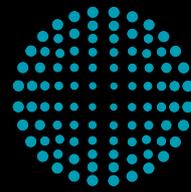
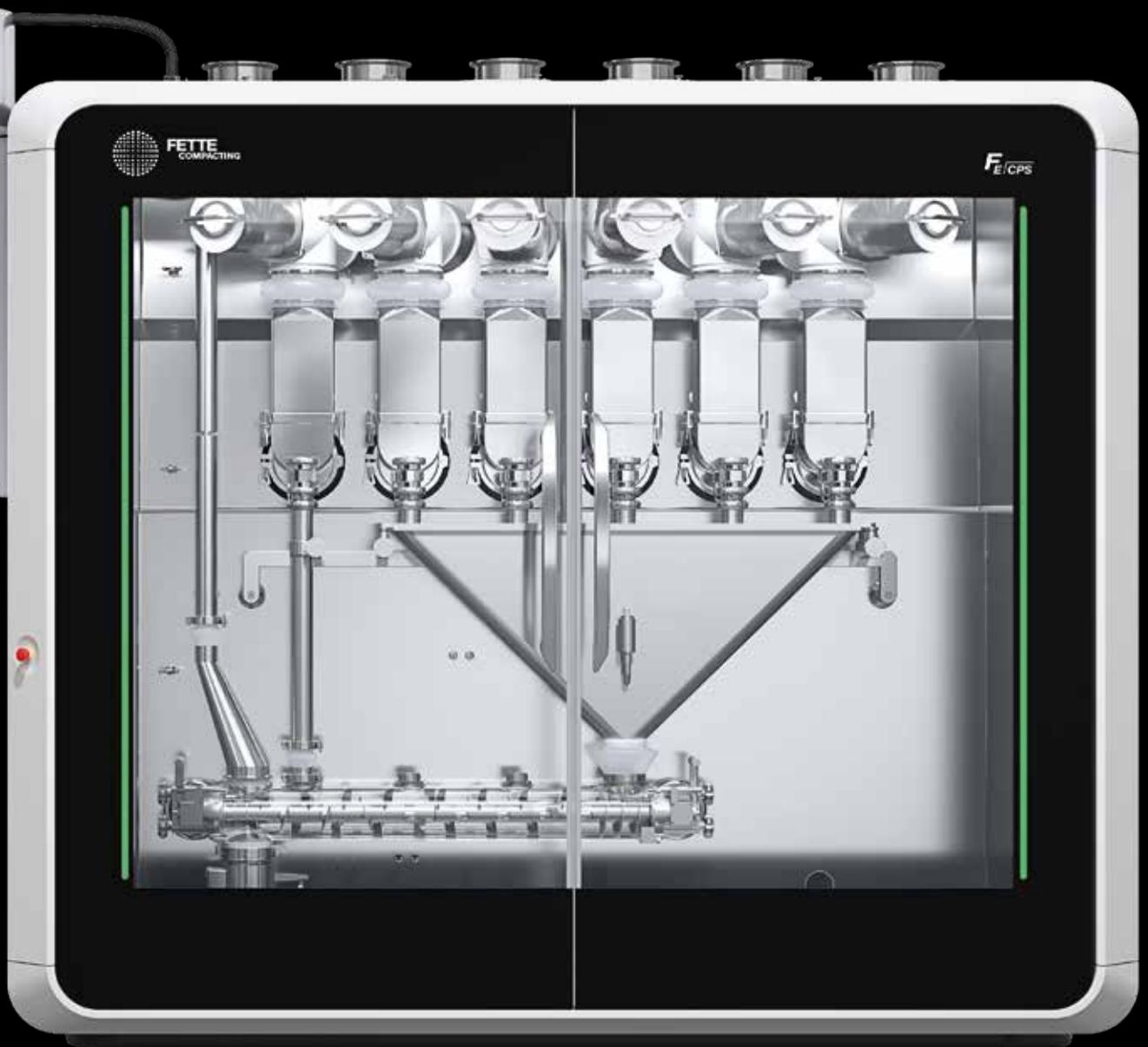


**CONTINUOUS  
MANUFACTURING**

reinvented



**FETTE  
COMPACTING**  
be efficient



**FE/CPS**



# CONTINUOUS MANUFACTURING

## Continuous Manufacturing reinvented

For more than a decade, Continuous Manufacturing has been trying to make its entrance in the industry of Oral Solid Dosage production. Acceptance and adoption of this new way of manufacturing tablets and capsules is progressing very slowly. This is due to several significant entrance hurdles, inherently related to the specific technical solutions offered so far by other OEMs and system integrators: highly customized and large installations requiring high investment cost for both equipment and infrastructure, high complexity requiring extensive scientific know-how and expensive skilled personnel, and last but not least lack of flexibility for multi-product manufacturing operations.

