



Innovative technology solutions for pharmaceutical and nutraceutical processes. From feeding to extrusion and bulk material handling.

» Extensive process expertise. Even for the most difficult to handle excipients and active ingredients.







Coperion and Coperion K-Tron can provide single source solutions for all of your extrusion, feeding and conveying needs. We are experienced partners to the pharmaceutical and nutraceutical industries and provide single components as well as complete systems. Our product lines are engineered to meet the rigid requirements of the industry, including strict adherence to cGMP guidelines and standards.

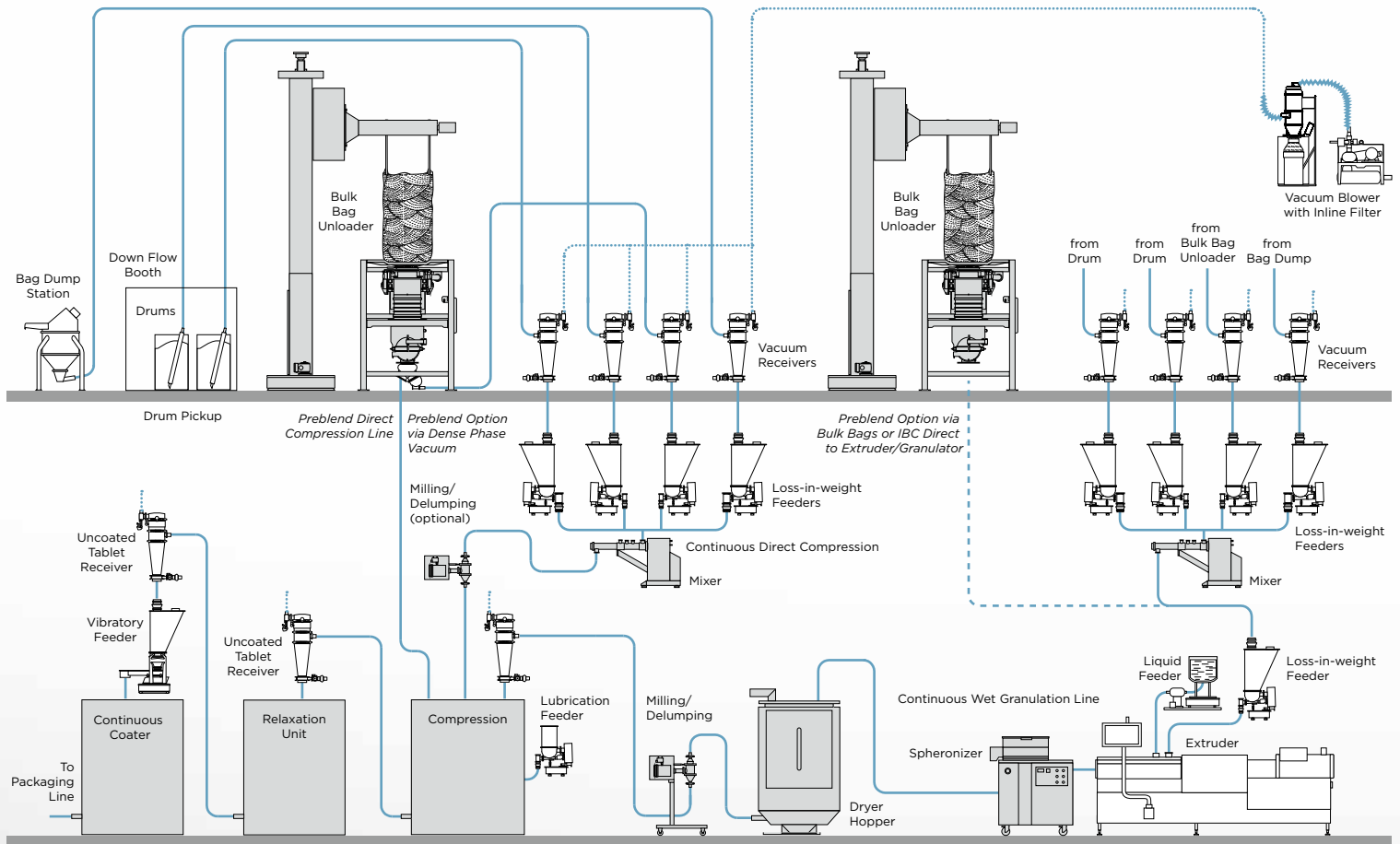
Our expertise in processing even the most difficult to handle excipients and active ingredients has resulted in global recognition of our equipment and engineered services, with a particular strength in providing continuous processing solutions. Our partnerships with pharmaceutical and nutraceutical companies of all sizes continue to grow. Collaborations with both world-renowned universities and leading pharmaceutical equipment manufacturers result in specialized technical solutions with an emphasis on safety, product and process quality.

Coperion's ZSK pharma extruders are a continuous processing solution, ensuring gentle product handling at short residence time and low temperature. For handling of both APIs and pharmaceutical excipients, highly accurate feeders in easy clean designs are provided for batch and continuous processes.

A wide variety of bulk material handling equipment is also available, such as rotary and diverter valves as well as bag dump stations and vacuum conveying systems. Our systems engineers are experienced in combining these products to provide the optimal solution for every application.

SCOPE OF SUPPLY

RAW MATERIAL HANDLING 	REFILL 	FEEDING 	PELLETIZING 	FINISHED PRODUCT HANDLING 	CONTROL SYSTEMS 
STATE-OF-THE-ART EQUIPMENT					
ENGINEERING COMPETENCE & PROCESS KNOW-HOW					
INSTALLATION & COMMISSIONING					
COMPLETE SYSTEMS					



➤ Helping you optimize your processes.

COMPREHENSIVE TEST CENTER CAPABILITIES

Coperion and Coperion K-Tron provide test centers for feeding and extrusion applications as well as hygienic components and conveying systems. These test centers are the ideal platforms for testing any challenges in a production or research environment, such as product behavior, new formulations and throughput rates. Our test centers are equipped to perform tests with placebo materials. Tests with APIs can be performed depending upon an individual risk assessment.

Collaborations with a variety of worldwide universities allow for additional extensive research, e.g. on material properties, computer modeling, extrusion, material handling and continuous processing.

TRANSFORMING BATCH TO CONTINUOUS OPERATIONS

Coperion and Coperion K-Tron provide equipment for continuous processes such as hot melt extrusion and extrusion granulation, wet granulation, dry granulation, direct compression, blending/mixing and coating.

Regardless of the exact continuous process utilized, the feeding and refill methods within the process are critical in maintaining process and product quality/efficiency. Highly accurate Coperion K-Tron loss-in-weight feeders with clean and quick-reacting receivers for automatic feeder refill are the perfect combination to ensure consistent material supply to the continuously operating Coperion ZSK pharma extruder. This process is reproducible and allows for reliable scale-up to higher throughput rates.

