



SYNTEGON
PROCESSING & PACKAGING

R&D Equipment.

Mixing. Drying. Granulating. Coating.
Capsule filling. Tablet compression.

5.800

employees

66.000

machines in the installed base

**Count
on it.**

30

locations

160

years of experience

1.4 billion

euros annual sales

1.100

service specialists

1.800

patented inventions

Syntegon Technology is your reliable partner for process and packaging technology in the global pharmaceutical and food industries. Whether you are an aspiring start-up or a global market leader, we offer intelligent and sustainable solutions for everyone.

Individual machines, systems or services – as a full-service provider, we take responsibility right up to fully integrated end-to-end solutions. Fields of application in the pharmaceutical industry are the production, processing, filling, inspection and packaging of liquid and solid active ingredients in all common

packaging materials. In the food industry, we offer solutions for the primary and secondary packaging of dry, liquid and frozen food as well as process technology for the production of confectionery.

We are at your side from project planning, development and implementation to comprehensive digitization, qualification and validation services. In addition, you always have access to our worldwide network of service specialists who support you throughout the entire machine life cycle.

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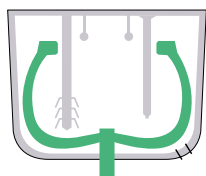
Laboratory scale High-shear mixer granulator system

Mixing. Granulating. Drying.

When it comes to homogeneous mixing results, granules of the highest quality and top production performance with short drying times, Hüttlin offers the right solution. With the Gentlewing bottom or top drive options, mixing and granulating enter new dimensions.

Maintaining a leading position in process engineering means enhancing the efficiency and economy of processes. Hüttlin makes use of the same technology, process management and geometrical details for both laboratory as well as production scale and therefore provides the best prerequisites for a successful scale-up.

Gentlewing high-shear granulation technology



Bottom drive

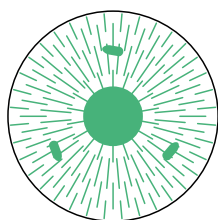


Top drive

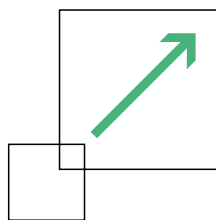


Z-shape impeller

Diskjet fluid bed technology



Diskjet



NexStep-software

Exceeding expectations with innovative solutions

The Hüttlin high-shear mixer granulator with top or bottom drive is the best choice for typical granulation applications in combination with a fluid bed dryer. The features UltraClean, SmartFlow, heating and vacuum unit with solvent recovery allow you to extend up to a Single Pot unit or a high-containment unit.

Gentlewing

- ❑ Maximum mixing quality with minimum mechanical stress on the product
- ❑ No wall caking due to very close clearances between the product vessel and Gentlewing
- ❑ Excellent discharge due to the Z-design of the Gentlewing impeller
- ❑ Effective drying without tilting or microwave technology (Single Pot)

Discharging

- ❑ Discharge speed is controlled by the speed of the Gentlewing and not the valve
- ❑ Wet mill is integrated in the control loop
- ❑ Blockage of the wet mill is prevented

Mycromix

Batch sizes ranging from 0.1 – 3.5 kg*



- 1 Mycromix
- 2 Container exchange mechanism
- 3 Exchangeable Mycromix containers

The smallest high-shear mixer granulator with bottom drive and CAx control system. The ideal solution for all laboratories in combination with the Solidlab 1 or Solidlab 2 Plus.

- ❑ Bottom drive
- ❑ Exchangeable container
- ❑ Gentlewing with torque measurement
- ❑ Chopper
- ❑ Optionally for organic processes
- ❑ Optionally with double jacket and heating / cooling unit
- ❑ Optionally with conventional three-blade impeller as mixing tool

Mycromix	
Container volume (l.)	0.5/1.0/2.5/5.0/10.0
Length (mm)	625
Width (mm)	640
Height (mm)	700
Electronic connection (kW) Ptot @ 50Hz	2.5
Weight (kg)**	100

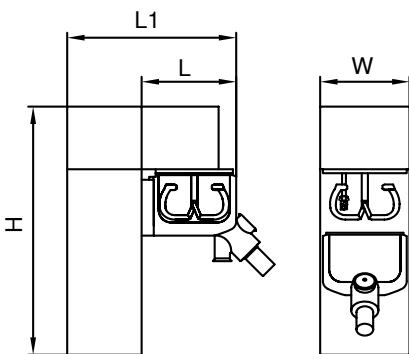
* at a product density of 0.5 kg/l
 ** depending on the selected options

Pilotmix

Batch sizes ranging from 3.5 – 60 kg*



Pilotmix T



Whether it is a small production unit or a step between laboratory and production, our product line offers all advantages and features that are also only available in production scale. This also applies to the new UltraClean cleaning-concept and the option of modular extension up to the Single Pot execution. Another ideal feature is the line solution with the Pilotlab as a dryer.

