

# Archimica

## Corporate Presentation

Strong. Steady.  
Focused on Technology.



# Archimica at a Glance - Strengths

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



Made in Europe



Premium Client  
Attention



Agile Capacity  
Availability



Highly Flexible Manufacturing  
and Development

# Profile

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APIs/GMP Building Block - 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 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 (2018).

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

## Technology/Differentiators

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Small Molecules.  
Up to OEB4 Potency Level.

Most Challenging Reagents and  
Reactions on Industrial Scale.

## Company

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Global Supply.  
More than 50 Countries 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>



170 m<sup>3</sup>  
Multi-Purpose  
APIs and GMP intermediates



50 m<sup>3</sup>  
Large-Volume Product



30 m<sup>3</sup>  
Anticancer Products

## Staff



Total Staff Number: 115



58% Production



22% Quality



10% Maintenance



10% Sales & Administration

# 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.

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 Filter	Reactors Distillation Centrifug, Filter, 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



# Generic API Portfolio

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Archimica Continuous API Supply Worldwide.

## Active Pharmaceutical Ingredients (APIs)

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Cytarabine - Anticancer

Diacerein - Antirheumatic

Glycerophosphoryl-Choline (GPC) - Anti-Alzheimer/Cognition Enhancer

Glycerophosphorylethanolamine (GPE) - Anti-Alzheimer/Cognition Enhancer

Hydroxyurea - Anticancer

Mianserin - Antidepressive

Oxcarbazepine - Antiepileptic

Sucralfate - Antiacidic/Antiulcer

Sulfathiazole - Antiinfective

## Products on Request

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

# 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<sup>TM</sup>.

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 July 2017.

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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