CONTROL SYSTEMS

Whether controlling a single feeder, a loss-in-weight feeder with refill combination, or a complete process including material handling and extrusion, Coperion and Coperion K-Tron can provide the optimal control solution.



KCM

The Coperion K-Tron Control Module (KCM) combines feeder control and motor drive modules in a compact housing, offering more flexibility and excellent performance. Each feeder has its own KCM, with integrated motor setup, diagnostics and operator interface functions.



K-VISION

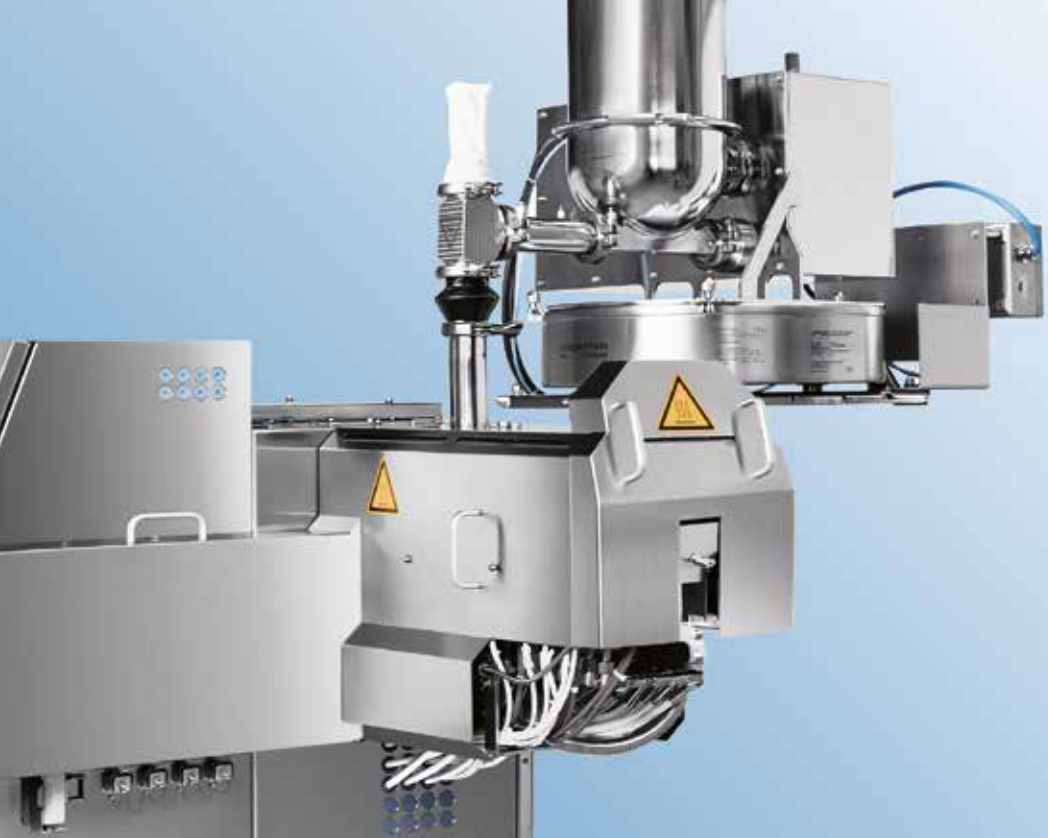
The K-Vision™ controller simultaneously controls up to 24 devices (feeders, refill receivers, etc.) in one or two lines via a 12.1 inch color LCD with a touchscreen. K-Vision provides recipe entry and a detailed overview of the process line with extensive real-time monitoring of feeder status and performance.



PLC CONTROLS

PLC controls with detailed HMIs can be provided to perform a wide array of advanced functions including recipe and function loop controls, bar codes/tracking, and complete system alarm analyses. In addition, control systems can also include separate screens/programming for cleaning sequences.





➤➤ Comprehensive application know-how.

Coperion and Coperion K-Tron have decades of experience in the material handling, feeding and extrusion of a wide variety of pharmaceutical and nutraceutical ingredients. From batch to continuous applications, high containment, nitrogen inert operations and/or specialty WIP and CIP designs, our process engineers can provide the expertise for even the most difficult to handle materials.

COMPETENCE IN VARIOUS APPLICATIONS

Batch and semi-continuous processes

- Automated batch dispensing of excipients, APIs and finished products
 - Loss-in-weight and gain-in-weight dispensaries
 - Reactor batch loading
 - Batching from centrifuges and vacuum dryers
 - Batch unloading from IBCs, FIBCs and supersacks
- Feeding, refill and pressure isolation of mills and micronizers
- Batching for packaging operations

Continuous processes

- Hot melt extrusion (HME)
 - Hot melt extrudates as basis for solid dosage forms with controlled/sustained release of APIs
 - Extrusion of adhesives with APIs for transdermal plasters/bandages/patches
 - Extrusion of adhesives for medical applications such as stoma
 - Extrusion of compounds for implants/biodegradable implants or contraceptive rings
 - Extrusion of medical plastics
 - Extrusion of dissolvable medicated films
- Wet granulation, wet extrusion
- Continuous coating
- Tablet press lubrication
- Continuous direct compression
- Continuous blending

Material transfer via pneumatic conveying

- Blender and reactor loading
- Loss-in-weight feeder refill
- Oral solid dosage forms to packaging
- Transfer of raw ingredients and/or blends to batch, semi-continuous and continuous processes

Experience with various sample materials

- Active pharmaceutical ingredients (APIs)
- Ascorbic acid
- Calcium, calcium stearate
- Cellulose derivatives
- Citric acid
- Colloidal anhydrous silicone
- Coloring agents
- Croscarmellose
- Crospovidone
- Lactose
- Lactose monohydrate
- Magnesium stearate
- Microcrystalline cellulose
- Polymers, natural or synthetic
- Potassium chloride
- Silicates
- Silicon dioxide
- Sodium chloride
- Sodium stearyl fumarate
- Starch
- Stearic acid
- Sugar alcohols
- Talc
- Vitamins



VALIDATION SERVICES AND CONTROLS CAPABILITIES

Coperion and Coperion K-Tron can provide an extensive array of validation documentation based on the lifecycle approach, including FRS/FDS, FAT, SAT-IQ and SAT-OQ protocols for standalone feeders, conveyors, extruders and complete systems.

Custom system PLC controls are available to meet CFR Part 21 compliance. Detailed HMIs can be provided to perform a wide array of advanced functions including recipe and ratio controls, bar codes/tracking and complete systems alarm analyses.

➤ Feeders. High accuracy addition of ingredients for both batch and continuous applications.

