

Archimica

Corporate Presentation

Strong. Steady.
Focused on Technology.



Archimica at a Glance - Strengths

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

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

Products

APIs.
Active Pharmaceutical Ingredients.

**GMP Building Blocks.
Reagents.**

Capacities

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

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

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

Regulatory/Quality

**Track Record of Successful
Agency Inspections.**
FDA (2017), AIFA (2018).

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

Technology/Differentiators

Small Molecules.
Up to OEB4 Potency Level.

**Most Challenging Reagents and
Reactions on Industrial Scale.**

Company

Global Supply.
More than 50 Countries Supplied.

**Backed by Prime Independent
Investor.**

Market Presence

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

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



Site Overview

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

Plant



Total Reactor Volume: 250 m³



170 m³
Multi-Purpose
APIs and GMP intermediates



50 m³
Large-Volume Product



30 m³
Anticancer Products

Staff



Total Staff Number: 115



58% Production



22% Quality



10% Maintenance



10% Sales & Administration

Manufacturing Overview

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 ³	0,2-0,8 m ³	3,0-4,9 m ³	3,4-10 m ³	0,7-6,6 m ³	0,8-9,7 m ³	0,1-1 m ³
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 ³	0,25 m ³	2,75 m ³	15 m ³	20 m ³	60 m ³	72 m ³	Volume Total 5,5 m ³

Therapeutic Areas and Substance Classes

Supporting Active Pharmaceutical Ingredient Supply for All Applications.

Therapeutic Areas



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



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

Archimica Continuous API Supply Worldwide.

Active Pharmaceutical Ingredients (APIs)



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



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

Quality System, Inspections, Certificates

Successfully Inspected and Accepted Worldwide.

Quality System



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

Quality Processes Handled
via TrackwiseTM.

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

US/EU Drug Master Files.

24 Active Drug Master Files in 39 Countries.

Inspections



FDA (USA).
Last Inspection April 2017.

AIFA (Italy).
Last Inspection July 2017.

KFDA (Korea).
Last Inspection October 2011.

Italian Ministry of Health.
Last Inspection June 2019.

Certificates



API Registration Form.
IT-API/104/H/2020.

GMP Certificate.
NBF/31/2020/V.

FEI Number
3002874947

DUNS Number.
429351620

Infrastructure - Operating Permits

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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