Zambon Vicenza Site presentation







GENERAL INFORMATION



VICENZA (ITA) History





General Info Audits & Permits

AUTHORIZED BY

- · AIFA
- ANVISA
- Belarussian MoH
- Russian MoH
- FDA (ongoing)

CERTIFICATION

Environment

UNI EN ISO 14001

- ✓ Clinical batches bulk in oral solid
- ✓ Biological products
- ✓ Sexual hormones freeze dried



Zambon Vicenza site: the Headcount







3 HEALTH & SAFETY



70 QUALITY OPERATIONS (QC 47; QA 23)



153 PRODUCTION



43 TECHNICAL SERVICES, AUTOMATION & INFRASTRUCTURE



26 PLANNING & LOGISTICS

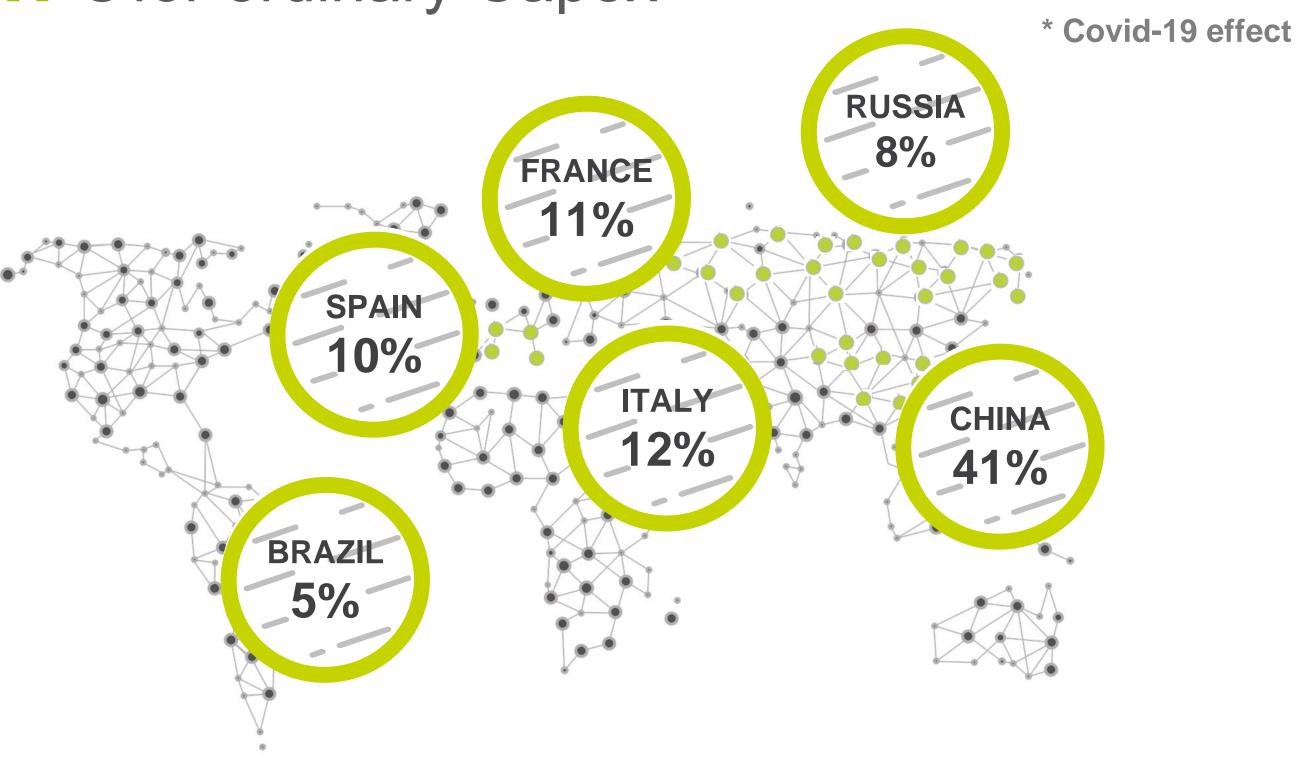
Total site HC: 302



Zambon Vicenza site: main figures

- Nearly 63 Mio units produced on a yearly basis (2020)
- Yearly investments of 4,5 million € for ordinary Capex
- More than 230 different SKUs
- About 88% of the products are exported

The Vicenza Plant is centre of excellence for the production of sterile products (liquid ampoules, liquid vials -aseptic filling-, lyophilised vials), oral solids & liquid forms.