Pilotmix	25	75	150
	T	T	T
Nominal size	25	75	150
Total volume (litres)	25	75	150
Electronic connection (kW) P _{tot} @ 50 Hz	15	18.5	30
Length L1 (mm)	985	1,475	1,890
Length L (up to wall; mm)	480	715	1,000
Width W (mm)	1,550	1,200	1,450
Height H1 (mm)**	–	–	–
Height H (mm)**	1,900	2,950	3,100

* at a product density of 0.5 kg/l

** depending on the selected options



1

1 Fluid bed systems
– drying, granulating, coating

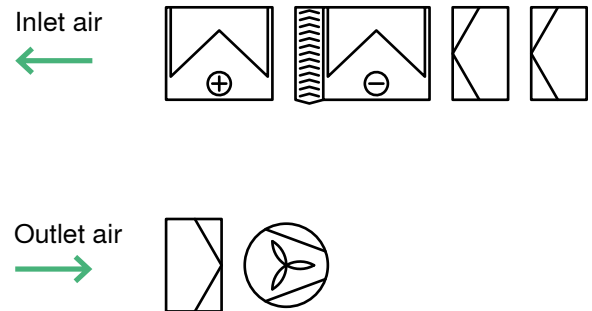
Customize your lab – fluid bed and drum coater

With the modular Solidlab technology you are able to run up to eight solid processes – just as you like.

Technological leaders create innovative solutions

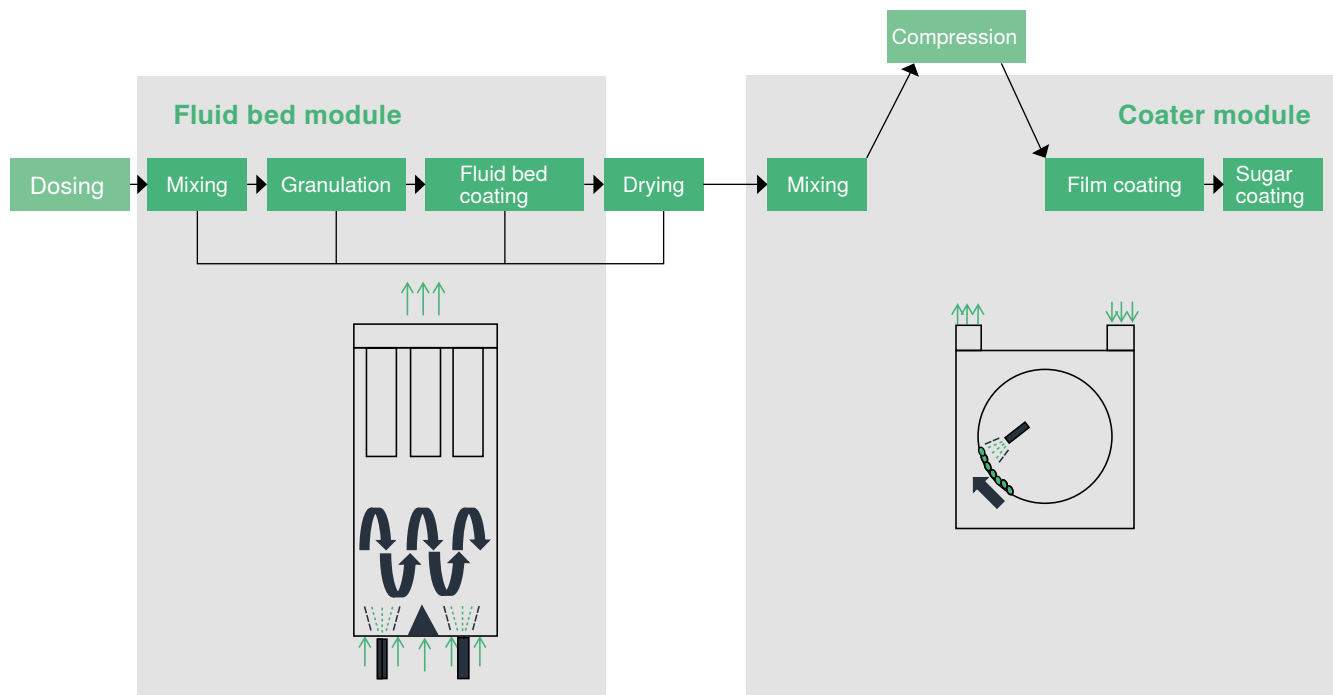
The higher your requirements for drying, granulation and coating/layering are, the more you benefit from the Hüttlin fluid bed technology. The spraying system with the three-component nozzle generates homogeneous granules and excellent coating. The unique process gas distributor plate Diskjet prevents adhesion of the product and offers the best conditions for reliable and reproducible processes.