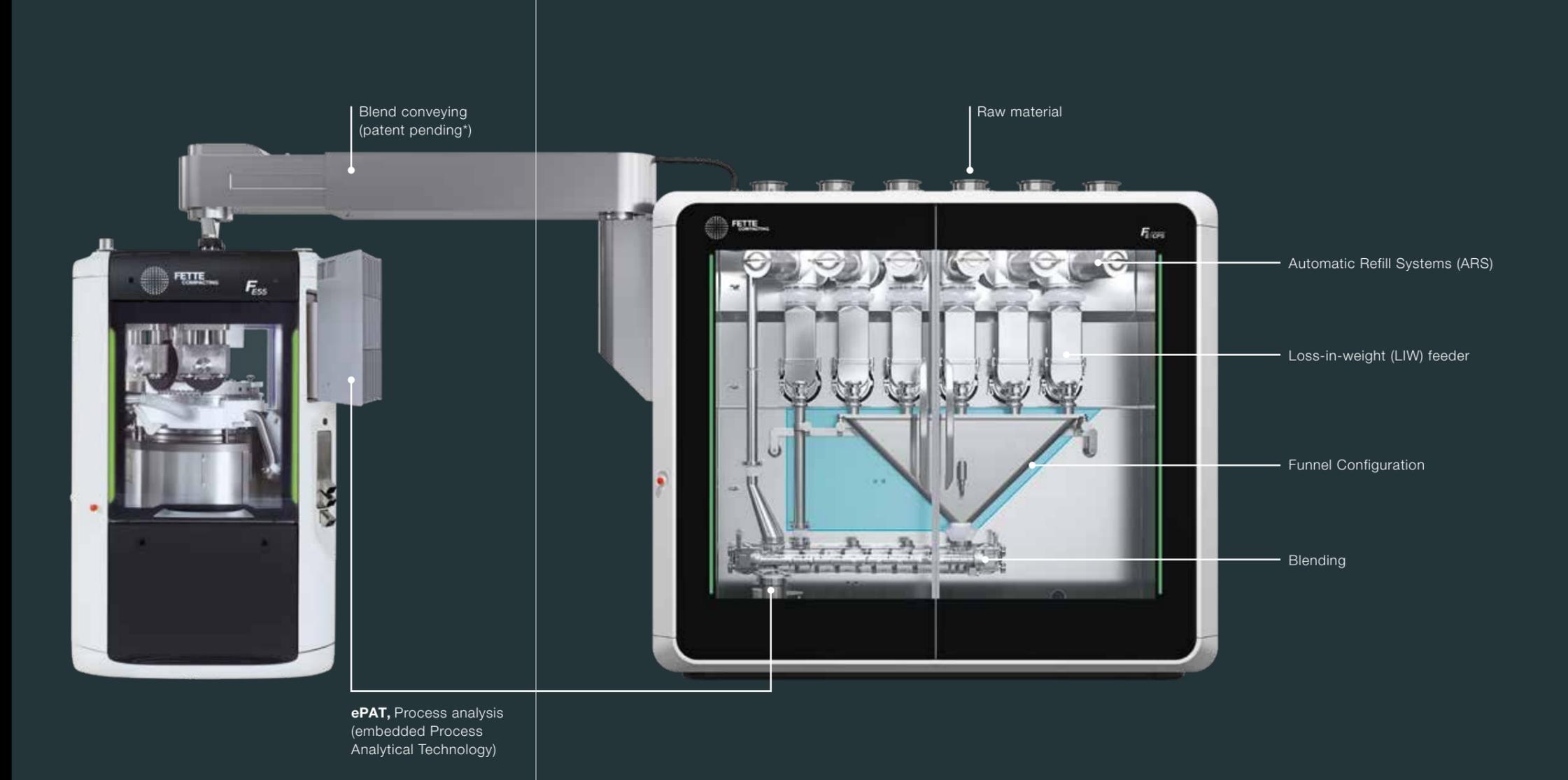
As the world's leading supplier of tablet compression technology, Fette Compacting is now offering a revolutionary new simple and compact solution for Continuous Direct Compression, which wipes away these hurdles, making Continuous Manufacturing accessible and economically justifiable for any size company in the pharmaceutical and nutraceutical industry.

Starting from a Quality-by-Design (QbD) approach, Fette Compacting has re-invented Continuous Manufacturing by re-thinking and re-designing every unit operation, as well as their integration into a compact standardized machine design. This has resulted in several revolutionary design improvements:

- linear arrangement of Loss-in-weight (LIW) feeders instead of typical circular set-up
- full separation between the process area and the technical area of the machine
- novel blender design featuring two in-line independent mixing zones and multiple inlet ports
- fully embedded Process Analytical Technology (ePAT), including Near-infrared spectroscopy (NIRS)
- compact design allowing one-floor arrangement

The FE CPS – Continuous Processing System – is the industry's new state-of-the-art solution for continuous dosing and blending of raw materials, including conveying and delivering the high-quality blend to any downstream powder processing equipment. When combined with a Fette Compacting tablet press, the result is a Continuous Direct Compression line with unique advantages in terms of investment requirements, product quality, production efficiency and operator safety.

