



Aseptic Powder Dosing Solutions



Beyond Technology

The new business model from Romaco sets valuable incentives for meeting customer requirements. For the design of innovative solutions, Romaco relies on its unique knowledge portfolio.

With its diverse brands, Romaco focuses on important technological fields of competence. The single product lines offer the optimum

prerequisite for the development of comprehensive solutions.

Romaco promises its customers professional project handling, fast delivery times and a reliable service. Through this, Romaco provides its customers with a considerable boost to their earning and financial power.



Creating Value – best price/performance ratio

Romaco wins over its customers by offering an outstanding price/performance ratio over the entire life cycle of its products. In this way, customers can systematically optimise their cash flow. With efficient production and service management, Romaco prepares its customers for future long-term commercial success.

Delivering Solutions – high application expertise

Romaco offers integrated solutions for the growing markets of pharmaceuticals, cosmetics, food and industrial applications. Here, the customer benefits from the synergetic effects that result from the close collaboration of all the Romaco brands. This internal technology transfer imparts a considerable development potential and is the basis for comprehensive solutions.

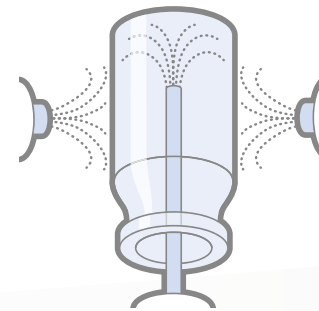
Exploiting Technologies – strong brands

Romaco is synonymous with European engineering on the highest level. With its seven brands, the company is widely recognised around the world. Continuity and progress are the keys to a strong positioning on the market. Romaco relies on the profound knowledge and the long-time experience of its employees.



» *The flexibility and reliability of Romaco Macofar machines and lines have been proven in numerous installations; they comply with even the most rigorous requirements for aseptic powder dosing.*«

Nicola Magriotis, Sales Director, Romaco S.r.l.



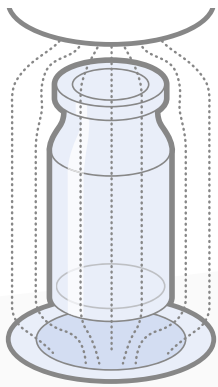
Delivering Solutions

Aseptic Powder Dosing to Meet the Most Rigorous Demands

Romaco Macofar is a recognised expert for highly innovative standalone equipment and lines for aseptic powder filling. High quality targets combined with specialist knowledge enable Romaco Macofar to develop end-to-end solutions adapted to individual customer requirements in the pharmaceutical and biotechnology sectors. This proven technology is employed all over the world for dosing a wide range of powders and filling them into cylindrical glass containers under sterile conditions.

Vial Washing

- Glass vials cleaned on both the inside and the outside
- Suitable for cylindrical containers with different dimensions without holder change parts
- Vials washed with a set of special nozzles
- Complete washing cycle with nine stations



Vial Sterilisation

- Depyrogenation of glass vials and ampoules
- All vials pass through heating and cooling chambers
- Containers heated to a maximum of 340 °C
- Temperature and compressed air monitored continuously



Filling into Glass Vials

- Designed to handle containers 15 to 52 mm in diameter and 35 to 120 mm in height
- Variable dosing from 30 mg to 1500 mg (single-dose output)
- Choice of single or double stoppering systems



Vial Stoppering

- Closing station either integrated in the liquid filler or available as a line component
- Standard closure with press-on rubber stopper
- Special closure types for subsequent freeze drying





Delivering Solutions

End-to-end Line Solutions for Filling Sterile Pharmaceutical Powders

The Romaco Macofar portfolio is comprised of complete aseptic lines with synchronised machines for washing, sterilising, filling, stoppering and capping containers.

A Romaco Promatic cartoner and case packer installed downstream complete the line. All machines are simple to operate and allow continuous monitoring of the production process.

As a recognised global supplier of aseptic lines, Romaco supports customers in planning and installing new equipment and machinery – from the initial feasibility study to final validation – providing the basis for valuable long-term partnerships. Line solutions created in this way can be individually adapted to each client's process and production requirements and linked up to other machines without any problems.