Air handling



2

2 Drum coater



Fluid bed benefits

Diskjet

- ❑ Optimized airflow angle and acceleration of the process air improving the ideal exchange of substance and energy, reducing strain on the filter system
- ❑ Best product mixing results due to homogeneous fluidization and toroidal product flow
- ❑ Process times can be significantly reduced

Filter system

- ❑ Sequential filter cleaning during the process
- ❑ No disturbance on fluidization
- ❑ No interruption of the process
- ❑ High yield
- ❑ Different filter materials can be selected to suit the respective processes

NexStep scale-up software

- ❑ Process development and optimization in R&D applied directly to production scale via this software
- ❑ Scale-up without intermediate steps

Three-component nozzle

- ❑ Extremely low spraying losses due to innovative positioning of the spray nozzles
- ❑ Microclimate preventing bearding and allowing longer process times without interruption
- ❑ Homogeneous granules are produced without the need of a dry mill
- ❑ Low mechanical stress and excellent coating results for pellets/fine particles
- ❑ Very short process times

Drum coater benefits

Anti-bearding cap spray gun

- ❑ Anti-bearding systems with superior spray pattern
- ❑ Enhanced droplet generation
- ❑ Tool-free, GMP compliant design
- ❑ Low profile shape with integral connections for reduced airflow turbulence
- ❑ Retro-fit capability to upgrade existing coating equipment

Flexible batch sizes

The drum coater has the ability to change drum sizes / diameters, which makes it ideal for use in the development of products with small production batches and the confidence of scale-up to larger production size coaters.

Open surface

The fully perforated side-vented coater drum and cabinet design allows highly effective drying capacity during the process.

Solidlab 1

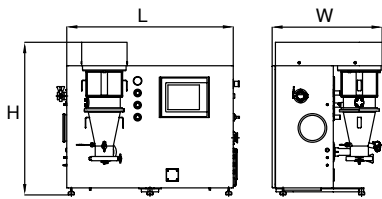
Batch sizes ranging from 0.05 – 1 kg*

The advantages of your Solidlab 1 at a glance:

- ❑ Up to seven functions in one device
- ❑ Modular system, compact design
- ❑ Common control software PROVICON
- ❑ Shared air treatment and sensor technology
- ❑ Open recipe creation and management
- ❑ Reproducible and controllable results
- ❑ High planning flexibility, many available options

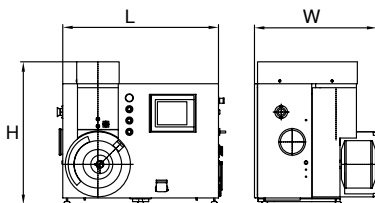
Solidlab 1

fluid bed module



Solidlab 1

drum coater module



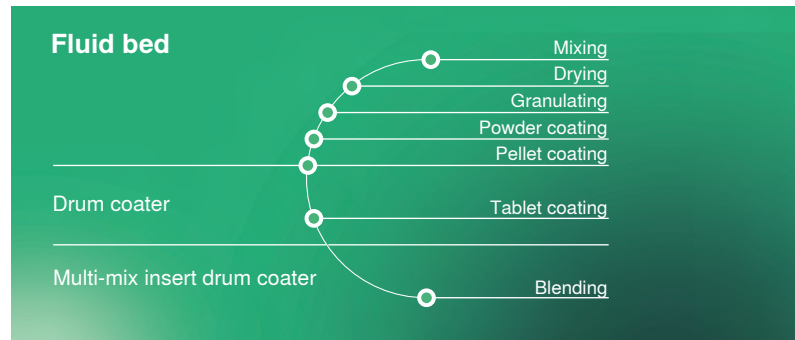
Testing feasibility

The Solidlab 1 laboratory unit processes batch sizes from 0.05 up to 1 kg and is the equivalent for the highest performance in the smallest space. The device supports you in developing your products and in examining your recipes. All important parameters and results are recorded by the software, and changes are documented. This makes the Solidlab 1 the ideal solution for your feasibility studies.

Fast conversion

The fluid bed or the coating module can be easily assembled at the base unit. Both are operated via a common, integrated air treatment and control system. A conversion to either module is possible in only a few steps.

Solidlab 1



Solidlab 1	Fluid bed	Fluid bed	Drum coater	Drum coater	Drum coater
Options		Optional product container		Optional drum	Optional multi-mix insert
Working volume max. (l.)	2	0.5	1.5	0.8	1.5
Working volume min. (l.)	0.4	0.1	0.5	0.25	
Working capacity max. (kg)	1 [*]	0.25 [*]	1.2 ^{**}	0.65 ^{**}	
Working capacity min. (kg)	0.2 [*]	0.05 [*]	0.4 ^{**}	0.2 ^{**}	
Air flow (m ³ /h)	70	70	70	70	–
Max. inlet air temperature °C	80	80	80	80	–
Dimensions L x W x H (mm)	1,100 x 730 x 1,010	1,100 x 730 x 1,010	1,100 x 770 x 1,010	1,100 x 770 x 1,010	1,100 x 770 x 1,010
Weight (kg)	205	205	240	240	240

