Aseptic Powder Dosing Solutions
Delivering Solutions – Application Expertise
We are thoroughly familiar with your products and applications! Romaco specialises in engineering technologies for solid pharmaceutical dosage forms. Our concepts and system solutions are inspired by the rich experience and know-how of our 600-strong team of employees.

Creating Value – Enhanced Performance
Profit from Romaco’s excellent value for money! We help you optimise your OEE balance systematically. With our efficient production and service management, we cut the running costs for your machines and increase your output in the long term.

Exploiting Technologies – Product Diversity
Our product diversity knows no bounds! The modular concept behind Romaco machines and equipment is the key to your success. With seven product lines, we are in a position to respond promptly and flexibly to changing market requirements. Together we are stronger!
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

» 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.
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 dosing systems

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

Vial Capping
- Closing station either integrated in the powder filler or available as a line component
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 PTT – serialization and aggregation data
- 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
- 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
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 depyrogenation tunnels comply with even the strictest regulations.

Romaco Macofar Depyrogenation tunnels

- 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
- 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 eliminates infiltration of non-sterile air through the gaskets
- Adjustable gates between chambers ensure a constant laminar air flow velocity
- Cooling chambers sterilised with dry air
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 ± 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 maintenance is separated from the dosing and filling areas

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 stopping 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 stopping stations
Exploiting Technologies
Romaco Macofar MicroMaxX series

Romaco to become number one in the Powder Filling systems

Totally focused on becoming the number one in Powder Filling Systems, Romaco has launched a new, innovative range of powder filling machine.
In order to meet new market requirements, Romaco is expanded its machinery portfolio to include the new MicroMaxX.
The new concept behind the technical design of the MicroMaxX Series leads Romaco closest than ever to the number one position in the world of aseptic powder process.

Machine features
- Slim table top structure
- Linear transport system
- Ergonomic design allows component loading from the operator side of the machine
- Full accessibility during production from machine front side through glove ports
- Easy to clean
- Suitable for both high speed powder filling and high speed liquid filling
- Dosage via dosing disc equipped with vacuum pressure system
- Easy assembly and disassembly of dosing disc from machine front side
- Use of brushless servomotor technology

Technical Highlights
- 100% C.W. system (C.W. tare, C.W. after first dosing station, C.W. after second dosing station available)
- Filling of one or two powder types in the same vial
- Performance up to 24,000 vph
- Suitable for cRABS (Restricted Access Barrier System)

Powder dosing unit
Check weigher: tare
Rubber stoppering unit
The new generation of automatic capping machines

The capping machines in the Romaco Macofar MAC series integrate the most advanced technology for sealing cylindrical glass vials with aluminum flip-off, alu-caps. The machines comply with all established guidelines and regulations for aseptic processes.

Main Machine Features
- Outstanding capping quality is provided by individual capping stations handling one vial at a time
- Sealing by means of individual idle blades
- Intermittent and continuous versions are both available
- Automation and simple operation via intuitive touch panel (HMI)
- Recipe management function
- Recording and management of production data
- Ergonomic design, compact machine, minimal footprint particle extraction systems are available as an option
- Capping system design reduces contamination to a minimum
- Machine is easily accessible for the convenience of cleaning
- Simple and efficient format changes

Technical Highlights
- Automatic adjustment of capping pressure on each vial
- Speed up to 24,000 vph
- Setting of capping pressure from HMI
- 100% actual capping pressure verification and recording of data in batch report
- Configured for installation of a cRABS (Restricted Access Barrier System)
- Minimum particles generation
- In line capping quality verification available as an option
- Rubber stopper presence and position check before sealing and rejection available as an option
- Compliance with FDA 21 CFR Part 11 available as an option
Comprehensive Range of Service from Initial Installation and Throughout the Operating Lifespan

Service Partnership Agreements

- New groups and machine functions improvements
- Machine overhauling and complete revamping
- Mechanical and electrical obsolescence overcoming

Remote Service

- Scheduled and emergency onsite interventions
- Periodic check-ups and machine status report
- Machine lifecycle assessment
- Expert hot-line connection for quick troubleshooting and problem solving
- Remote-connection for online diagnostics and machine parameters control
- Call-4-Service function for immediate assistance

Remote Assist with smart glass

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 site

Complete service portfolio:

- Favored set of commercial conditions (bonuses, discounts, special rates)
- Dedicated support plan with fixed SLA

Retrofits, Upgrades & Revamping

- Machine overhauling and complete revamping
- Mechanical and electrical obsolescence overcoming

Maintenance & Check-ups

- Scheduled and emergency onsite interventions
- Periodic check-ups and machine status report
- Machine lifecycle assessment

Remote Service

- Expert hot-line connection for quick troubleshooting and problem solving
- Remote-connection for online diagnostics and machine parameters control
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PartGuard

Training