High Quality Standards

- Suitable for use in conventional clean-rooms
- Optionally available with a RABS (Restricted Access Barrier System)
- In-line product quality control function
- Statistical process control possible
- Monitoring for viable and non-viable particles
- Dedicated project management with a single contact

Quality Control in Real Time

- PAT (Process Analytical Technology) system in conformity with FDA and EMEA
- Automation improves operating reliability
- Process variable management
- Online measurements and controls reduce the global cycle time for production
- Highly automated processes mean less waste and reworking

GAMP Compliant Validation

- Factory (FAT) and site (SAT) acceptance tests
- Design qualification (DQ)
- Installation qualification (IQ)
- Operational qualification (OQ)
- Performance qualification (PQ)

Secondary Packaging Solutions

- Romaco Promatic PC 4000 continuous motion cartoner
- Romaco Promatic P 91 intermittent motion cartoner
- Romaco Promatic SM 2000 stretch bander
- Romaco Promatic PAK case packer





High Performance Ensures Precise and Smooth Handling

The automatic, intermittent motion washing machines in the Romaco Macofar WM 8000 series are known for their exceptionally high performance and flexibility. These machines are renowned for their ergonomic design and strict balcony architecture. The ultra-reliable transport system ensures precise and smooth handling of cylindrical containers, including those that are geometrically unstable. Flexible, programmable washing cycles contribute to a thorough cleaning process that is easy to validate.

Universal Transport Gripper

- Containers with different diameters are transported without having to change the format
- Even the most difficult containers are gripped gently and efficiently

Variable Washing Cycles

- Standard cleaning process with set of special nozzles
- Washing cycle can be customised on the control panel
- Eight or nine stations possible per washing cycle
- Self-draining washing circuits
- Additional wash, drying cycle or siliconising can be integrated on request

Technical Highlights

- Maximum output: 24,000 containers an hour
- Separate “white” and “grey” areas
- Washing principle allows combination of air and water
- Containers optionally pre-cleaned in an ultrasonic bath
- Cleaned vials are automatically discharged
- Washing circuit sterilised with free-flowing steam

Exploiting Technologies
Romaco Macofar WM 8000 Series



Vial loading



Vial washing



Universal grippers





Compliance with Strict Regulations

A pyrogen is a substance that induces fever. During the manufacture of parenteral pharmaceuticals these substances must be removed from the product and from all containers and stoppers. This process is known as depyrogenation. The Romaco Macofar T 600 and T 800 depyrogenation tunnels comply with even the strictest regulations.

Romaco Macofar T 600 and T 800

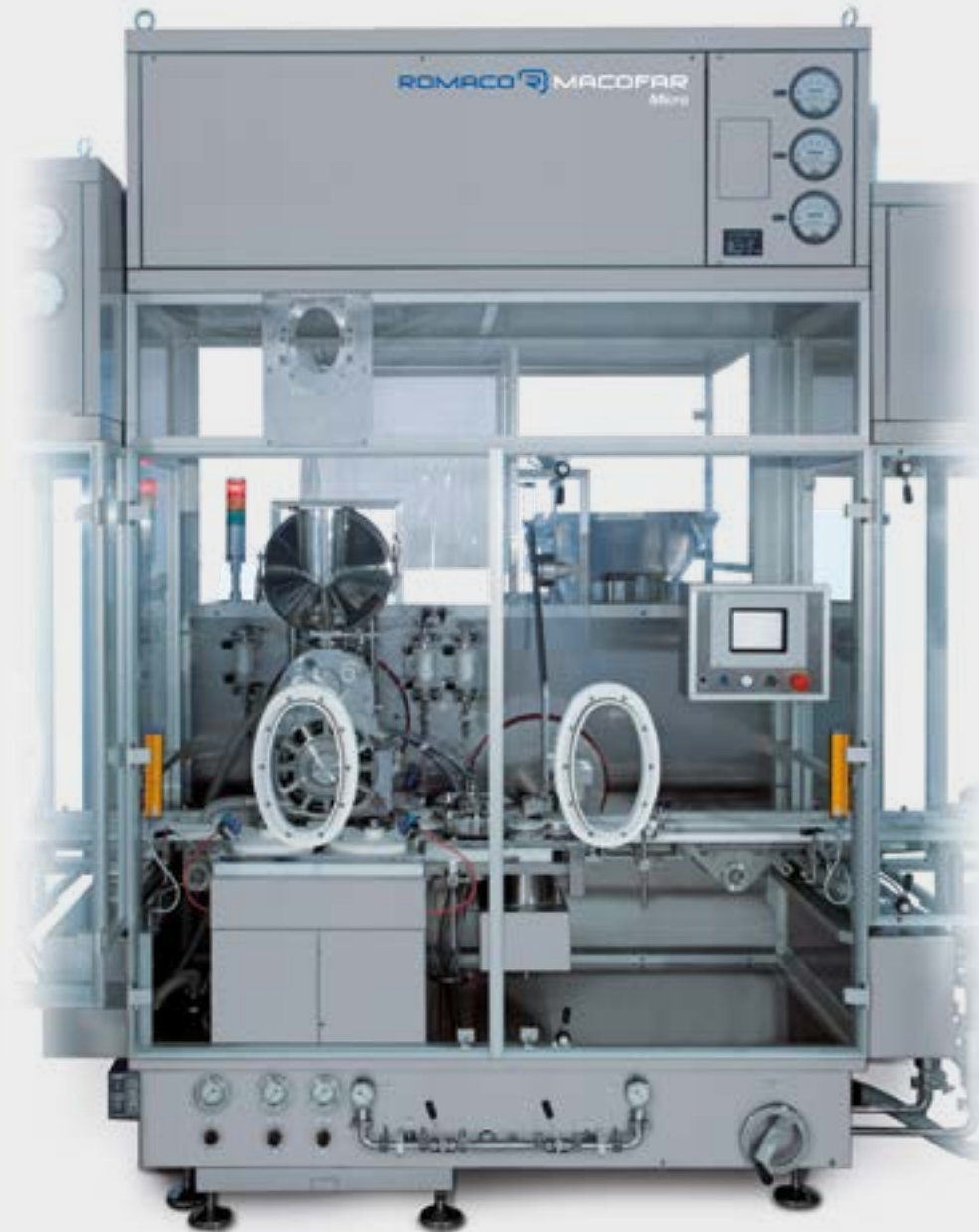
- Containers heated to a maximum of 340°C using sterile air
- Sterilisation and depyrogenation with a unidirectional laminar flow
- Vials cooled to ambient temperature in the downstream cooling area
- Controlled environment conforms to ISO 14644-1 and ISO 5 over the entire tunnel length
- Sterilisation in the tunnel complies with even the strictest regulations
- Validation with LAL test