*at a product density of 0.5 kg/l / **at a product density of 0.8 kg/l

Exchange of fluid bed module in just a few steps



Exchange of fluid bed module



Solidlab 2 Plus

Batch sizes ranging from 0.25 – 12 kg*



Best process results due to high-performance spray system

Solidlab 2 Plus	Fluid bed		Drum coater				
	Options	Standard					
Working volume max. (l.)	3* (S)	24* (L)	Available drums	2	4	8	16
Working capacity max.(kg)	1.5*	12*	Available drums	1.6**	3.2**	6.4**	12.8**
Working capacity min. (kg) depending on process & product	0.25*	1.5*	Available drums	0.8**	1.6**	3.2**	6.4**
Air flow max. (m³/h)		450	450				
Max. inlet air temperature [°C]		80	80				
Dimensions L x W x H (mm)	1,290 x 1,270 x 1,980		1,130 x 952 x 1,982				
Swiveled out			1,862 x 1,946 x 1,982				
Weight (kg)	600		800				

*at a product density of 0.5 kg/l / **at a product density of 0.8 kg/l

The advantages of your Solidlab 2 Plus at a glance:

- ❑ Up to eight functions in one device
- ❑ Modular layout, compact design
- ❑ Common control software PROVICON
- ❑ Common air treatment and sensor technology
- ❑ Open recipe creation and management
- ❑ Reproducible and controllable results
- ❑ High planning flexibility, many available options

Easy scale-up

The Solidlab 2 Plus laboratory machine handles batch sizes from 0.25 up to 12 kg. Fluid bed and drum coater use a common air handling unit. Since they are constructed like full scale production machines, they are enabled to execute an easy scale-up of all production parameters.

Consistent control and shared air handling

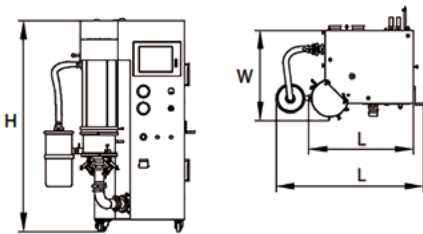
Both fluid bed and coater are operated by a uniform common software. This significantly reduces the need for operative personnel and training. The shared air handling system is located in the technical room, which not only contains the air handling unit but also the control cabinet enabling a space saving layout.



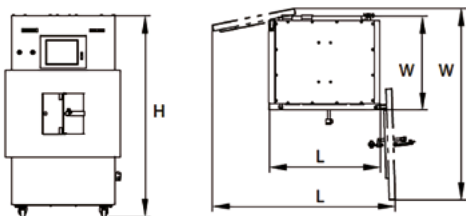
Here is what makes the Solidlab 2 Plus unique:

- ❑ The only fluid bed solution available on the market for the development of both batch and continuous manufacturing processes
- ❑ The only solution available on the market that covers all process steps in one and the same product container: granulation, drying, pellet coating
- ❑ Fully automatic Design of Experiments (DoE)
- ❑ Fast scale-up from lab to batch-production volume without intermediate steps
- ❑ Combined with the feeder-blender-unit the Solidlab 2 Plus becomes the Xelum R&D for continuous manufacturing – no scale-up required
- ❑ Containment and automated cleaning for operator safety

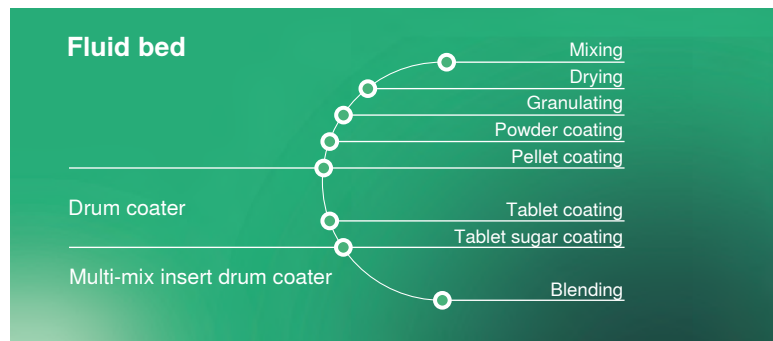
Fluid bed



Drum coater



Solidlab 2 Plus



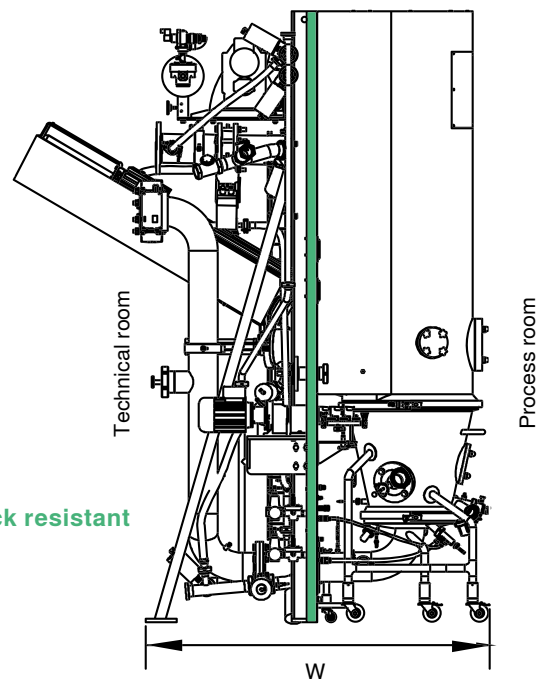
Pilotlab

Batch sizes ranging from 4 – 50 kg*



Pilotlab

The Pilotlab can be used as a small-size production unit or as an intermediate step from laboratory towards production. The reduction insert assures highest flexibility to the Pilotlab, with batch sizes ranging from 4 up to 50 kg. Another ideal feature is the inline solution with the Pilotmix high-shear mixer/granulator.