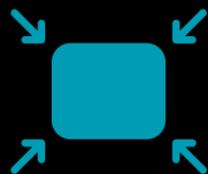
# Reinvented again in seven areas



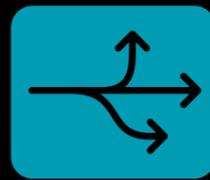
\* Patentnumber: CN114080270A;  
EP3989911A1; JP2022538269A;  
US2022258114A1; IN202117057139



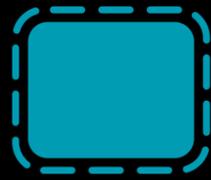
**Modular**  
Offering maximal flexibility – both in set-up (installation) and use (application)



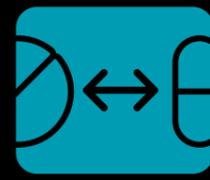
**Compact**  
Allowing one-floor set-up in existing production facilities



**Generic**  
Suitable for a wide range of formulations and operational throughputs



**Containment**  
Inherently closed double-barrier machine design, offering maximal operator safety



**Fast changeover**  
Full product changeover and cleaning in one shift



**Embedded PAT (ePAT)**  
Machine, process and quality control integrated in one single controller, including NIR spectroscopy for blend uniformity and 100 % tablet assay analysis



**TRI.EASY**  
Easy to set-up, operate and maintain, one terminal for all processes

# Modular, offering maximal flexibility in use and installation set-up



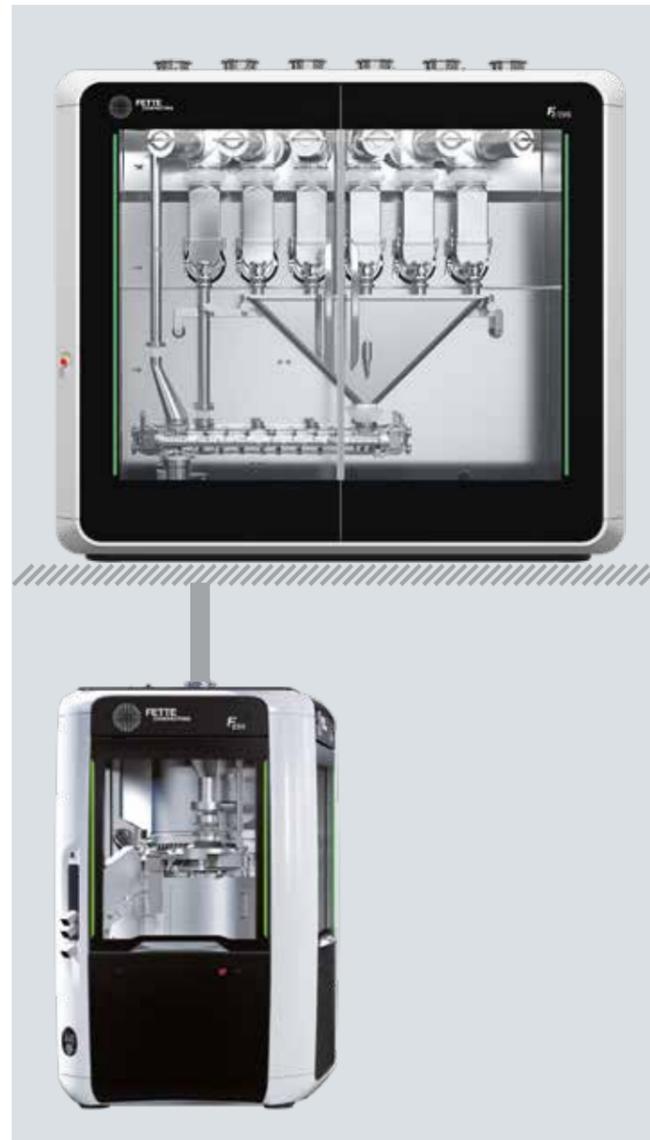
The modular design of the FECPS makes it extremely versatile – both in terms of its installation in a production facility, and its application in a wide range of manufacturing processes.

The FECPS continuous dosing and blending unit can be integrated with any type of downstream powder processing equipment, such as a tablet press, capsule filler or granulation equipment. It can also be used in a stand-alone mode, producing a high-quality dry powder blend, being fed into an Intermediate Bulk Container (IBC) or a sachet-filling machine.

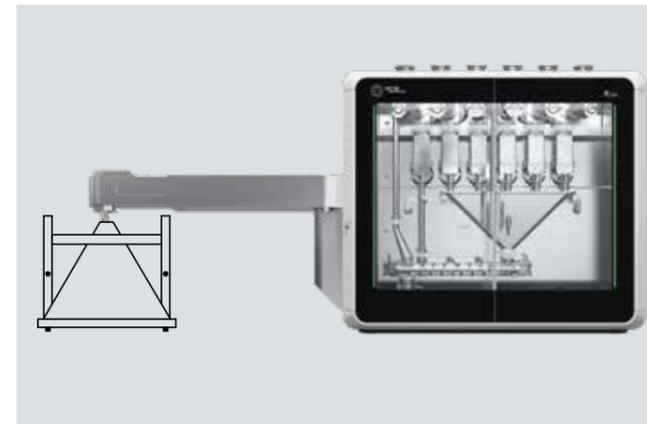
The FECPS can be installed on the same level as the downstream process equipment, resulting in a **horizontal** set-up of the line. In such a **single-floor set-up**, a purpose designed vacuum conveying device performs the blend transfer without any risk for segregation. The line can be installed in one single room (1-floor/1-room set-up) or in two adjacent rooms (1-floor/2-room set-up), offering maximal flexibility for installation in an existing tablet manufacturing facility.