Technical Highlights

- Transport on a conveyor belt made of stainless steel wire mesh; no abrasion due to two anti-jam belts that advance with the containers
- Mesh belt sterilised by unidirectional, vertical laminar flows
- Integrity of the seal on the absolute filters assured by ceramic fibre gaskets
- Vacuum between upstream and downstream cleanroom areas eliminates infiltration of non-sterile air through the gaskets
- Adjustable walls inside the heating chambers ensure a constant laminar air flow velocity
- Cooling chambers sterilised with dry air

*Exploiting Technologies
Romaco Macofar T Series*





The Right Machine for Every Job

The Romaco Macofar Micro 6, Micro 9 and Micro 18 are intermittent motion micro-dosing machines for dosing sterile powders at mechanical speeds of between 5,000 and 18,000 vials an hour. The powders are filled using a vacuum / pressure system. The cylindrical glass vials are then sealed with a rubber stopper.

Micro 6 / 9 / 18

- Intermittent filling process for dosing sterile powders
- Vacuum / pressure dosing system reduces residual powder at the end of the batch to a minimum
- Ultra-precise dosage with a maximum error of $\pm 2\%$
- High speed statistical weighing system at each dosing port checks approximately 4% of the total production
- Through-wall installation facilitates a smaller cleanroom because packaging is separated from the dosing and filling steps

Dual Dosing Disc Solution as an Option

- Machine can be optionally equipped with two identical dosing discs
- Dual dosing disc solution allows two different powders to be dosed into the same vial
- No need to prepare API powder mixtures
- Increased flexibility and efficiency: reduced costs for pre-mixing and handling powders

Ergonomic, cGMP Compliant Design

- Strict balcony architecture fulfils even the most rigorous standards for aseptic powder filling
- Easy access reduces downtime to a minimum
- Compliance with the latest cGMP standards for aseptic powder filling: rubber stoppers can be fed at either the front or rear of the machine

Technical Highlights

- Maximum filling speed: 5,000 (Micro 6), 9,000 (Micro 9) or 18,000 (Micro 18) vials an hour
- Quick, easy and repeatable format changes
- Automatic height adjustment of the dosing and stoppering group; no manual adjustments required
- Flushing with nitrogen before, during and after filling
- Liquid filling group to allow product validation (media fill test)
- Drying unit reduces humidity in the dosing area
- Vertical laminar flow over the dosing and stoppering stations

*Exploiting Technologies
Romaco Macofar Micro Series*



Powder dosing with vacuum pressure



Stoppering unit





The New Generation of Automatic Capping Machines

The capping machines in the Romaco Macofar CSP series integrate the most advanced technology for sealing cylindrical glass vials with aluminium, flip-off, press-on, screw or pilfer-proof caps. The machines comply with all established guidelines and regulations for aseptic filling.