The Site area: main figures





Address: Via della Chimica, 9 Vicenza (VI) - Italy



Portfolio & Core Competence

COVERED BUSINESS SEGMENTS & CORE PRODUCTS

Contract manufacturing, technology transfers and analytics

Regulatory and pharmacovigilance services



Ampoules

LIQUID AMPOULES (closed, final sterilization)



Vials

LIQUID vials (aseptic filling)
LYOPHILISED vials



Solid

COATED & UNCOATED
TABLETS
EFFERVESCENT TABLETS
SUGAR COATED



Liquid

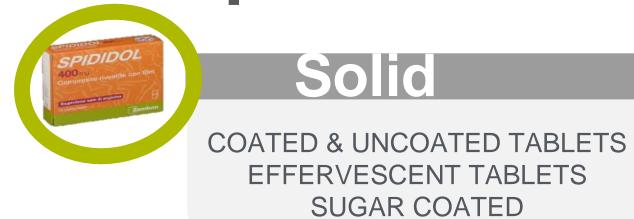
VIAL AND BOTTLES

SYRUPS FROM 50 TO 200ML DROPS FROM 8 TO 15ML



The site area: Capacity & Capabilities

- Solid Dosage Form 650 Mio tabs/year
 - Coated & Uncoated tablets
 - Effervescent tablets
 - Sugar coated
- Liquid Dosage Form (Syrups, Liquids, Drops and Suspension)
 - Vials 24 Mio
 - Bottles 22 Mio
- Sterile Filling:
 - Liquid ampoules closed, final sterilization 400 Mio
 - Vials (aseptic filling) & lyophilised vials 33 Mio
- Packaging lines:
 - Solids: no. 3 Blister Alu-Alu Blister Alu-PVC
 - Liquids: no. 3 (1 for Drops and 2 for Syrups)
 - Steriles: no. 4 (2 for Ampoules, 2 for Ampoules&Vials)