With hundreds of installations worldwide, the Coperion K-Tron pharmaceutical feeder has become the standard for high accuracy feeding of pharmaceutical liquids and powders. The introduction of the newest generation of pharmaceutical feeders has simplified the arrangement of multi-feeder clusters for continuous processing with the additional benefit of quick changeover and modularity. Whether for continuous feeding or automated batching of APIs and excipients, the Coperion K-Tron innovations

in design coupled with our world-renowned digital weighing and controls technologies ensure superior performance. Coperion K-Tron pharmaceutical feeders are available in both volumetric and gravimetric loss-in-weight configurations. Vibratory and liquid feeders are also available. Pharmaceutical designs feature AISI 316L stainless steel construction, with minimum surface finishes on contact components of Ra 0.8 micron. In addition all elastomers are constructed of FDA-approved materials.



K3-PH SCREW FEEDERS

The new K3 pharmaceutical screw feeders feature a modular design with quick change feeder bowl. In addition, the new D4 compact scale is designed for superior performance with a drastically reduced footprint. Twin screw feeders are ideal for difficult flowing materials such as APIs, lubricants and excipients.

Feed rates:

0.13-2012 dm³/h (0.005-71.1 ft³/h)

TWIN SCREW MICROFEEDERS

The family of Coperion K-Tron microfeeders is ideal for feeding free-flowing powders at extremely low rates. Our microfeeders are designed for modularity to allow quick exchange of all feeder configurations, with the same controls and weighing technology. Versions are available with 12 mm and 16 mm screws.

Feed rates:

0.031-0.0011 dm³/h (0.0006-11.7 ft³/h)

VIBRATORY LOSS-IN-WEIGHT FEEDERS

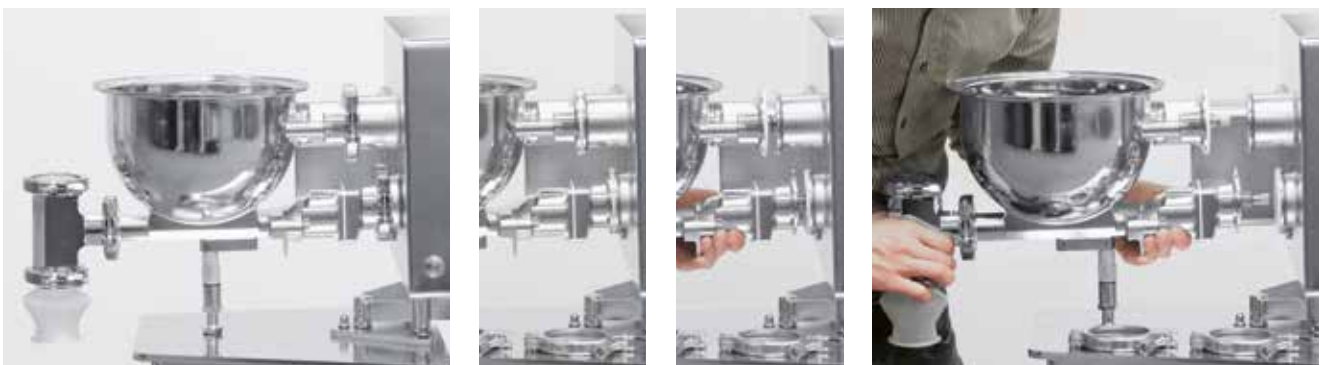
The vibratory feeder is ideal for fragile or fibrous materials, uncoated tablets, as well as limited applications for certain difficult flowing pharmaceutical powders. The feeder includes an innovative vibratory drive as well as isolated weighing module for high accuracy feeding.

Feed rates:

2-900 dm³/h (0.07-31.77 ft³/h)

QUICK CHANGE DESIGN FOR SCREW FEEDERS

The Quick Change design makes decoupling of the feeding unit for changeover or cleaning quick and easy.





INNOVATIONS IN FEEDING TECHNOLOGY

ActiFlow™ bulk solid activator

The ActiFlow bulk solid activator reliably prevents bridge building of cohesive materials, eliminating the need for mechanical vertical agitation or ancillary flow aids. It is a non-product-contact device and is completely self-tuning, adjusting the frequency and amplitude to compensate for changes in hopper fill level or material flow, thus preventing material bridges before they can form.

Electronic Pressure Compensation EPC

The EPC system is ideal for situations where additional pressure or vacuum forces may influence the accuracy of the feeder, such as closed systems, or continuous systems (e.g. blenders, extruders or mills/micronizers). This system can automatically detect changes in pressure within a feeder and adjust the weight signal accordingly, without the need for mechanical pressure balancing, piping or tubing.

K-Sampler

The K-Sampler package is a test sampling system for the evaluation and validation of the mass flow performance of gravimetric feeders. This system measures and characterizes the output of a feeder in terms of repeatability and deviation from setpoint, by automatically and consecutively taking samples from the feeder output. This system is ideal for material feed characterization as well as feeder performance validation.

Continuous pharmaceutical refill

The combination of Coperion K-Tron's innovative refill array, extremely fast controls (450 measurements per second) and digital load cells provide the highest accuracy for batch and continuous systems. The use of this innovative refill array results in a more consistent mass flow and the ability to quickly revert back to the loss-in-weight control when the refill is completed.

External spray lubrication of tablet presses

The Coperion K-Tron lubricant feeder is used for accurate delivery of an atomized spray of lubricant powder directly into tablet press tooling. This external spray lubrication system can be provided for a number of tablet press designs. Installations have proven that the atomized spray of the lubricant directly into the press can improve tablet hardness, significantly reduce the sticking and picking to the tablet press tooling and even reduce the overall lubricant consumption.



LIQUID LOSS-IN-WEIGHT FEEDERS

Coperion K-Tron's liquid loss-in-weight feeders provide accurate continuous gravimetric control of liquid addition to continuous granulators and extruders.

Feed rates:

dependent on the configuration

➤➤ Pneumatic conveying and material transfer solutions. From continuous pressure and vacuum systems to batch weighing and scaling.

The Coperion K-Tron line of conveying equipment is specifically designed to convey delicate materials such as tablet granulations, APIs, excipients and even finished capsules and tablets. The P-Series system designs are available for both dense phase and dilute phase vacuum transfer for a wide variety of applications including capsule filler, tablet press, blender and coater loading, feeder loading and refill, inline screening and sieving, and general ingredient conveying or transfer. Full containment

options are available with split butterfly valves on the receiver discharge. P-Series vacuum conveyors are designed with complete cleaning and ease of disassembly in mind. They are available as standalone units as well as integrated packages for the automatic refill of Coperion K-Tron pharmaceutical design feeders. Complete systems packages are available for conveying pickup options from supersacks, drums, boxes, IBCs and FIBCs.



