

Zambon Switzerland Ltd. Site presentation





CH - CADEMPINO PLANT

GENERAL INFORMATION

Zambon Switzerland Ltd. site: the milestones

- 1965** Foundation of Zambon Switzerland (former Inpharzam) in Lamone
- 1980** Inauguration of current industrial and administrative center in Cadempino
- 1993** Inauguration of dedicated area for production of injectable powders CMO (carbapenem)
- 1995** FDA Approval for the production of Monurol (antibiotic, granules in sachet)
- 2003** Injectable products: production expansion, second filling line installation
- 2004** FDA Approval for injectable products (carbapenem)
- 2013** Start of secondary packaging operations for carbapenem
- 2018** FDA and Swissmedic inspection
- 2019** FDA Inspection
- 2020** Swissmedic inspection

Audits & Permits

The Swiss plant can be considered a **centre of excellence** for the production of **sterile injectable** (carbapenem), **granules in sachet** and **effervescent tablets**.

The products are exported in several countries in the world. The site is routinely inspected by:

FDA
(AMERICAN
AUTHORITY)

ANVISA
(BRAZILIAN
AUTHORITY)

SWISS MEDIC
WITH **EU MUTUAL
RECOGNITION**

Zambon Switzerland Ltd. site: main figures

- Nearly **76 Mio** units produced on a yearly basis (2020)
- Yearly investments of **6 million** SFr.
- More than **350** different end consumer pack presentations
- Almost **97%** of the products are exported: EU countries (mainly France, Italy, Germany, Spain, Russia), ROW and the US.

The Swiss Plant is centre of excellence for the production of carbapenem, granular and effervescent tablets.

The site area: main figures

- The total site area is about **41'400** sq. meters, among which 19'000 are fenced. The facilities consist of 5 buildings and cover 9'012 sq. meters for each floor (total of 3).
- 9'988 sq. meters are occupied by paths and squares (65%) and green areas (35%).
- Maximum capacity packaging: oral solids **76 Mio**; sterile **16 Mio**
- Maximum capacity sterile filling: **30 Mio**
- Number of packaging lines: oral solids **8**; sterile **1**
- General warehouse capacity: **6.800** pallets
- Carbapenem warehouse capacity: **500** pallets