Liquid

VIAL AND BOTTLES

SYRUPS FROM 50 TO 200 ml DROPS FROM 8 TO 25 ml



Ampoules

LIQUID AMPOULES

(closed, final sterilization) FROM 1 TO 20 ML



Vials

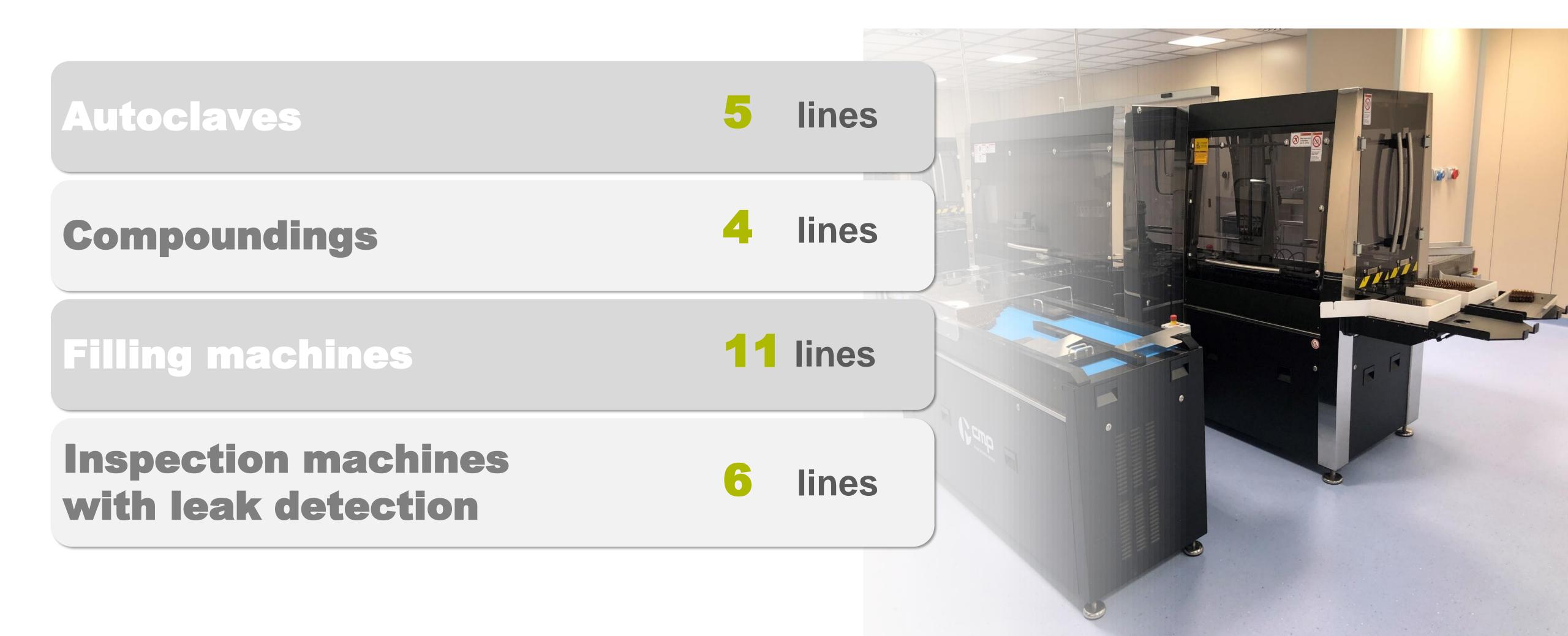
LIQUID vials (aseptic filling) LYOPHILISED vials



STERILE PRODUCTS



TECHNOLOGY Bulk Injectable Ampoules





TECHNOLOGY Bulk Injectable Vials

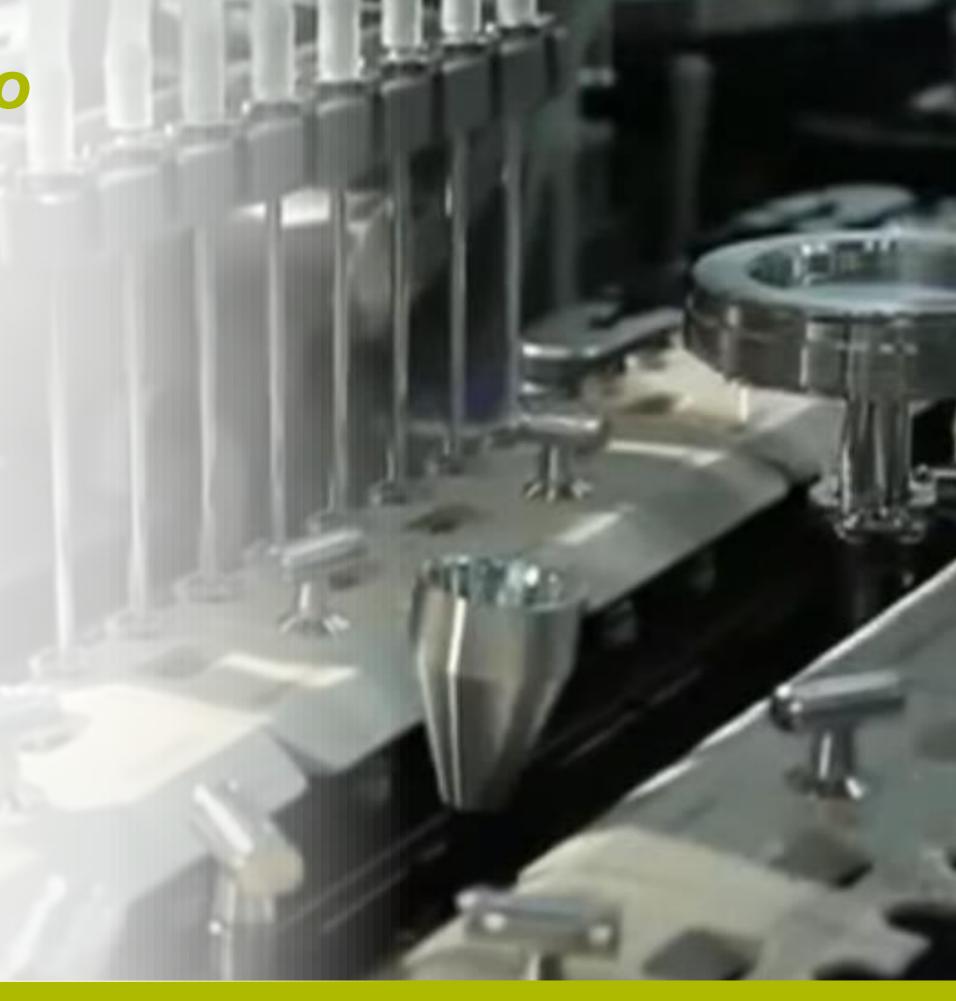
- ✓ Compounding
- ✓ Vial Washer
- **✓** Sterilizing Tunnel
- **✓** Filling And Stoppering Machine
- ✓ Freeze Dryer 27 Sm Surface (2 Macs)
- ✓ Fd Alus (Automatic Loading Unloading System)(2 Macs)
- ✓ Fd Alus (Automatic Loading Unloading System)(2 Macs)
- **✓** Crimping Machine

