil

Aurothiomalate Sodium

Azanidazole

Bromfenac

Capecitabine

Citicoline

Dihydralazine sulfate

Disopyramide

Fludarabine

Hydralazine hydrochloride

Iodocasein

Lithium Carbonate

Pentetrazole

Pirenzepine Dihydrochloride

Sulfapyridine

Thenfadil

Tolmetin

Vidarabine

# Quality System, Inspections, Certificates

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Successfully Inspected and Accepted Worldwide.

## Quality System



Quality System Based on EU  
GMP part II, ICH Q7.

Quality Processes Handled  
via Trackwise™.

Deviations, Out-of-Specifications (OOS), CAPA,  
Change Control.

US/EU Drug Master Files.

24 Active Drug Master Files in 39 Countries and 4  
active CEP.

## Inspections



FDA (USA).  
Last Inspection April 2017.

AIFA (Italy).  
Last Inspection December 2021.

KFDA (Korea).  
Last Inspection October 2011.

Veterinary Ministry of Health.  
Last Inspection June 2019.

## Certificates



GMP Certificate (Human).  
IT-API/104/H/2020.

GMP Certificate (Veterinary).  
NBF/31/2020/V.

FEI Number  
3002874947

DUNS Number.  
429351620

# Infrastructure - Operating Permits

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Integrated Responsibility for Environment, Health and Safety.

## Environment & Health



### Residual Thermal Oxidizer.

All Waste Gas Streams.

### Waste Water Treatment on Site.

Backed by External Partners.

### Solvent Recovery.

Backed by Flexible Tank Farms.

## Safety



### IPPC-based Authorization.

Integrated Pollution Prevention and Control.

Highly flexible and broad permit for all technologies, reagents and solvents.

### Compliance with IED Directive 2010/75/UE.

Best Available Technology.

### Compliance with Directive 105/15 2012/18/EU.

Seveso Directive.

Prevention and Control of On-Shore Major Accident Hazards involving Dangerous Substances.

# History

Archimica's Evolution - 75 Years of Continuity of Supply into the World's Pharmaceutical Market.



# Contacts



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