P10 MODEL PNEUMATIC RECEIVER

- With butterfly valve
- Holding capacity of 7 dm³ (0.4 ft³)
- Conveying capacity up to 600 kg/h (1,320 lb/h)*



P30 MODEL PNEUMATIC RECEIVER

- With butterfly valve
- Holding capacity of 27 dm³ (1 ft³)
- Conveying capacity up to 1,000 kg/h (2,200 lb/h)*



P100 MODEL PNEUMATIC RECEIVER

- With butterfly valve
- Holding capacity of 90 dm³ (3.2 ft³)
- Conveying capacity up to 3,600 kg/h (7,920 lb/h)*

* All conveying rates are based on a distance of 15 m (50 ft) and bulk density of 0.5 kg/dm³ (31 lb/ft³). Rates vary with material characteristics, conveying distance and plant layout.

SPECIALTY DESIGNS FOR SPECIFIC APPLICATIONS

Coperion K-Tron offers a number of specialty designs for pneumatic loaders and receivers, all dependent upon the requirements of the product and the process. Options are available for conveying of potent or hazardous materials, including systems design for conveying of explosive ingredients. Modifications to the Coperion K-Tron P-Series designs include the addition of retractable spray balls in the receiver body for WIP cleaning, as well as specialty swing out filter head designs to allow for easy access of the filters.



➤ Rotary and diverter valves. For conveying and discharging ingredients.

Coperion rotary and diverter valves are designed for highest demands with regard to safety and reliability. Parameters such as particle size, cohesion and adhesion influence the flow properties of pharmaceutical ingredients and are a key factor in the

correct design and layout of bulk material handling components. Our intensive research and development of new technologies has resulted in innovative and easy-to-clean rotary and diverter valves.



ROTARY VALVES

Coperion's range of sanitary design rotary valves vary in size from 80 to 350 mm inlets, allowing for maximum versatility for numerous pharmaceutical installations, including use as explosion barrier protection in API milling applications as well as use in pharmaceutical excipient conveying lines. The valves are available in a variety of executions depending on cleaning and accessibility requirements, and include options such as two-sided access to both the rotor and motor endplates.

SMALL ROTARY VALVES

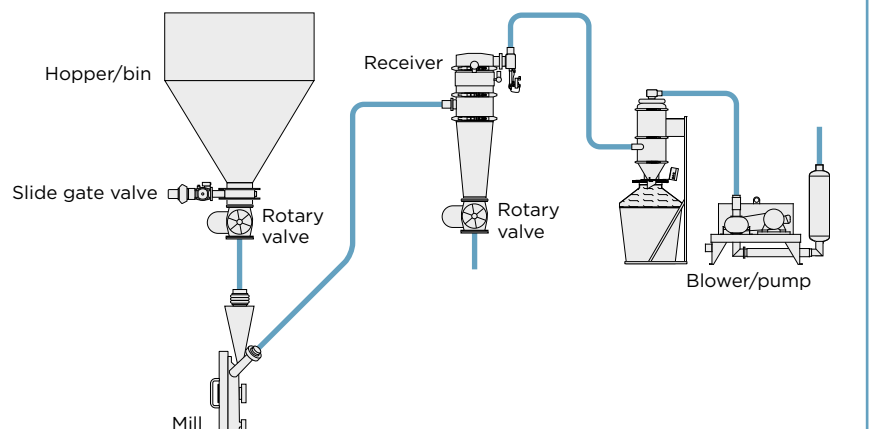
Coperion's smallest rotary valve, the ZZB/ZZD, is constructed of a solid stainless steel housing in optimal hygienic design. It is equipped with quick-release clamp connections on both inlet and discharge and is available in DN 80 mm and DN 100 mm sizes. These valves are ideal for feeding, isolation and metering into the smallest mills and micronizers. Rate ranges of the ZZB/ZZD are between 50 and 1,000 kg/h.

DIVERTER VALVES

Coperion's sanitary diverter valves have a single channel, conical design for easier dismantling and accessibility. They are ideal for installation in conveying lines or in gravity pipes up to 5 bar (g). Valves are available for wet cleanable applications such as residue-free CIP operations and for use in hazardous locations.

MILL WITH EXPLOSION PROTECTION

Coperion's PSR and ATEX-rated rotary valves are ideal for pressure isolation.



➤ First-class twin screw extruders. For continuous mixing of pharmaceutical active ingredients.

Continuous extrusion via twin screw extruders for pharmaceutical solid dosage form production is growing in popularity as a preferred option to more traditional granulation techniques. Coperion is a pioneer in the development of high-end closely intermeshing, co-rotating twin screw extruders, beginning with laboratory scale and extending to continuous pharmaceutical

production systems. The Coperion ZSK twin screw extruder offers a variety of unit operations within one piece of equipment, such as distributive and dispersive mixing, granulating and devolatilization. The production method provides gentle product handling at short residence time and low temperature.

➤ SPECIAL FEATURES OF COPERION'S ZSK PHARMA EXTRUDERS

- Modular barrel design with customized process length (L/D) to each individual product
- Modular screw design with broad selection of screw elements for high process flexibility
- Intensive mixing and dispersion via twin screws for excellent product quality
- Specific torque up to 18 Nm/cm³ allowing high ratios of throughput/rpm resulting in minimized product temperatures and API degradation
- All parts in contact with the product made of stainless steel with minimized surface roughness
- Use of FDA-compliant oils/lubricants
- Self-cleaning of the twin screws avoids dead spaces and results in short residence times
- Complete documentation of all process parameters (V-lifecycle) based on URS (User Requirement Specification)
- Simple handling and quick dismantling using quick-release couplings
- PLC and visualization systems conform to CFR Part 11
- Reliable scale-up due to geometrical consistency within the ZSK series
- Professional process engineering support with know-how from over 30 years of experience in pharmaceutical applications



➤ ZSK 18 MEGAlab TWIN SCREW EXTRUDER IN PHARMACEUTICAL DESIGN WITH COPERION K-TRON GRAVIMETRIC LOSS-IN-WEIGHT FEEDER, COOLING BELT AND SP PHARMA STRAND PELLETTIZER



› WEAR AND CORROSION-RESISTANT SCREW ELEMENTS



› BARREL WITH OVAL LINER FOR ADVANCED WEAR PROTECTION



TYPICAL AREAS OF APPLICATION OF COPERION'S PHARMA EXTRUDERS

- › Pharmaceutical hot melt extrusion (HME)
 - Solvent-free production of solid dispersions or solids solutions of APIs (also BCS class 2 & 4), thus enhancing their bioavailability
 - Hot melt extrudates as basis for solid dosage forms with controlled/sustained release of APIs
 - Degassing of water to counteract API re-crystallisation
 - Encapsulation and taste masking
- › Wet extrusion of APIs as basis for granules for capsule filling
- › Extrusion of adhesives with APIs for transdermal plasters
- › Extrusion of adhesives for medical applications such as stoma
- › Extrusion of compounds for implants/biodegradable implants or contraceptive rings
- › Extrusion of medical plastics (wound plasters/butterfly closures)

TECHNICAL DATA

ZSK	Max. torque per shaft Md [Nm]	Specific torque Md/a ³ [Nm/cm ³]	Max. screw speed [rpm]	Max. motor power N [kW]	Screw diameter [mm]
18 MEGAlab*	38	11.3	1,200	10	18
26	140	15	1,200	37	25
32	315	18	1,200	83	32
40	510	13.6	1,200	135	40
70	3,500	18	1,200	924	70

* Laboratory extruder

STRAND PELLETIZER SP PHARMA

Coperion's pelletizers SP pharma have been successfully used for the production of pharmaceutical agents for many years. The SP pharma is designed according to GMP design and fulfills pharmaceutical requirements such as continuous processing without any dead space, smooth surfaces, easy cleaning and

the exclusive use of certified materials. Beside the SP pharma, Coperion provides a wide variety of conveying and cooling units for pharmaceutical applications, such as conveying belts or chill rollers.




