Press Release

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Romaco at Achema 2024

Energy and cost-efficient processing and packaging solutions

Romaco will showcase a wide range of sustainable processing and packaging solutions at this year's Achema. Thanks to energy efficient processes that make sparing use of resources, the one stop solutions supplier can considerably improve its machines' carbon footprint. The new KTP 420X C containment tablet press from Romaco Kilian will be the highlight at the upcoming exhibition.

As a one stop solutions supplier, Romaco will be taking advantage of this year's Achema to present its broad portfolio of machinery. From powder processing to the finished pallet, the manufacturer's technologies cover the entire process chain in the pharmaceutical, nutraceutical, food and chemical industries.

The all-in-one machinery supplier strictly focuses on aspects of sustainable product development. Romaco's energy efficient technologies make sparing use of resources and improve the carbon footprint of its machines while cutting the manufacturing costs for users. The company's success in meeting climate change objectives is audited by independent organizations. Romaco recently earned a silver medal in the EcoVadis Sustainability Rating and, with a total score of 67, is among the 11% top-rated businesses. In addition, the SBTi (Science Based Targets initiative) has confirmed the achievement of Romaco's targets for reducing Scope 1 and 2 greenhouse gas emissions in 2023. In 2024, Romaco also became a member of the UNGC (United Nations Global Compact).

Kilian KTP 420X C containment press

The containment version of Romaco Kilian's KTP 420X C rotary tablet press fulfills all requirements for processing active pharmaceutical ingredients up to OEB Level 3 with medium toxicological potency. This includes numerous medications, for example for treating hypertension, ventricular ulcers or bronchial asthma. The

containment tablet press is configured with a Restricted Access Barrier System (RABS) featuring glove ports to protect the operator as well as a Rapid Transfer Port (RTP) for contamination-free material transfer. Negative pressure in the compaction area and electric door locks as well as dust-tight docking systems and a dust-tight tablet chute moreover ensure GMP compliance. The efficient implementation of high-quality containment processes is additionally supported by the proven hygienic design of the KTP 420X C. The hermetical separation between the compaction and technical areas prevents tablet dust from entering the mechanical compartment. The compaction area itself is designed as a deep-drawn, single-piece run-off containment with polished surfaces and large radii, so that far less effort is necessary for cleaning. Protective clothing is only required for cleaning the press and is not essential during production. The very good OEE (overall equipment effectiveness) and extremely low TCO (total cost of ownership) are key characteristics of the Romaco Kilian KTP 420X C. With a maximum output of 475,200 tablets per hour, the technology is classed as a high-speed press for containment applications.

KTP 1X R&D tablet press from Romaco Kilian

The KTP 1X is the newest generation of Romaco Kilian's R&D tablet presses for laboratory use. This single-stroke press was designed as an all-in-one instrument for research and development activities. It is suitable for pressing mono-layer, bi-layer and triple-layer tablets as well as tab-in-tab formats. Depending on the model, it achieves compression forces of up to 80 kN with a maximum output of 1800 tablets per hour. This versatile R&D press enables the various tableting parameters, such as compression force or the possible tableting speed, to be automatically determined. The smart measurement system evaluates huge amounts of data in next to no time for this purpose. The KTP 1X is moreover capable of simulating any standard rotary press, making it much easier to conduct scale-up trials. In addition to the production of clinical samples, the technology also allows detailed troubleshooting and hence supports process optimization. Thanks to the machine's extremely good rigidity, the punch position in particular can now be measured more precisely. This high measuring accuracy goes hand in hand with extremely low product consumption, which is why the KTP 1X is not only very accurate but also cost-efficient and sustainable. Only a few test series are required to obtain meaningful results, as the compression studies are highly automated. With its very small compaction area, the machine has a small footprint and is quick

and easy to clean – for even greater time and energy savings. What's more, the KTP 1X ships with a data module that gives users access to raw measurement data worldwide at any time, even when the tablet press is not in operation.

TPR 25 Pilot mobile tablet coater from Romaco Tecpharm

Romaco Tecpharm is expanding its Optima product family with the TPR 25 Pilot mobile tablet coater. All inlet and exhaust airflow systems required for the coating process have been integrated into this compact pilot-scale unit for simple plug & play commissioning. As a modern all-in-one solution, its applications cover everything from development activities and scale-ups to the production of very small batches. The pilot coater is designed to handle batches weighing anything from 1 to 25 kg, making it suited for an extremely wide batch size range from 5 to 100 percent. The coating pan's enormous flexibility is made possible by fully automated processes requiring no manual adjustments. The TPR 25 Pilot is equipped with Tecpharm's patented Optima spray arm, which is controlled by a sonar system that automatically adjusts the distance between the spray gun and the tablet bed. Thanks to the spray arm's intelligence, the coater does not have to be stopped and opened to correct the spray distance while the process is running. In addition to this, the extendable Optima spray arm has movable nozzles to ensure the ideal spray angle in any situation. The process air flowing through the tablet bed follows a precisely controlled path, which can be automatically adapted to the fill level in the drum with the aid of an exhaust flap that opens steplessly. This results in remarkably accurate application of the coating suspension and ultra-efficient drying of the tablet bed. From a sustainability viewpoint, Romaco Tecpharm's TPR 25 Pilot consequently impresses with significantly shorter processing times coupled with lower energy and spray liquid consumption.