Pressure shock resistant

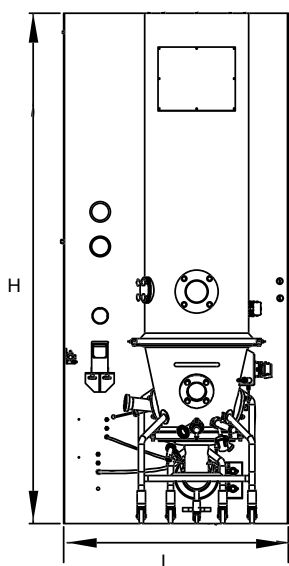
*at a product density of 0.5 kg/l



Dynamic filter lowered



Mobile container



Pilotlab	S	L
Usable container volume (liters)	24	95
Air flow (m3/h)	500	1,000
Number of spray nozzles	2	3
Electrical connection (kW)	30	30
Dimensions L x W x H (mm)	1,300 x 1,660 x 2,950	1,300 x 1,660 x 2,950
Weight of Pilotlab (kg)	1,500	1,500
Weight of air handling (kg)	550	550
Weight of fan (kg)	500	500
Weight of control cabinet (kg)	650	650

Capsule filling GKF 60

The new interface between formulation development and clinical trial material manufacturing:

The R&D capsule filler GKF 60 offers high versatility, state-of-the-art quality control features, new dosing technologies and a unique operator protection concept.

Basic features:

- Small foot-print:**
 (approx. W 1.0m x D 0.9m x H 1.9m)
 Fully automatic capsule handling,
 up to 60 capsules / minute



GKF 60



GKF 60

- Flexibility:** Three individual dosages possible (fixed dose combinations)
- PAT Technology:** Gravimetric 100 % net weighing of each dosed component
- Cabin options:** OEB4 containment with open aperture and air exhaust (no gloves, air exhaust unit with H14 filter installed separately) OEB5 with gloves and controlled/monitored vacuum
- Cleaning:** wetting (OEB4) or WIP (OEB5), focus on avoidance of cross-contamination

Possibilities to dose solids and liquids

Dosing Technologies		Typical performance	
		Filling weight (mg)*	Approx. working volume (ml)*
Dose-to-weight ("Piezo")	Vibration feeder with newly developed agitation technology	0.1 - 25	0 - 40
Tamping pin	Mini bowl - For compaction of powders	25 - 1,000	150 - 280
Dosator	For powders (compaction) or pellets (vacuum)	10 - 1,000	150 - 250
Dosing wheel (vacuum)	Adjustable volume and vacuum strenght	< 1 - 50	50 - 100
Tablets/Mini-tablets	Freely adjustable dosing counts	50 - 900	100 - 200
Mini-tablets	Counting or weighing (net)	50 - 900	50 - 100
Pellet chamber	Freely adjustable dosing volumne	20 - 800	20 - 100
Piston pump	For liquid fillings of various viscosities	20 - 1,200	20 - 100

*Output depends on product properties

Capsule filling

GKF 720



The advantages of your GKF capsule filler at a glance:

- Proven machine technology
- Versatile filling options
- Flexible use for different products, also in combination
- Intuitive operation via HMI
- Containment concepts (OEB 3-5)
- Fast and easy modification
- Good accessibility from all sides
- Fast, easy but thorough cleaning
- Various PAT technologies for quality control (QC) available
- High yield / high OEE
- Special feature: APD technology (automated process development) based on Design of Experiments (DoE)

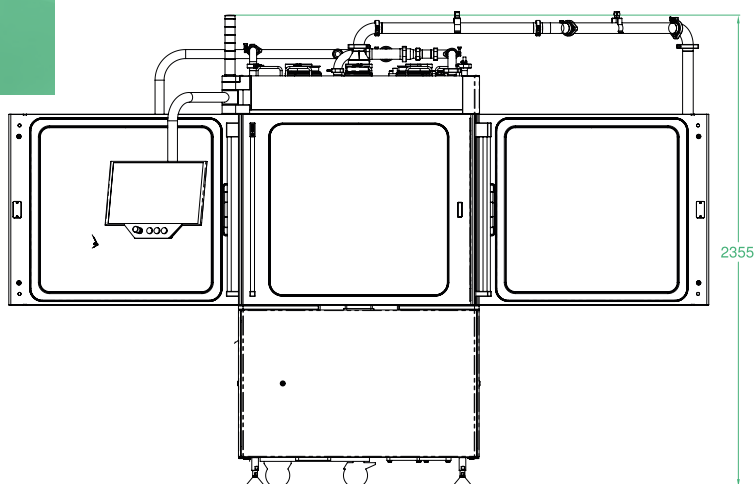
One platform for all requirements.