 **coperton**
ACTION
loader 1

➤ The entire range of pharmaceutical and nutraceutical processing.

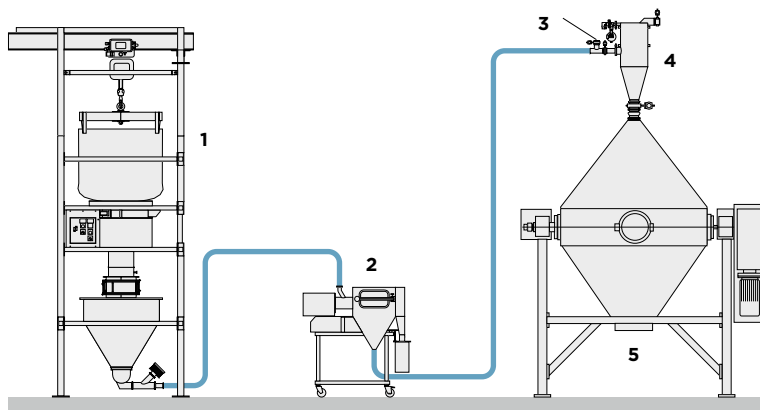
The global systems engineering services provided by Coperion and Coperion K-Tron ensure the most efficient integrated processes with an emphasis on safety and automated design. Application experience and design expertise ensure that pharma-

ceutical and nutraceutical processing systems are ideally configured for every application. The complete portfolio allows customers to process any required throughput from laboratory to production scale.

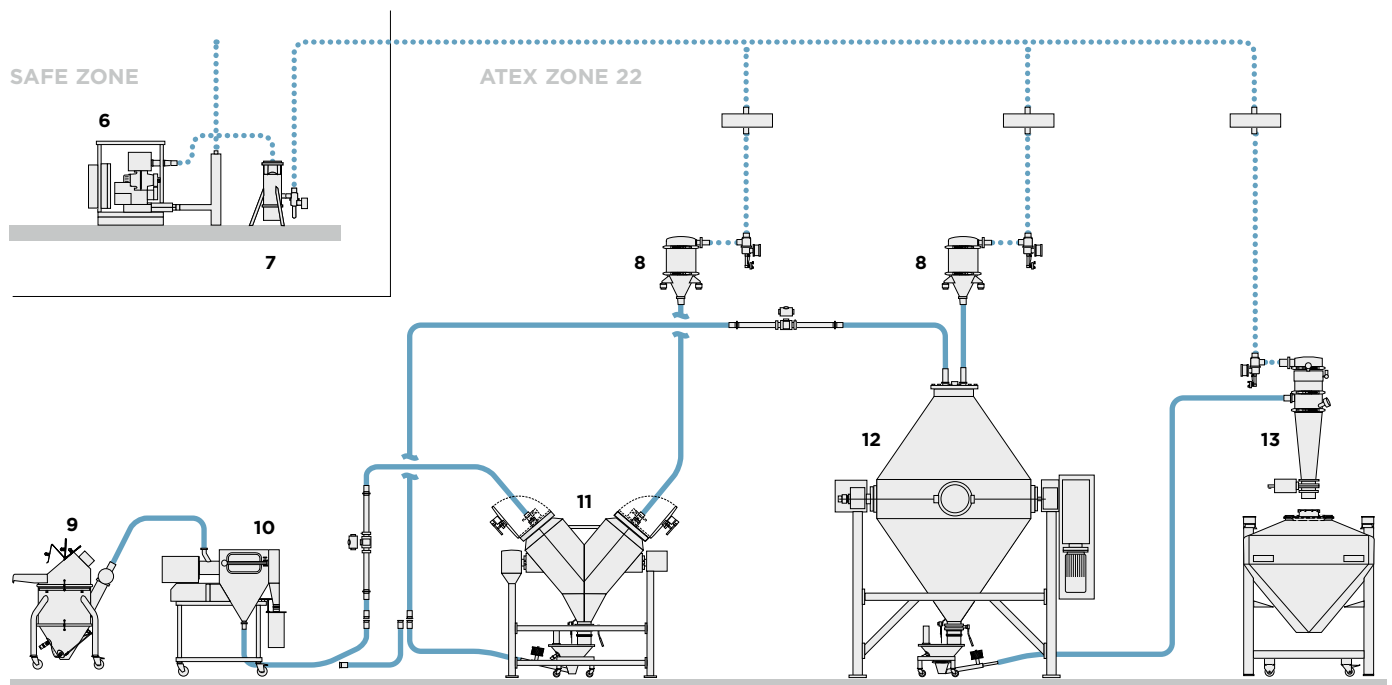
➤ DIRECT AND INDIRECT BLENDER LOADING WITH INLINE SIEVING

Raw ingredients can be gently conveyed through inline sieves for loading to blenders. In addition, final blends can also be conveyed without blend segregation via dense phase vacuum transfer. Vacuum conveying is often used to move materials through sieves or conical screen mills to help improve overall

throughput of the process, contain dust and prevent exposure while improving end product quality. Blenders which can withstand full vacuum can be directly loaded, with the use of a simple filter receiver located after the blender to handle excess dust.