Sealing with Stationary Guide

- Each container fed to the machine is instantly clamped from below
- Lifting and turning plate presses the container against a rigid plate
- Laterally mounted blade bends the cap bottom to seal the container

Sealing with Rotating Head

- Each container entering the machine is clamped between a stationary base plate and a rotating head
- Cap is positioned on the container, then tightly and securely fastened as the head rotates

Automation and Simple Operation

- Intuitive touch panel operation (HMI)
- Formulation management function
- Recording and management of production data
- Compliance with FDA 21 CFR Part 11 as an option

Ergonomic Design – Compact and Optimally Accessible

- Very small footprint
- Capping system design reduces contamination to a minimum
- Particle extraction system available as an option

- “White” and “grey” areas optimally accessible
- Machine cleaning time shortened
- All parts in contact with the cap can be changed quickly and easily
- Format changes completed in a few simple steps

Technical Highlights

- Minimum particles generation
- Highly suitable for Laminar Flow
- Automatic adjustment of capping pressure
- Collection in trays at the outlet
- Configured for installation of a RABS (Restricted Access Barrier System)
- Isolators can be supplied to protect the operator and the environment from hazardous substances

*Exploiting Technologies
Romaco Macofar CSP Series*



cGMP compliant capping process



Capping station



Capping with blade





Creating Value – Romaco generates added value for the customer across the entire life cycle of its solutions

- Romaco is interested in a long-term solution partnership with its customers
- Romaco is familiar with its customers' critical success factors throughout the different life cycle phases of our jointly developed solutions
- The range of services from Romaco is specifically designed for these phases and is delivered through the appropriate modular components
- Romaco optimises the internal processes so that the customer can benefit from more secure decisions within the time gained
- In April 2014 the new business unit Romaco Systems was founded within the Romaco Group: the aim of this unit is to integrate the offering of the Romaco Group into comprehensive solutions

We understand the business model of our customers and with a diverse portfolio we offer the best price/performance ratio for generating additional cash flow.

Benefit for the customer

Across the entire life cycle

- Minimal life cycle costs and low TCO guarantee fast amortisation of the financial investment
- The wide range of customer service products ensures sustainable value creation

In the investment phase (designing value)

- Professional consulting to increase decision-making security
- Short processing and delivery times give maximum scope for investment decision and thus optimum decision flexibility
- Customised solutions development for the optimum preparation of the implementation phases (ramp-up and production)
- Reliable and customer-orientated project management according to efficient milestone principles provides professional delivery

In the ramp-up phase (leveraging value)

- The production phase is reached more quickly due to shortening of ramp-up
- Transfer of expertise provides increased security to the customer in implementing production systems at the highest level
- Minimisation of ramp-up costs

In the production phase (harvesting value)

- Maintenance of the value stream due to quick customer service response times
- Best delivery times in service, format and spare parts
- Consulting on the optimisation of the OEE
- Continuous training of the customer team
- Extension of the life span

Creating Value

Creating Value describes our constant willingness to secure our customers' – and our own – financial success.



Comprehensive Range of Services from Initial Installation and Throughout the Operating Lifespan

Commissioning

- Installation: project planning and execution
- Commissioning and initial briefing of operators
- Process validation support
- Ramp-up support with shortened start-up phase

Maintenance

- Telephone advice available from Romaco experts
- Expert system guarantees coherent and efficient assistance
- Remote online support: prompt and reliable diagnostics using digital access
- On-site service: local emergency support provided where necessary
- Maintenance contracts: preventive maintenance reducing breakdowns to a minimum

Training

- Qualified training and seminars for machine operators and maintenance personnel
- FDA compliant training concepts with continuous performance reviews
- Provided on the customer's site or at the Romaco training centre

Production Optimisation

- Support for customers regarding the systematic optimisation of OEE values
- OEE audits on the customer's premises
- Detailed analyses of internal processes and downtime
- Combination of lean expertise and technical plant know-how

Retrofit, Expansion and Relocation

- Standard packages and customised solutions for machines in all series
- Special feed systems for complex products and specific layouts
- Plant relocation planning and execution

Original Parts

- Format sets compatible with all machines in the same series
- High-precision parts that fit exactly
- Format centre: each part is rigorously tested by Romaco before it leaves the factory
- Machine parameters and qualification documentation included in the scope of supply



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