From galenical development (R&D set-up) to small scale batch manufacturing, based on more than 50 years of experience in capsule filling.



GKF 720

The GKF 720 is a highly flexible machine, designed to dose powders, granules, pellets, (micro-) tablets or liquids into hard capsules. With an output of up to 43,500 capsules per hour, it is the first of its generation to have a modular design and flexible plug-in station: a dosing module can be changed in less than five minutes. The exchange is simple and failsafe. Special focus was put on efficient product change-over and cleaning.

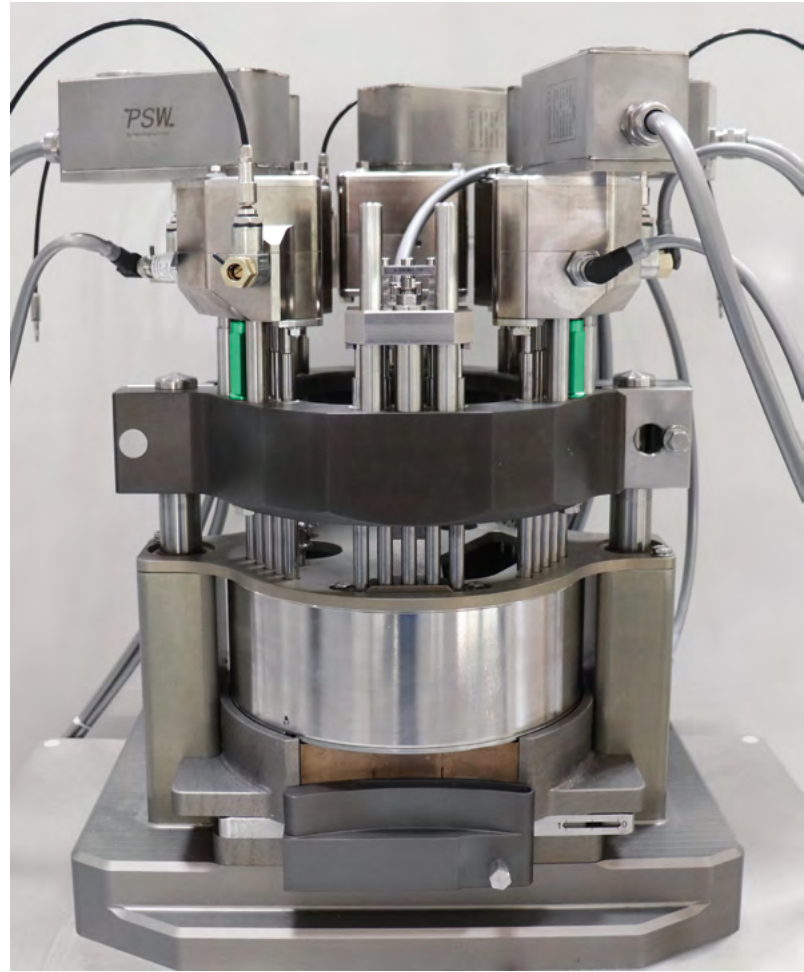


Dosing and PAT technologies

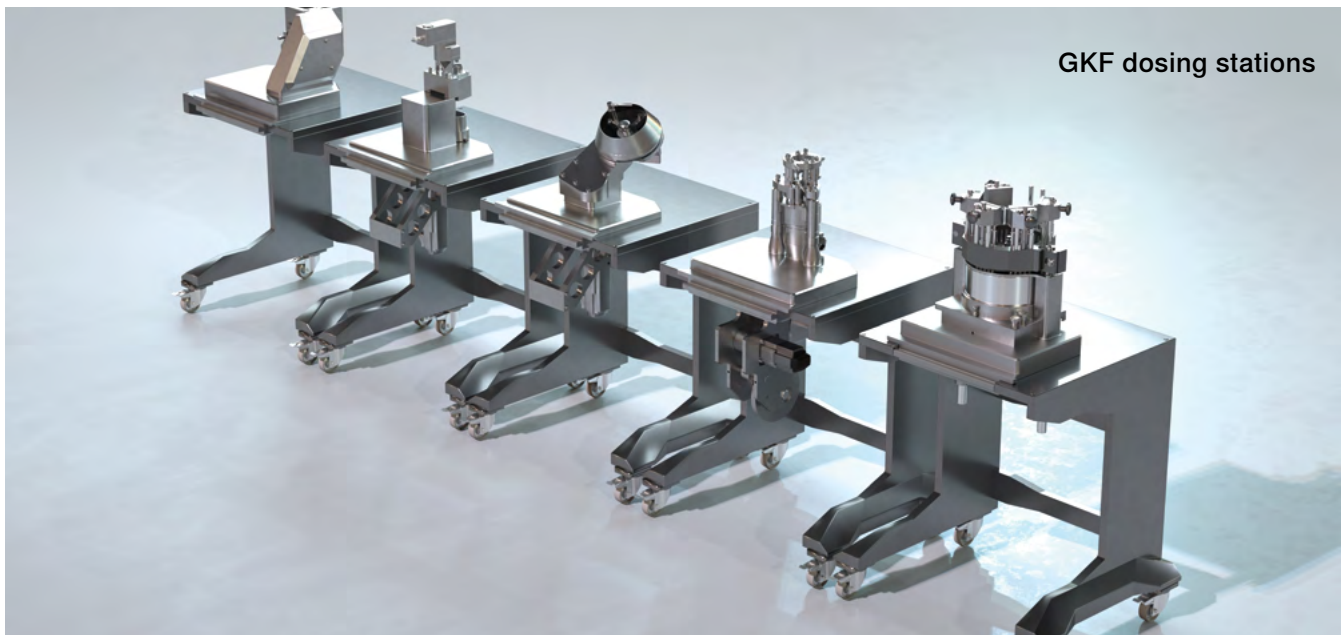
Equipped with the respective filling station, the GKF 720 achieves precise filling results from free-flowing to cohesive powders, as well as for products of a liquid or pasty nature.