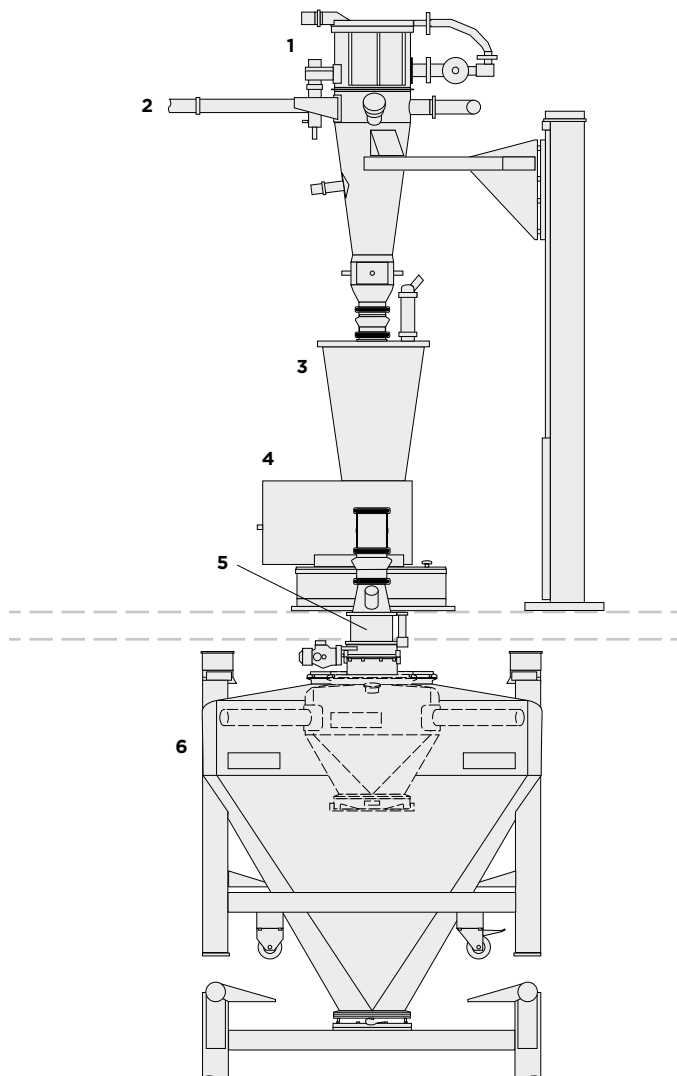


- 1 Bulk bag unloader
- 2 Inline sieve (optional)
- 3 WIP inlet
- 4 Vacuum conveyor
- 5 Blender
- 6 Vacuum blower
- 7 Secondary filter
- 8 Filter receiver
- 9 Bag dump station
- 10 Inline sifter
- 11 Inline V blender
- 12 Double cone blender
- 13 Vacuum receiver



➤ **BATCHING AND AUTOMATED DISPENSARIES**

Coperion K-Tron feeders and pneumatic receivers are used to automate accurate batching of both APIs as well as excipients direct to the batch blender or IBC. Materials are conveyed from the product sources, which can be IBCs, FIBCs, drums, bulk bags, or lined boxes directly to the feeders, which in turn accurately batch into the process below. Batch dispensing is available in both loss-in-weight batching using Coperion K-Tron gravimetric feeders (as shown in the diagram), or gain-in-weight batching via Coperion K-Tron volumetric feeders batching to hoppers on load cells below. By utilizing high accuracy batching, ingredient costs as well as inaccuracies due to human handling can be greatly reduced.

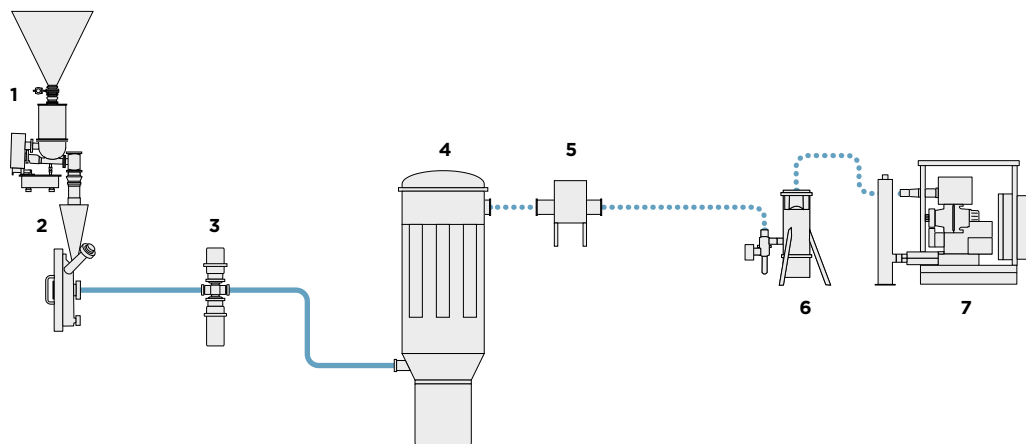


- 1 P-Series receiver
- 2 Flexible tubing
- 3 Hopper
- 4 Feeder
- 5 Split butterfly valve
- 6 IBC refill station

➤ **MICRONIZATION SYSTEMS - FEEDING OF MILLS**

Coperion K-Tron volumetric and gravimetric feeders are used to feed material directly to the size reduction mill or micronizer. Since particle size is also highly dependent upon consistent and accurate feed rate, Coperion K-Tron feeders are able to

deliver material consistently to the milling process below. For applications involving contained micronization within isolators, specialty designs are available for mounting to the isolator wall.