High Autom Lyo
Department

Coming soon, 30 Mio € Capex

- 2 Compoundings: 1 With Homogenizer;1 Without Homogenizer
- ✓ Vial Washer
- ✓ Sterilizing Tunnel
- **✓** Filling And Stoppering Machine Under Isolator
- ✓ Freeze Dryer 30 Sm Surface (2 Macs)
- ✓ Fd Loading System Under Isolator With Automatic Pusher
- ✓ Crimping Machine Under Isolator

3B Department





TECHNOLOGY Injectable Packaging

- √ Packaging Line 8 for Ampoules
- √ Packaging Line 9 for Ampoules
- √ Packaging Line 3 for Ampoules & Lyos
- √ Packaging Line 6 for Ampoules & Lyos





NON STERILE PRODUCTS



TECHNOLOGY Solids

Bulk

- ✓ Compactor WP 149
- **✓** Biconic Mixer
- **✓** Rotogranulator 020
- **✓** Rotogranulator 001RT
- ✓ Fluid Bed Granulator
- ✓ Tablet Press Machine LX21
- **✓** Tablet Press Machine GRP34
- **✓** Tablet Press Machine SYNTESIS 700
- ✓ Coating Machine 200 L
- ✓ Coating Machine 500 L
- ✓ Coating Machine 400 L

Packaging Blisters Alu-Alu - Blisters Alu-PVC

- ✓ Packaging Line 4 for Tablets
- ✓ Packaging Line 5 BIS for Effervescent Tablets
- **✓** Packaging Line 7 for Tablets





TECHNOLOGY Liquids

Bulk

- √ 2 Reactors for Drops (1.300 4.600 L)
- √ 2 Reactors for Syrups (3.500 8.000 L)
- ✓ Intermediate Liquid Storage Tanks (4)
- √ Raw Material Tanks (2) 8.000 L

Packaging

- ✓ Packaging Line 1 for Drops
- ✓ Packaging Line 2 for Syrups
- ✓ Packaging Line 2 BIS for Syrups





MARCO POLO



Marco Polo Development Plan



The Factory Today

67.300 sq m total Surface

28.000 sq m Buildings

sq m Walkable surface, considering each floor

Mio packs Total Ampoules Capacity

Operating from Q4 2021

+2.300 sq m Floor surface

Investment 27,5 Mio €

sq m Walkable surface, +7.800 Walkable surface considering each floor

100 Mio packs Total Ampoules Capac Ampoules Capacity



Rendering Marco Polo