Alternatively, the FECPS can be installed above the powder processing machine, resulting in a **vertical** set-up of the line. In such a **two-level set-up** the powder transfer is achieved solely by gravity.

The integration of the FECPS with a tablet press results in a Continuous Direct Compression line. The FE55 by Fette Compacting is the preferred tablet compression machine for this purpose because of its process versatility, having three consecutive compression stations, and its high output.



Modular – flexible in installation:  
vertical or horizontal set-up

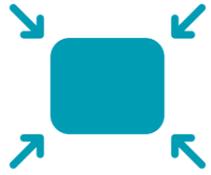


FECPS used in stand alone configuration and can be connected with any type of down stream equipment. IBC, capsule filling machine, granulator, sachet filler etc.



Horizontal set-up  
FECPS connected with tablet press:  
Continuous Direct Compression line (CDC)

# Compact, allowing one-floor set-up in existing facilities



The FECPS is an extremely compact unit that fits in a standard pharmaceutical production room.

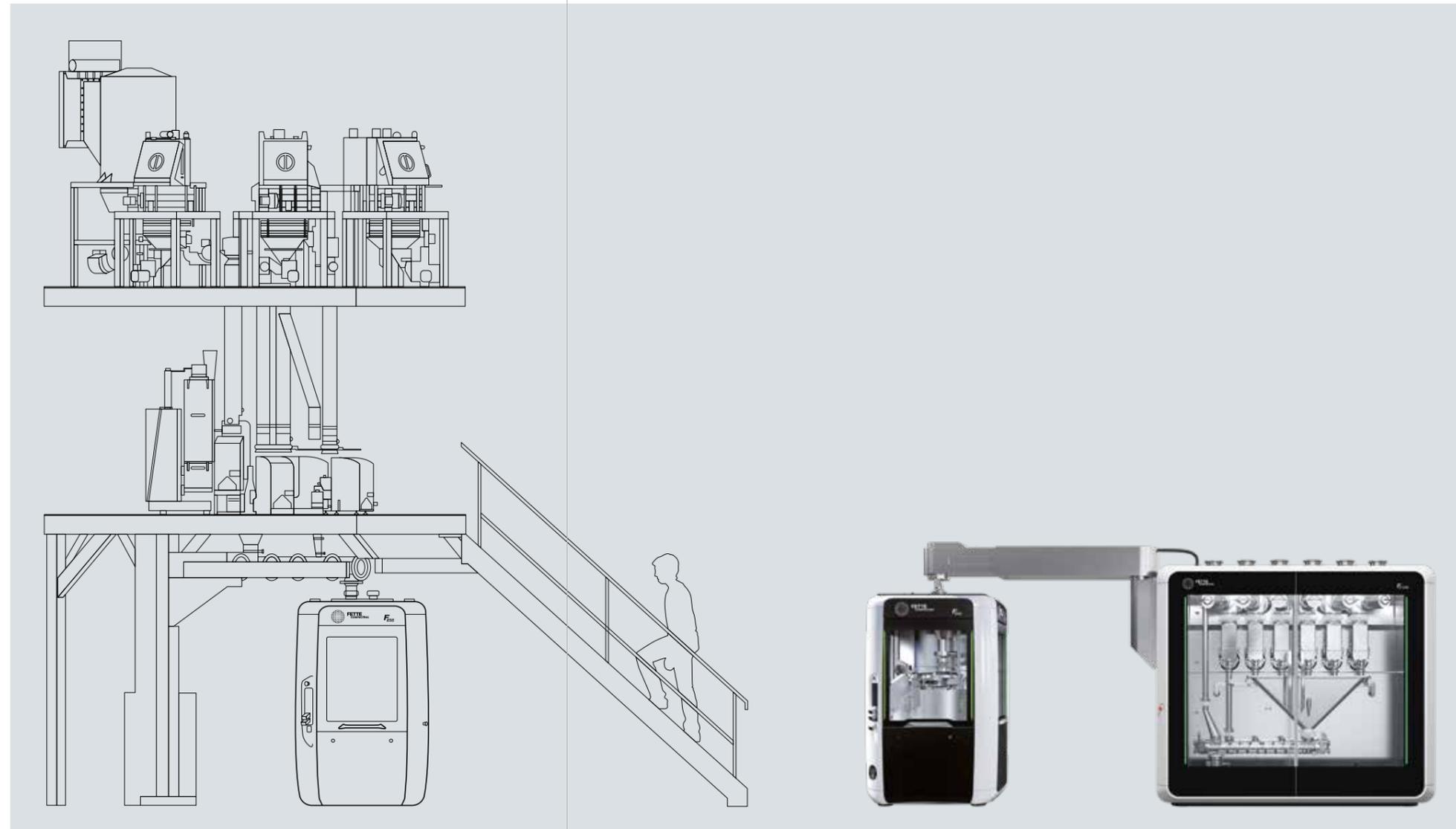
Its footprint is significantly smaller than any competitive system as no operator platforms and stairs are required to access the unit for routine operations and maintenance.