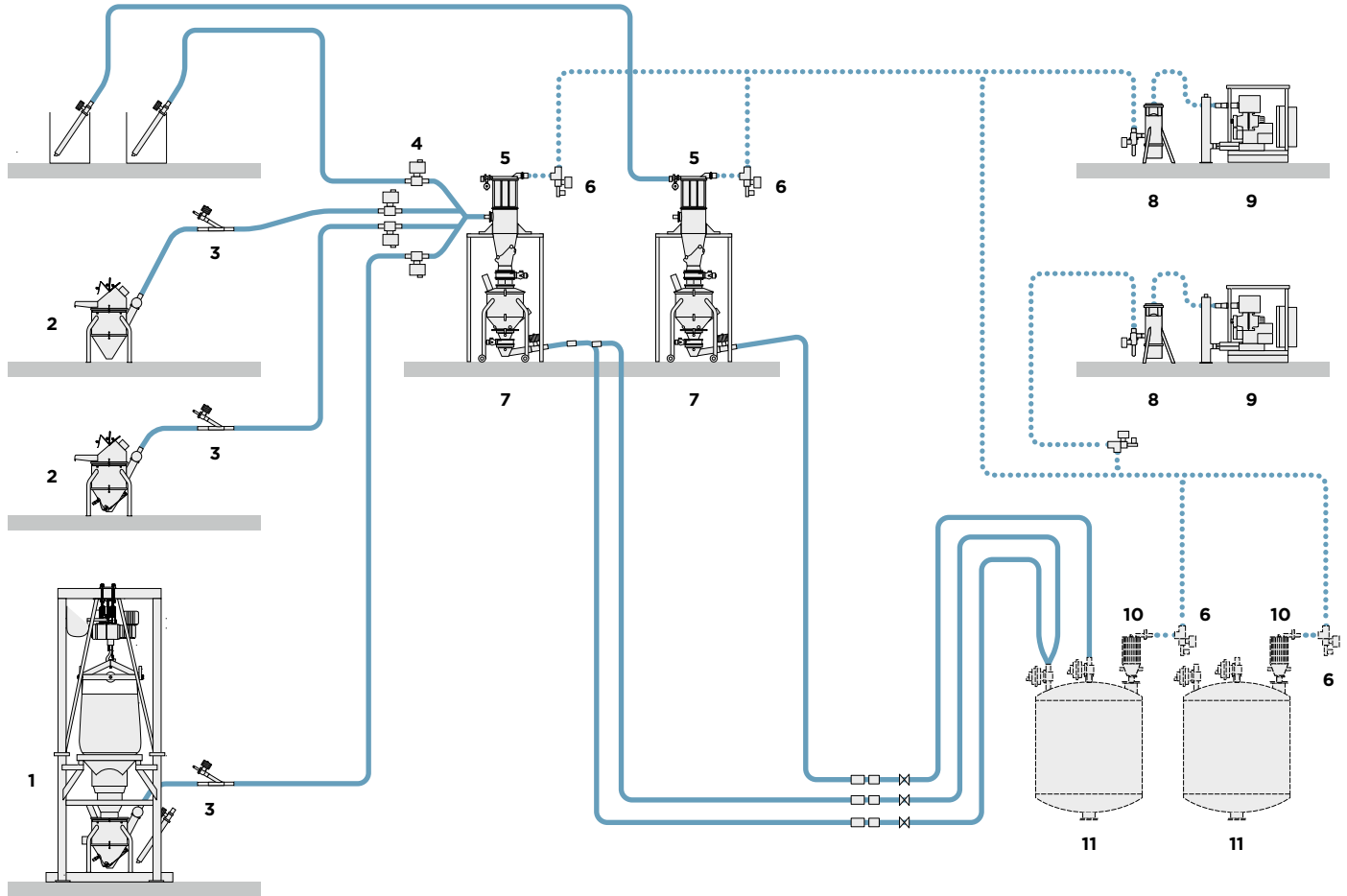


- 1 Feeder
- 2 Spiral jet mill
- 3 Particle size analyzer
- 4 Collector
- 5 HEPA filter
- 6 Secondary filter unit
- 7 Vacuum blower/pump

> LOADING OF REACTORS OR MIXING TANKS

Coperion K-Tron pneumatic receivers and/or volumetric feeders can be supplied for accurate gain-in-weight batching and loading of buffers and other powders to mix tanks or reactors.

Specialty systems for accurate and contained loading of powders via drums, bags, IBCs and bulk bags are available.

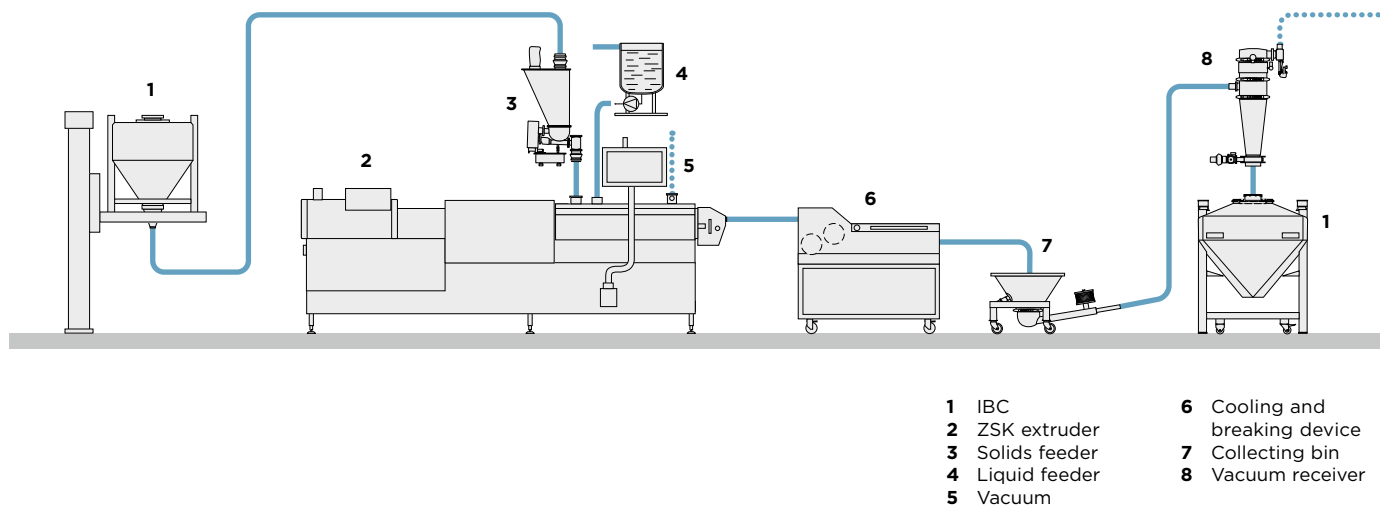


- | | |
|---------------------------|-------------------------|
| 1 Bulk bag unloader | 7 Mobile feed bin |
| 2 Bag dump station | 8 Secondary filter unit |
| 3 Line clear | 9 Vacuum blower/pump |
| 4 Line select ball valves | 10 Remote filter |
| 5 Batch weigh receiver | 11 Mixer |
| 6 Vacuum select valves | |

➤ **HOT MELT EXTRUSION (HME)**

Hot melt extrusion with Coperion's ZSK pharma extruders is a solvent-free process that yields solid molecular dispersions or solutions by a melt blending process, in which the API is dispersed and/or dissolved into a polymeric matrix. Gravimetric Coperion K-Tron feeders ensure highly accurate and continuous feeding to the ZSK extruder. Due to the intensive mixing and dispersion via the twin screws in the extruder's process section, the bioavailability of APIs with poor solubility or permeability is