VENTILUS® Pilot fluid bed processor from Romaco Innojet

The VENTILUS® Pilot fluid bed processor from Romaco Innojet is a mobile all-rounder for pilot scale applications or small batches. The technology impresses with excellent results in terms of flow properties as well as powder and granulate compressibility. Mounted on four wheels, this compact machine fits through any standard door frame and is designed for plug & play installation. An all-in-one solution intended for batch sizes from 4 to 25 litres, it granulates, dries or coats particles of any size from 10 µm to 2 mm. The technology meets all the requirements for laboratory use as well as for GMP-compliant production of clinical samples. The spray liquid is applied optionally according to the conventional top

spray method or using a bottom spray system with a central nozzle – either the ROTOJET® or the new FLEXIJET®. The latter was specifically developed for granulation processes and is not only very easy to handle, but also quick to clean. The cylindrical container featuring the ORBITER® booster permits controlled, gentle batch intermixing. The homogeneous flow conditions improve product quality and reduce the spray liquid consumption while simplifying scale-ups. In addition, the VENTILUS® Pilot is suited for hot melt coating processes, which merely requires connection of the patented Innojet IHD hot melt system. The processing time is consequently up to 85 percent shorter and the processor's carbon footprint is significantly lower.

Unity 600 blister line from Romaco Noack

Romaco Noack's new Unity 600 blister packaging line combines high efficiency with a sustainable system concept. This double-lane, high-speed line achieves a maximum output of 600 blisters and 350 cartons per minute and enables flexible processing of blister packs up to 145 mm long and 90 mm wide. Its innovative transfer system eliminates the need for conventional vacuum pumps, significantly improving the energy efficiency of the monobloc, which consists of a blister machine with rotary sealing and a continuous motion cartoner. The vacuum for transferring the blisters to the cartoner and for removing the cartons and leaflets is instead produced in a more climate-friendly Venturi process. Venturi pumps are comparatively small, need less maintenance and give off much less heat, so that the cooling requirements in the cleanroom are greatly reduced. The blisters are transferred to the cartoner by a carousel-shaped indexing wheel with a downstream stack transfer unit, which ensures that the cartoner is only supplied with complete blister stacks. As a new feature, any gaps are mapped in the software and compensated. Since good blisters are no longer held back, a manual blister top-up magazine can be dispensed with. Furthermore, this highly automated transfer solution allows seamless tracking and tracing of the blisters from the product feeding unit onward. Due to its very good line clearance and short changeover times, Romaco Noack's flexible-format Unity 600 blister packaging line also scores with excellent OEE (overall equipment effectiveness).

Oftalmica aseptic liquid filling machine by Romaco Macofar

The Romaco Macofar Oftalmica was specially developed for filling additive-free ophthalmic products but can also handle nasal sprays and injectables. The machine meets all the requirements of the revised Annex 1 of the EU GMP

Guidelines and can be supplied with oRABS or isolation technology. The Oftalmica is ideal for filling sterile, highly viscous and oily suspensions as well as foaming liquids into narrow-mouth bottles. Its dosing station with up to eight separately driven rotary piston or peristaltic pumps enables filling in two phases, which is especially recommended for products with very poor flow properties. All in all, the Oftalmica achieves a maximum output of 12,000 bottles per hour with a filling volume of between 1 and 30 ml. To simplify product changes, the formats of the individual machine stations and the bottle transport system were designed for a very wide range of container sizes. All parts support plug & play installation and removal in a few simple steps and can also be sterilized in an autoclave. Vacuum belt conveyors ensure safe transfer of lightweight plastic bottles. The Oftalmica can be configured with up to three closing stations and processes the entire range of ophthalmic closures, including Aptar and Nemera devices. Torque control is assured for 100% of the screw caps. Additionally, a 100% weight control system can be implemented to check the filling volume of the bottles both before and after filling. On request, the technology is offered as a turnkey solution with upstream and downstream equipment, for example for cartoning and case packing.

On show at Achema in Frankfurt/Main (Germany) from June 10 to 14, 2024 (Messe Frankfurt, Hall 3.0, Stand B49).

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 specializing 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 CO_2 emissions.

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

Romaco operates from six production sites worldwide, 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 930 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 nine Sales & Service Centers and a dense network of local agent organizations. 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. Kilian KTP 420X C containment press
   KTP-420X-C_Kilian_Romaco.jpg

2. KTP 1X R&D tablet press by Romaco Kilian
   KTP-1X_Kilian_Romaco.jpg

3. TPR 25 Pilot tablet coater by Romaco Tecpharm
   TPR-25-Pilot_Tecpharm_Romaco.jpg

4. VENTILUS® Pilot fluid bed processor by Romaco Innojet
   VENTILUS-Pilot_Innojet_Romaco.jpg

5. Unity 600 blister packaging line by Romaco Noack
   Unity-600_Noack_Romaco.jpg

6. Oftalmica aseptic liquid filling machine by Romaco Macofar
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