We offer customized solutions for critical product properties and product combinations – regardless of their physical properties.

- ❑ Pellet/Powder/Tablet/Liquid/Special dosing station
- ❑ Mini bowl station/vacuum wheel dosing (fixed & volume adjustable dosing wheels)
- ❑ Microdosing station
- ❑ Enhanced segment cleaning
- ❑ Single capsule ejection
- ❑ ASB function (automatic troubleshooting)
- ❑ Capsule cap and body detection scanner
- ❑ “No body no fill”/“No cap no fill” on all filling stations
- ❑ Integrated gravimetric scale for in-process control (IPC)
- ❑ NWDS (Net Weight Detection System)
- ❑ WIP (wash-in-place)
- ❑ Wetting function via integrated spray nozzle



APD Module: automated process development, based on Design of Experiment (up to 50 trial runs in less than two hours)



GKF dosing stations

FlexiTab XL

FlexiTab XL – Fully automated single punch tablet press with enhanced DAQ software for R&D & Galenics.

FlexiTab XL in cooperation with Röltgen, Germany.

As a single punch machine the FlexiTab XL is designed for early stage tablet development, the production of clinical trial batches, the screening of powders and granules for subsequent product development as well as the assessment of multi-layer drug dosing and characterization of powder properties.

Your benefits:

- ❑ Movable execution
- ❑ External magnesium stearate lubrication of punches and dies
- ❑ Air blast die cleaning and vacuum dust extraction
- ❑ Laser type die fill monitoring
- ❑ Reporting features (USP 1062 and cGMP)
- ❑ DAQ 4 data acquisition software
- ❑ Press parameters displayed in real time
- ❑ No relevant residues in product hoppers



Technical specifications			
	1 Layer	2 Layer	3 Layer
Output per hour	900*	600*	300*
Max. tablet diameter	25,4 mm** (29 mm)		
Max. fill depth	21 mm		
Max. operating pressure	60 kN (150 kN)		
Punch / die type	TSM / Euro B/D		

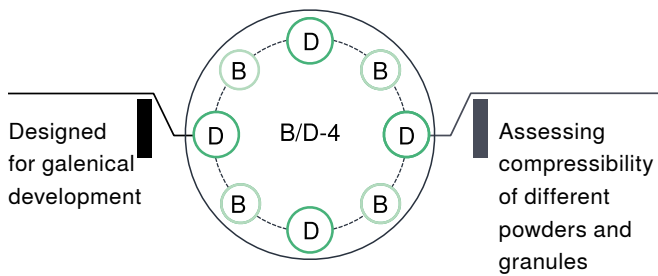
* Output depends on characteristics of material

** When using EU or TSM 1 tooling



TPR 200 Plus compression for research & pilot plant

The Syntegon TPR 200 Plus is a newly upgraded and very compact, medium output tablet press with great flexibility, improved handling and advanced operator protection. For research & development there are two turret versions available, combining either four B stations and four D stations or eight B stations and eight D stations. The modular Data Acquisition System (DAQ) is capable of measuring and presenting a wide range of data including a tool for the evaluation of powder and granule behaviour during compression. The machine can be operated with a several different feeding system starting with 50 g to batch production. Options include an OEB 3 protection cabin with glove port access and dry cleaning possibility.



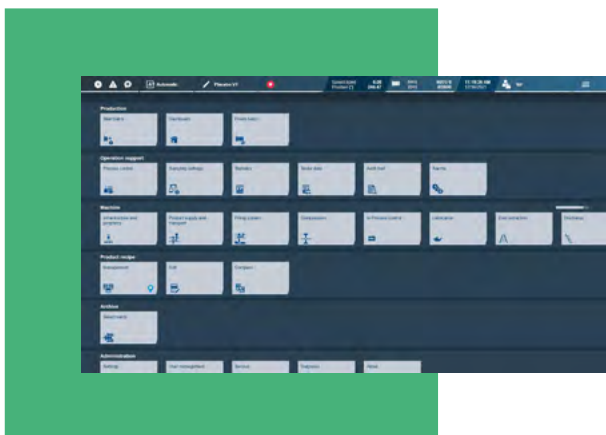
- ❑ Pre-compression force
- ❑ Main-compression force
- ❑ Lower compression force
- ❑ Lower punch tightness
- ❑ Upper punch tightness
- ❑ Ejection force monitoring
- ❑ Upper punch displacement
- ❑ Lower punch displacement
- ❑ Scraper force monitoring
- ❑ Protective OEB 3 Light Containment
- ❑ Modular feeder system
- ❑ MUPS (Multi unit pellet system)
- ❑ Bi-layer
- ❑ Thermosensitive formulations
- ❑ Sticky products
- ❑ Continuous manufacturing