Furthermore, the height of the unit allows for the docking of various raw material charging devices within the height of a standard tablet compression room.

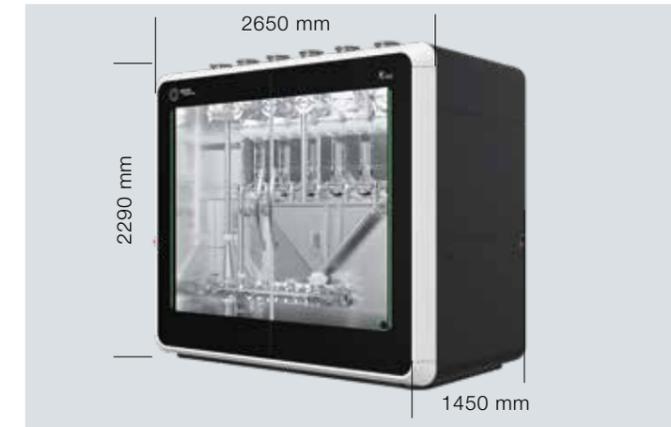
Even in horizontal connection with downstream equipment, the size is so compact that it also can fit into a standard room.

Thanks to its compact dimensions and its extreme flexibility of installation, the FECPS can be installed in most existing tablet production facilities. Additionally the installation of the machine is extremely easy and fast as the unit only needs to be placed in its room and utilities connected. Investment cost in facilities and installation are therefore reduced to an absolute minimum.

Alternatively, in case of greenfield projects, the compact and modular design allows to reduce the dimensions of the clean rooms significantly, leading to major savings in both Capex and Opex.

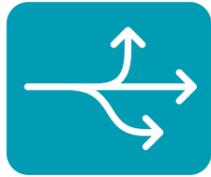


Conventional set-up vs. FECPS



→ Compact dimension

# Generic, maximal processing flexibility



From the early development phases of the FECPS onwards, a Quality-by-Design (QbD) approach was used which enabled Fette Compacting to design a flexible dosing-blending-conveying module that is robust towards handling a wide variety of ingredients and formulations at versatile throughputs (i.e. 5–200 kg/h).

A standardized, generic machine and process design for the FECPS was derived from the same philosophy as a tablet press. By exchanging a minimal amount of format parts and recipe parameters, the FECPS is rapidly tailored to optimally process any formulation:

- various sets of twin-screws for optimal LIW-feeding performance over all throughput ranges
- multiple funnel configurations to connect each ingredient infeed stream to its optimal blender inlet port
- possibility for combining both high-shear and low-shear mixing within a single blender

The generic design of the FECPS allows applications in both production and R&D-environments. A fast changeover to R&D-mode allows operation of the FECPS for gaining product and process understanding in the multiple stages of product formulation development:

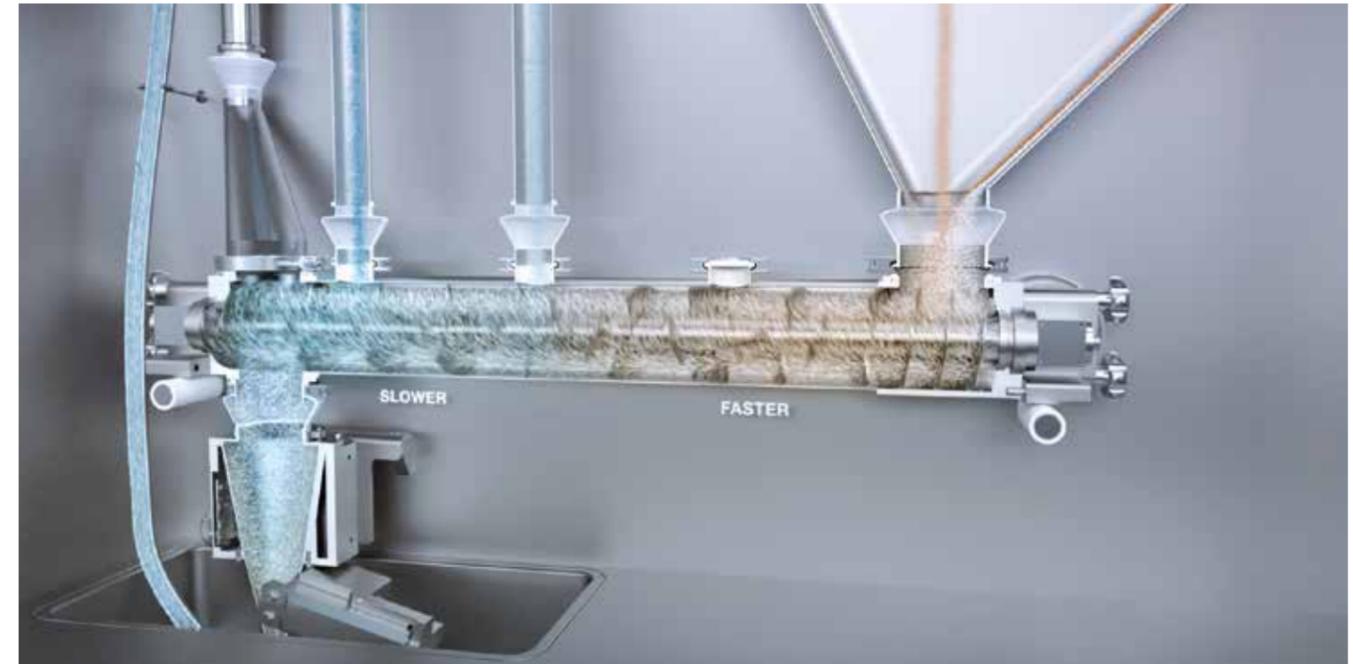
- scientific testing of individual unit-operations & formulations
- efficient execution of design-of-experiments (DOE) by embedded features and functionalities



