

Archimica

Corporate Presentation

Strong. Steady.
Focused on Technology.



Archimica at a Glance - Strengths

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

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

Products

APIs.

Active Pharmaceutical Ingredients.

GMP/non-GMP Building Blocks.

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.

Kilo lab

1-200 Kg annually

Batch size - 1 - 10 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 (2024).

Broad Scope.

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

Technology/Differentiators

Small Molecules.

Up to OEB4 Potency Level.

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

Company

Global Supply.

More than 50 Countries Actively 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)

7 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

Kilo Lab



500 L - Scale up/filing products

Staff



Total Staff Number: 116



55% Production



25% Quality



10% Engineering & 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.

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

Kilo Lab



Capable of handling: 1 to 10kg batch size
Three stages of manufacturing -
Glass Radley reactors ; SS reactors -
Filtration & drying -
Powder processing

Ancillary Equipment



Sieves - Ultra Filters -
Ion Exchange Chromatography Columns

Multi-Purpose Capabilities - Broad and Flexible

Seamless from 100 gm 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 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 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

Phthalazines

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

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

SO₃·Py (sulfur trioxide/pyridine)

ClSO₃H (chlorosulfonic acid)

CrO₃ (chromium trioxide)

Ac₂O (acetic anhydride)

HOAc (acetic acid)

Py (pyridine)

AlCl₃ (aluminium chloride)

POCl₃ (phosphorous oxychloride)

1-100 mt/a

NH₂OH (hydroxylamine)

NaOCN (sodium cyanate)

Natural source materials (lecithin, aloine)

1-20 mt/a

N₂H₄ (hydrazine)

NH₃ (ammonia)

HCHO (acetaldehyde)

HCOOH (formic acid)

HF/HCl/HBr (hydrogen halides)

KCN (potassium cyanide)

CH₃N (trimethylamine)

F₂/Cl₂/Br₂ (halogen gases)

H₂ (hydrogen)

CH₂O (ethylene oxide)

Styrene oxide

Dess-Martin Periodinane

R-SO₂Cl (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

Archimica Continuous API Supply Worldwide.

Active Pharmaceutical Ingredients (APIs)



Anticancer

Cytarabine (nucleoside analogue) - CEP

Hydroxyurea (modified urea) - CEP

Antirheumatic

Diacerein (anthraquinone) - CEP

Antipsychotic

Mianserin (tetracyclic) – CEP ongoing

Oxcarbazepine (dibenzazepine)

Antiacidic/Antiulcer

Sucralfate (saccharose sulfate)

Antiinfective

Sulfathiazole (sulfonamide)

Generic API Portfolio

Archimica Continuous API Supply Worldwide.

Products on Request - Active Pharmaceutical Ingredients (APIs)



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

Bromfenac – EUDMF/USDMF
Capecitabine – EUDMF/USDMF
Citicoline – EUDMF
Dihydralazine sulfate – EUDMF
Disopyramide – EUDMF
Hydralazine hydrochloride – EUDMF/USDMF
Lithium Carbonate – EUDMF/USDMF
Pirenzepine Dihydrochloride - EUDMF/USDMF
Sulfapyridine – EUDMF/USDMF
Thenfadil – EUDMF
Tolmetin – EUDMF

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 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 October 2024.

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

Integrated Responsibility for Environment, Health and Safety.

Environment & Health



Residual Thermal Oxidizer.

All Waste Gas Streams.

Wastewater 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 - 77 Years of Continuity of Supply into the World's Pharmaceutical Market.



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Archimica

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