

Press Release

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New liquid filling machine for sterile ophthalmic products Oftalmica by Romaco Macofar

Romaco Macofar's Oftalmica was specially developed for aseptic filling of sterile eye drops, nasal sprays and injectables. Meeting all GMP requirements for safe processing of highly viscous, oily and foaming liquids, the machine additionally offers fast format changes and short cleaning times.

The Oftalmica is Romaco Macofar's latest technology for aseptic filling of sterile eye drops. This newly launched liquid filling machine is the pharmaceutical machinery manufacturer's answer to the growing demand for ophthalmic products with no added preservatives. Much stricter GMP regulations apply when these modern pharmaceutical formulations have to be filled under sterile conditions, and the Oftalmica fulfils them all – especially where the sterility assurance level is concerned. The machine is therefore fitted with an oRABS barrier system (either passive or active) and can also be supplied with integrated laminar flow technology if required. The Oftalmica is moreover prepared for bio-decontamination with vaporised hydrogen peroxide (VHP). Glove ports provide full access to all critical components without having to open the doors of the liquid filling machine, meaning the permissible SAL values for cleanroom class A are reliably maintained inside the machine. This facilitates process validation and production can be resumed more quickly.

Easy handling of highly viscous, oily and foaming liquids

The Oftalmica is used to fill all kinds of liquids, including highly viscous, oily or foaming fluids. The machine can be equipped for this purpose with up to eight separately driven rotary piston pumps made of ceramic or stainless steel, which can be individually controlled on the HMI. The Oftalmica's dosing station also enables a two-phase filling process to achieve a constant, high filling capacity while at the same time reducing the load on the pumps. This approach is especially recommended for products with poor flow properties. In addition, filling in two steps

has proved successful for bottles with very small necks, because ultra-fine filling needles with a correspondingly lower flow rate are used here. The same applies when filling foaming products whose flow rate is limited solely by their physical properties. Thanks to the two-phase filling technology, the Oftalmica by Romaco Macofar has a maximum output of up to 12,000 bottles per hour – regardless of the specifications of the liquids being filled or the dimensions of the containers. If required, the Oftalmica can also be supplied with peristaltic pumps.

Ideal for many different products, containers and closures

The Oftalmica processes a vast range of plastic and glass bottles with a filling volume of between 1 and 30 ml and can be used to apply any standard closure system. Depending on the type of closure, the machine can be configured with up to three closing stations. The lightweight plastic bottles are held on the belt by vacuum as they travel through the machine, which leads to optimal process stability. For filling, the bottles are transported to the dosing station in clusters by a walking beam transfer system. Two weighing systems ensure one hundred percent weight control both before and after filling. The empty and full bottles can be inerted on request for oxygen-sensitive products. As an option, the Oftalmica can also be utilised to fill nasal sprays or sterile injectables.

Fast product changes, short cleaning times

Overall, the Oftalmica offers numerous advantages whenever frequent product changes are common. To reduce the time for retooling, the formats were designed for a wide range of container sizes. All parts additionally support plug & play removal and installation in a few simple steps. What's more these handy format parts can be autoclaved, which makes them easy to clean. On request, the dosing pumps too can be cleaned fully automatically using a CIP (cleaning in place) or SIP (sterilisation in place) system. GMP-compliant, easy to operate and high performing – these are the hallmarks of the new Oftalmica liquid filling machine by Romaco Macofar.

For more information on Romaco, visit our website and social media channels: www.romaco.com – [Showroom](#) – [LinkedIn](#) – [YouTube](#)

Romaco Group

Romaco is a leading international supplier of processing and packaging equipment specialising in engineering technologies for pharmaceutical products. The Group

provides individual machines, lines and turnkey solutions for manufacturing, filling and packing powders, granulates, pellets, tablets, capsules, syringes, liquids and medical devices. The company also serves the food and chemical industries. Through its various technologies, Romaco is committed to sustainable production and to systematically reducing CO₂ emissions.

The Romaco Group has its headquarters in Karlsruhe (Germany) and is part of the Truking Group, a globally operating high-tech enterprise based in Changsha (China). Truking's core competency is handling and filling pharmaceutical liquids.

Romaco operates from five European business sites, with a broad portfolio comprised of seven established product brands. Noack and Siebler (Karlsruhe, Germany) supply blister, heat-sealing and rigid tube filling machines. Macofar (Bologna, Italy) markets technologies for filling sterile and non-sterile powders and liquids. Promatic (also Bologna, Italy) specializes in cartoners, track & trace systems and case packers. Kilian (Cologne, Germany) is a leading manufacturer of tablet presses. Innojet (Steinen, Germany) is in the business of granulating and coating fine solid particles. Tecpharm (Barcelona, Spain) offers tablet coating technologies.

More than 850 highly skilled and committed Romaco employees are dedicated to the development of future product technologies and to the continuous implementation of internal improvement processes. The Romaco Group's multi-brand system solutions are sold worldwide through eight Sales & Service Centres and a dense network of local agent organisations. Over 12,000 installations delivered by Romaco are currently in use in more than 180 different countries.

The following pictures are enclosed with the press release:

1. The Oftalmica aseptic liquid filling machine by Romaco Macofar
Oftalmica_Macofar_Romaco.jpg



2. The Oftalmica by Romaco Macofar is ideal for aseptic filling of sterile eye drops, nasal sprays and injectables.

Ophthalmica_Macofar_Romaco_applications.jpg



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