Different formulation, uniform powder flow – through ultrasonic



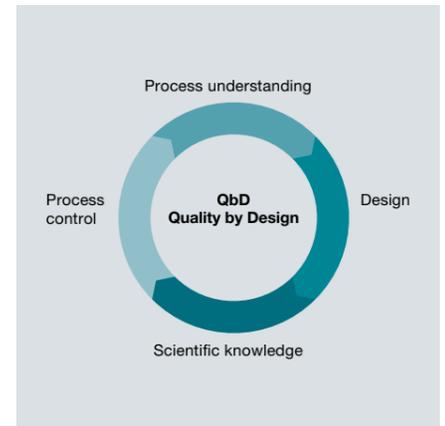
Multiple funnel configurations



Two-zone blender (patent pending\*): possibility to blend with high shear and low shear in defined zones



Various sets of twin screws



FECPS development: realized with a QbD approach

\* Patentnumber: CN114534547A; EP4005663A1; JP2022084552A; US2022161207A1; IN202114053971

# Containment Operator Safety



The FE CPS is characterized by a revolutionary novel machine design, offering unmatched advantages in terms of compactness, accessibility and process flexibility, but also in terms of product containment and operator safety.

In order to achieve this, a radically different approach was chosen whereby the Loss-in-weight (LIW) feeders are installed in a line as opposed to the conventional circular set-up. This linear set-up of the feeders allows them to be installed through a stainless steel wall, creating and separating a **process area** and a **technical area** within the machine.

The LIW feeders have a quick-release design whereby the product contact parts can easily and without tools be detached from the technical part, containing the loadcell, drives and controller. The product contact part is located in the process area, while the technical part is located in the technical area.

The same concept is applied to the other unit operations, such as the Automatic Refill Systems (ARS) and the continuous blender: all product contact parts are located in the process area and are easily removable from the unit. All support elements, drives, sensors and controls are located in the technical area, in the back of the machine.

The process area is located in the front of the machine and contains all product contact parts. It is isolated from the technical area of the machine by the separation wall and from the outside of the FE CPS machine by two large sealed doors. The process area is kept under a controlled negative pressure.

All unit operations (ARS, LIW feeder, blender) are dust-closed by design and have dust-tight interconnections using bellows. This is the first powder containment barrier. The isolated process area forms the second barrier. This inherently closed double-barrier machine design offers maximal operator safety during machine operation.

The technical area of the FE CPS contains all actuators, motors, sensors, valves, load cells, electrical and pneumatic components and generally all parts which cannot be exposed to the product. The technical area is easily accessible from the back of the machine and allows for technical inspection or maintenance work. This can even be done without opening the process area of the machine, allowing technical personnel to do troubleshooting without breaking the product containment.

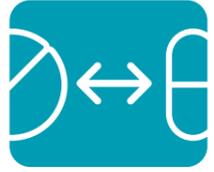


↑ Separation between process area (patent pending\*) and technical area

\* Patentnumber: CN114534615A; EP4005764A1; JP2022084551A; US2022161211A1; IN202114051127

← Isolated process area: containing all product contact parts

# Fast changeover, full product changeover and cleaning in one shift



The specific FECPS design makes product changeover and cleaning of the unit extremely easy and fast:

- The product contact parts of all unit operations are designed to be lightweight and quickly detached from their support in the process area.
- The total number of removable elements is limited and can easily be transferred to a washing room for further disassembly and off-line washing.
- The remaining empty process area is widely accessible, compact and has smooth walls, making cleaning extremely easy.

The components to be removed from the process area are:

- Automatic Refill Systems (ARS)
- Quick-release part of the LIW feeders
- Funnel configuration
- Blender
- Blend conveyor inlet hopper

Each of the components can be dismantled without tools and is designed such that one person can remove and install the parts in an ergonomic way.