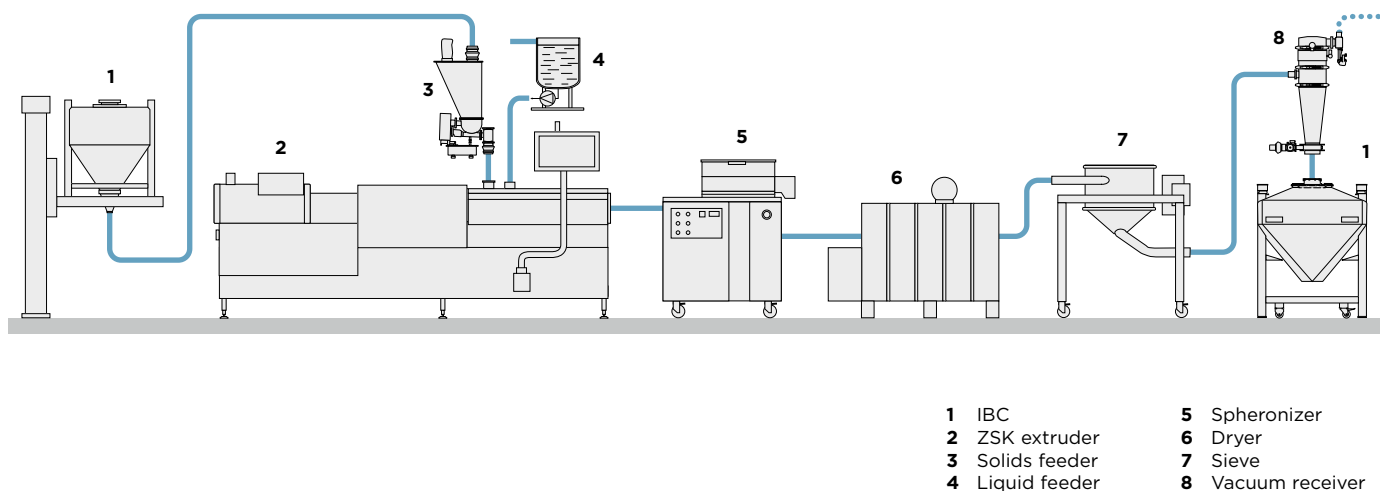
enhanced significantly. Water and/or air are removed by means of a vacuum port in the extruder which improves drug stability and allows production of tablets with superior mechanical properties. Directly after the extruder, the hot melt is cooled quickly to immobilize polymer and API and is then broken into small pieces. Coperion K-Tron P-Series vacuum conveyors allow contained transport of the cooled extrudates to storage containers or downstream milling and tableting.



➤ **WET EXTRUSION**

Wet extrusion/spheronization is a multiple-step process producing uniformly sized particles, e.g. spheres or pellets. These particles are typically filled into hard capsules but can also be used for tablet compression. Compared to other granulation methods, wet extrusion yields high drug-loaded pellets with reproducible characteristic such as good flow properties, low dusting, low friability and ease of coating.

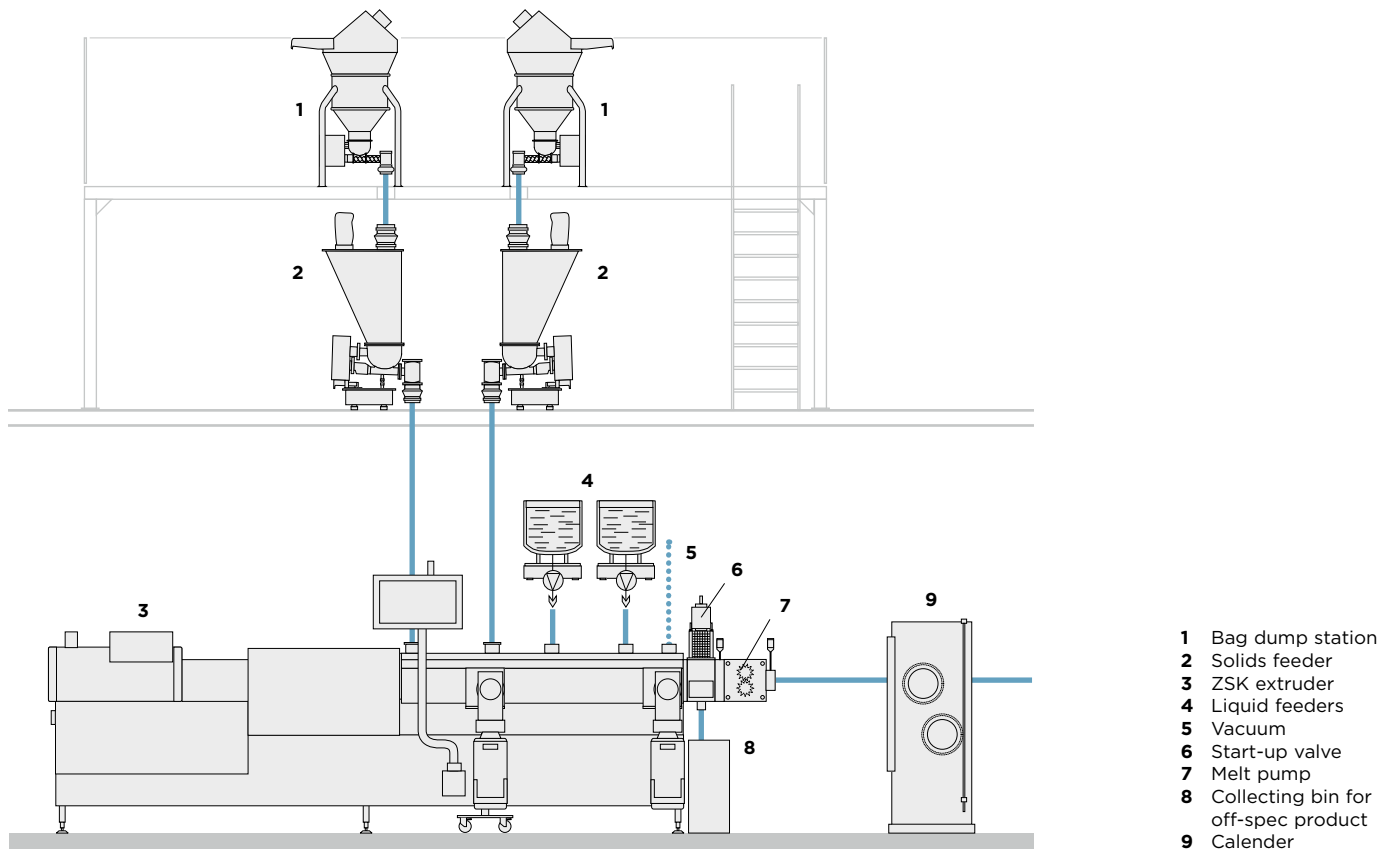
One or even more active ingredients, excipients and a granulation liquid are fed accurately by Coperion K-Tron gravimetric feeders. The twin screws in the process section of the ZSK extruder produce a homogeneous wet mass, which is extruded through a die plate, resulting in cylindrical pellets with uniform diameter which break at similar lengths under their own weight. The next step is spheronization in which the rod shaped pellets are rounded to spherical pellets.



› EXTRUSION OF PRESSURE SENSITIVE ADHESIVES FOR TRANSDERMAL PLASTERS

Continuous manufacturing using ZSK pharma twin screw extruders is an established production process for pressure sensitive adhesives. These adhesives are highly viscous, permanently tacky substances that are applied onto a substrate, e.g. a patch. They typically consist of rubbers for cohesion and elasticity, resins for tackiness and oils and waxes to adjust softness and viscosity. By adding APIs either in solid or liquid form during the process, a medicated adhesive is obtained which delivers the

API across the skin. The ZSK performs plasticizing, masticating, melting, mixing and devolatilization in one continuous process, which results in a highly efficient process compared to time-consuming batch processing. A diverter valve allows off-spec product to be discarded during start-up or shutdown or can be used for in-line quality control in combination with PAT, allowing only in-spec product to pass to downstream processes.



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