Zambon Switzerland site: the Headcount



6 SITE DIRECTION



1 HEALTH & SAFETY



50 QUALITY OPERATIONS (QC 32 ; QA 16; RA 2)



140 PRODUCTION UNITS



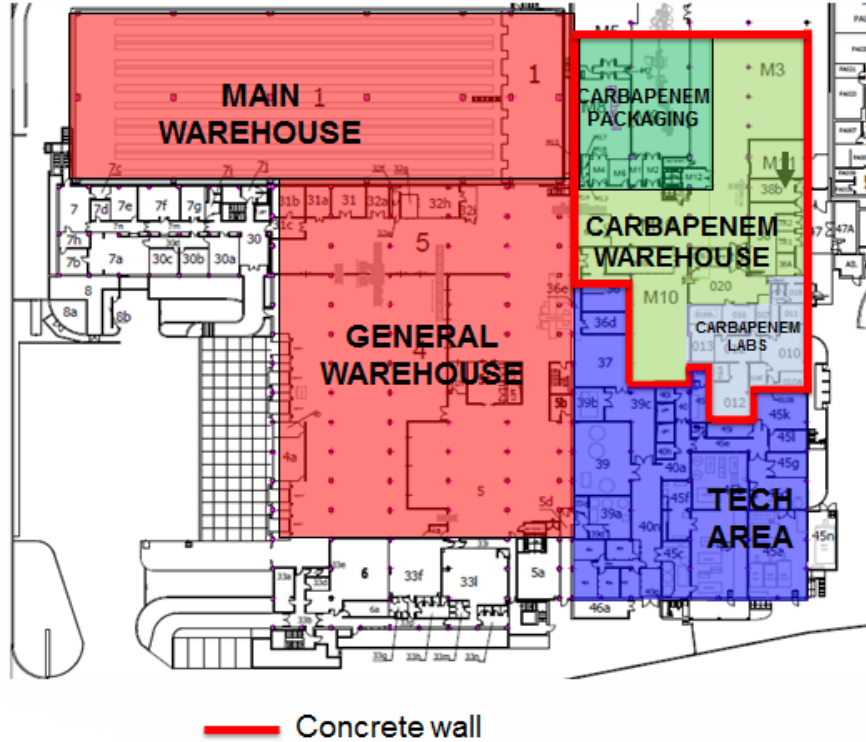
11 ENGINEERING AND METROLOGY



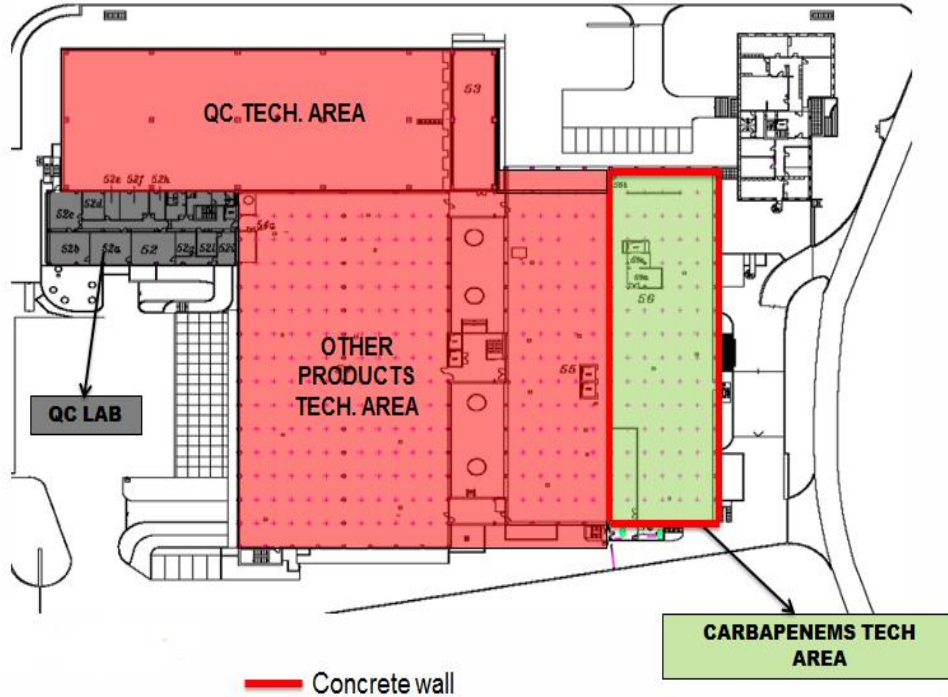
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**Total site HC:
230**

Zambon Switzerland site: Ground Floor



Zambon Switzerland site: Technical Floor



The site is specialized in:



STERILE INJECTABLE

Antibiotic powder
filled in asepsis
(segregated areas)



ORAL SOLIDS

Solid dosage forms
Effervescent tablets
Granules



Sterile Key Equipment

POWDER ASEPTICALLY FILLED:

- POWDER FILLING (2 lines)
- SECONDARY PACKAGING (1 automatic line, 1 semi-automatic line, Shring Sleeves)
- Dosage vials from 600 mg. to 1500 mg.
- Unit for pack from 1 to 25 vials
- Serialisation and Aggregation



Oral Solids products

- Pharma Technology Laboratory
- MANUFACTURING (Fluid Bed, rotogranulation, mixing and tumbling)
- SECONDARY PACKAGING (sachet lines, Alu Alu blistering lines)
- Range sachets dosage from 1 gr. to 9 gr.
- Sachets Pack from 1 to 60 units
- Blister Pack from 3 to 100 unit
- Serialisation and Aggregation process



Oral Solids products

FOSFOMYCINE TROMETAMOL

Nearly **19 Mio** units produced in 2020 (0.5 Mio for US market).

Therapeutical use in Women 's Healthcare.

API: Fosfomycin Tromethamol

Action: Specific Antibiotic

Indication: treatment of uncomplicated urinary tract infections (cystitis)

Formulation: granules in sachet



Oral Solids products

API: NAC (N-Acetylcysteine)

20.5 Mio units produced in **2020**

Area: Respiratory

Action: Mucolytic with antioxidant properties

Formulation: effervescent tablets and granules



API: IBUPROFENE

10 Mio units produced in **2020**

Area: Pain

Action: Analgesic & Anti-inflammatory with rapid onset of action

Formulation: granules



Zambon Switzerland Ltd. site: the location

In Ticino since 1965, the site is located about 5 Km away from Lugano, in the small town of Cadempino, in a centric position between Milan and Zurich.



Address: Via Industria 13, CH 6814 Cadempino

GPS coordinate: 46°1'57.47" N latitude and 8°55'50.941" E longitude



Manufacturing & Technological Support (MTS)



MANUFACTURING

- Pilot scale
- Cost containment
- Processes know how

TROUBLESHOOTING

- Process robustness
- Business Continuity
- Risk reduction
- Product life cycle management

INNOVATION

- Competitive advantage
- Future strategy
- New product development

THANK YOU!