The specific machine design and cleaning concept allows a full cleaning and product changeover of the FECPS by one person in one shift, the parts can be removed in less than 10 minutes. All removable components can be duplicated as a fast changeover set. When using such FCO set, the off-line component cleaning can be done while the FECPS is operational again, reducing the changeover time further still.

As the FECPS is the only system on the market for continuous dosing and blending with a truly fast and easy product changeover capability, its integration in a production line finally makes efficient multi-product continuous manufacturing of OSDs possible.



↑ All product contact parts are easily removable from process area



← Front doors rotating 270 degrees – offering maximum accessibility and minimal footprint

# Embedded Process Analytical Technology, ePAT



Whether the FECPS is operated in stand-alone mode or as part of a Continuous Direct Compression line, one single control system performs all machine, process and quality control functions. The control system architecture consists of one high-speed embedded controller and an industrial PC for HMI, including central recipe management and reporting. This simple hardware architecture, combined with 100% proprietary software from Fette Compacting, significantly reduces the system's validation requirements and results in a robust, reliable control system.

Process Analytical Technology is fully embedded in the control system:

## NIR spectroscopy

- In-line product quality monitoring using embedded spectroscopic sensors, i.e. sensor spectrometers are directly connected to the machine's embedded controller
- NIR blend uniformity measurement (BU) using an active measurement head, available at various positions: blender outlet, tablet press infeed or inside the feed frame (Fill-O-Matic, FOM)
- NIR tablet uniformity measurement (TU) during tablet ejection on the die table enables 100% inspection of all tablets, including the rejection of individual tablets that do not meet the specifications
- MVA/chemometrics classification/quantification prediction engine running on the embedded controller; full access to all supported models of this engine via the offline model builder
- PAT method management is integrated in the central product recipe management
- Complete system, including PAT method management, is cGMP compliant
- Robust industrial execution
- MES OPC interface for partial PAT method management and retrieval of prediction values

## BU-NIRS sensor

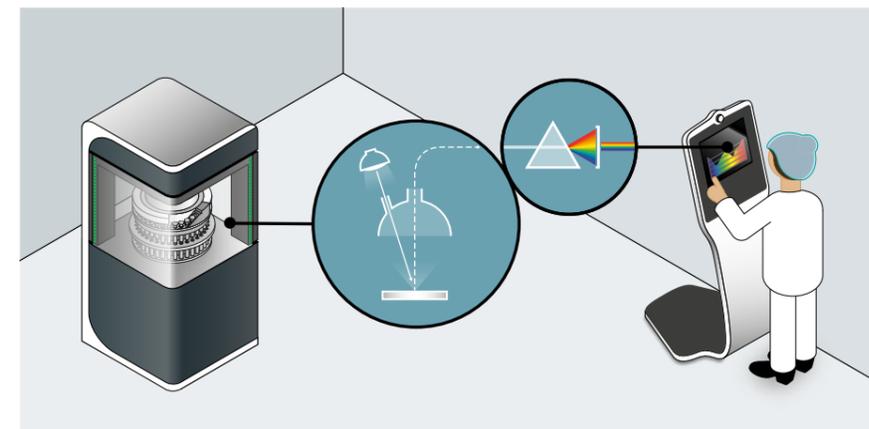
- Measures blend uniformity
- Fast, performs up to 10 independent measurements per second
- Flexible, can be installed in various positions
- Internal white reference
- Active measurement head: less light fibers
- Redundant light bulbs
- Robust
- Easy to handle and install

## TU-NIRS sensor

- Unique development for Fette Compacting
- The only sensor measuring 100% of the tablets on the ejection
- Super-fast, measures up to 120 tablet per second
- Super-fast single rejection of the out of spec tablets based on the NIR measurement
- Internal white reference
- In-line cleaning concept
- Robust
- Easy to handle and install



The NIR technology helps reduce batch-release time and costs.



↑ ePAT sensors available in multiple measurement positions

NIR spectroscopic sensor for blend uniformity and content uniformity measurement

# TRI.EASY, easy set-up, operation and maintenance



The new user interface offers a quick overview of the parameters of the entire continuous process.

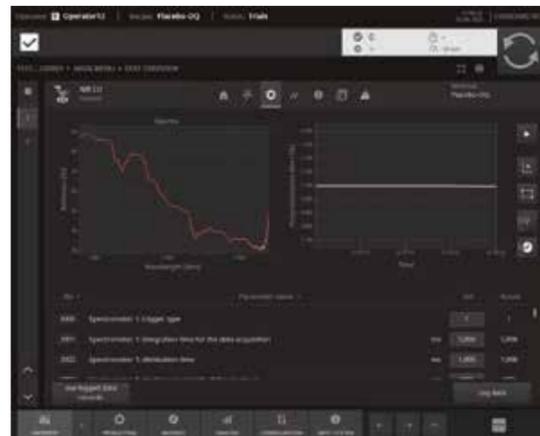
One important hurdle for the industry-wide adoption of Continuous Manufacturing is the high complexity of the technical solutions offered by equipment suppliers. This leads to time-consuming validation processes and the need for highly skilled and specialized personnel.

Fette Compacting set itself the goal to develop a simple standardized solution, which can be easily set-up, operated and maintained by experienced personnel, available in any tablet manufacturing operation.