Bi-layer tableting

The flexibility of the TPR 200 Plus continues to impress with the capability to manufacture bi-layer tablets with a set of conversion parts. Designed to ensure clear separation and no cross contamination between layers, the control system provides first layer sampling capability and individual layer weight control.

APD feeder for automated process development

The APD technology is used in the development of formulations for solid dosage forms, especially tablets, to determine the optimal manufacturing parameters for a specific product to ensure quality and minimize product loss. The APD feeder technology offers an automated systematic approach to find the most suitable production parameters.



New software and HMI design

Our TPR 200 Plus provides highest usability through an intuitive HMI and a state-of-the-art control system. The HMI offers a menu guidance function and an integrated help function for navigation and troubleshooting. The help message guides the operator to the dedicated location in the operator manual in the HMI so that any occurring messages and alarms can be addressed directly. In addition, the data acquisition system (DAQ) is able of capturing and visualizing a wide range of tableting process relevant data. This is a valuable feature for evaluating the behavior of powder and granules during compression.

TPR 200 Plus	Standard Die						Integrated Die	
	4 x 4	8 x 8	20	25	30	32	25	30
Stations								
Punch type	4 x 4 B/D****	8 x 8 B/D****	20 D	25 B	30 BB	32 BBS	25 D***	30 B
PCD (mm)	280	280	280	280	280	280	280	280
Max. turret speed (rpm)	100	100	100	120	120	120	100	120
Min. output - tablets per minute (setpoint)	400	800	2,000	3,000	3,600	3,825	2,500	3,600
Max. output* - tablets per hour	24,000	48,000	120,000	180,000	216,000	229,500	150,000	216,000
Max. tablet diameter (mm)	25 / 16**	25 / 16**	25	16**	13	11	25	16**
Max. primary compression force (kN)	50	50	50	50	50	50	50	50
Max. main compression force (kN)	100	100	100	100	100	100	100	100
Max. filling depth	18	18	20	18	18	18	20	18

* The output depends on tablet size and product characteristics

** Larger tablets possible on request

*** Higher output possible on request, depending on punch geometry and product characteristics

**** Reduced output with R&D turret setup max. 60 rpm and runtime max. 4h/day

OSD customer centers worldwide

Schopfheim, Germany

Process & new technologies, focus on wet granulation, pellet coating, continuous granulation & tableting:

- ❑ Lab area 500 m²
- ❑ Customer support by senior pharmacists
- ❑ R&D and production equipment from 50 g to 240 kg from powder to coated tablet
- ❑ Continuous equipment from powder to tablet up to 30 kg/h
- ❑ Analytical equipment



Waiblingen, Germany

Process & new technologies, focus on tableting and encapsulation

- ❑ Customer meeting rooms and training center
- ❑ Eight fully equipped cleanrooms
- ❑ New generation of machines and features for testing, feasibility studies and project surveys etc.
- ❑ Controlled environmental conditions (production conditions)
- ❑ Handling of formulations with high potency (up to OEB 5)
- ❑ Analytical equipment



Hangzhou, China

Process & product transfer, focus on OSD process technology

- ❑ Lab area 500 m²
- ❑ 3 separate testing room
- ❑ State of art Syntegon OSD testing solution
- ❑ Advanced IPC instruments



Minneapolis, MN, USA

Process & new technologies, focus on oral solid dose processes, granulation, coating, tableting, encapsulation

- ❑ One showroom (approx. 75 m²), lab space (approx. 60 m²) and utility & material storage space
- ❑ Solidlab 2 fluid bed module
- ❑ Solidlab 2 tablet coating module
- ❑ Flexitab XL tablet press
- ❑ Capsylon 705



Innovative services tailored to your needs.

A comprehensive service portfolio lays the foundation for smooth production processes. We at Syntegon support you throughout the entire machine life cycle, from spare parts management to digital line optimization. Service agreements are a key element of our portfolio structure. We minimize production risks and maximize the efficiency of your equipment by working with you as equal partners.

Together, we tailor our solutions to your individual needs. You benefit from fixed conditions and guaranteed services.

Our global network of experts supports you with maintenance planning, technical support, and modernizations, as well as operator training and expert services. With our digital solutions, you gain control over your production processes and create transparency on product and machine data – anytime, anywhere. Whether it is switching to sustainable materials or upgrading to automated technologies, together with us you will take the next steps towards the factory of the future.

How can we help you? Please get in touch with us: www.syntegon.com/services



Connect with our team.

Syntegon Technology GmbH

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