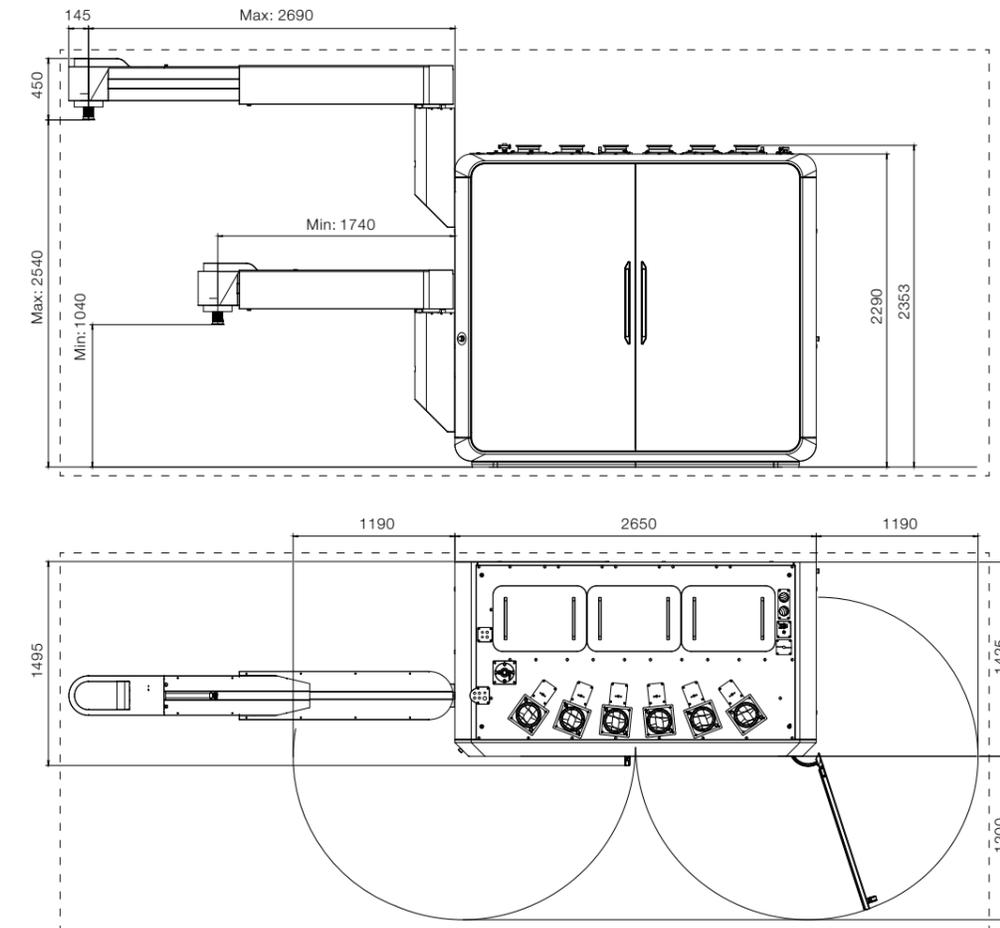
Process engineers can set up the FE CPS using a very similar approach as for a tablet press: by selecting only a few format parts and optimizing unit operation parameters, the FE CPS covers a wide range of different formulations and throughputs.

Tablet press operators can start-up, run, stop, disassemble, clean and changeover the FE CPS also in a fashion very similar to that used for a tablet press, while technical personnel can easily perform the necessary calibration and maintenance tasks by accessing the FE CPS from the technical area in the back of the machine.

The FE CPS represents the full embodiment of TRI.EASY: optimal set-up, operation and maintenance.



## Technical Data



<b>Throughput capacity</b>	5 ~ 200 kg/h (formulation and tablet dependent)
<b>Number of dosing stations</b>	2 to 6
<b>Number of blender mixing zones</b>	2
<b>Feeder-blender funnel configuration</b>	Various configurations – formulation dependent
<b>Ingredient characteristics</b>	Powder density: 0.2 ~ 0.8 kg/l *
<b>Ingredient inlets</b>	DN150 tri-clamp connection
<b>Main connection ratings</b>	Operating voltage 400–480 V, frequency 50/60 Hz ±5%
<b>Voltage supply</b>	3-phase + PE
<b>Power</b>	6 kW
<b>Compressed air supply</b>	6 bar / 300 l/min peak volume flow
<b>Air extraction rate</b>	200 m³/h
<b>Air extraction negative pressure</b>	–0.2 hPa
<b>Air extraction unit connection</b>	70 mm
<b>Dimension</b>	Machine height: 2,300 mm, Ingredient inlet: 2,355 mm Total height including blend conveyor arm: 3,000 mm
<b>Weight</b>	approx. 5,000–5,500 kg **

In the interest of further development, subject to technical alterations.

\* Assumption of typical values, others on request

\*\* Depending on exact configuration

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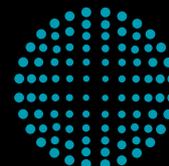
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