

Continuous Granulation and Drying



Collette™ Technologies

Continuous Oral Solid Dosage Production

ConsiGma™, the innovative continuous high shear granulation and drying system by GEA Pharma Systems, can be operated as continuous production system in a batch operation, but can also be integrated into a truly continuous oral solid dosage production line.

To complete the continuous process line, GEA Pharma Systems integrates ConsiGma™ with the GEA Pharma Systems continuous blender for premixing the raw materials and the GEA Courtoy MODUL™ P rotary tablet press.

An advanced control system and online measurement tools enable real time release of the product thereby achieving the full potential of a continuous production line.

1 | Powder supply

IBC with Preblended material:



The simplest way to load ConsiGma™ in an existing plant is to preblend the materials in an IBC and lift it above the feeder for charging.

OR Multiple feeders:

Active ingredients which are difficult to blend in an IBC can be fed separately to ConsiGma™ and mixed in the granulator. Up to 4 individual feeders are possible. Homogeneous mixes of very low concentrations can be achieved.

OR Continuous blender:

Alternatively, a continuous preblending operation can be used to complete a fully continuous plant. This option can be applied where more than 4 components need to be blended.



2 | Powder feeder

Accurate dosing of the ingredients (mixed or separate) to the ConsiGma™ granulator, based on loss in weight.

3 | Liquid addition system

Accurate dosing of granulation liquid to the ConsiGma™ granulator, based on loss in weight. The system is suitable for water, solvents, binder solutions and solutions or suspensions of the active or other ingredients.



4 | ConsiGma™ high shear granulator

Innovative continuous high shear granulator for mixing, wetting and granulation using a plug-flow principle. Careful control of the process parameters enables particle design resulting in granules of a better intra-granular porosity with superior compressibility characteristics.

5 | Transfer of wet granules

By vacuum or gravity.

6 | ConsiGma™ segmented fluid bed dryer

The continuous flow of granules is split into small packages for drying to maintain plug-flow. The drying curve of each package is monitored, as a fingerprint of

the process, and controlled to maintain a constant end humidity over the whole batch. On-line measurement of moisture content using the LightHouse™ Probe technology is possible.

7 | Granule Conditioning Unit

Each package of product is milled and evaluated on critical quality attributes (e.g. particle size, humidity, content uniformity). A sampling system can be included to double-check the on-line measurements.



8 | Inline mini-blender

The external phase (lubricants, desintegrants, etc.) is mixed with the finished granules before tableting.

9 | Modul P – rotary tablet press

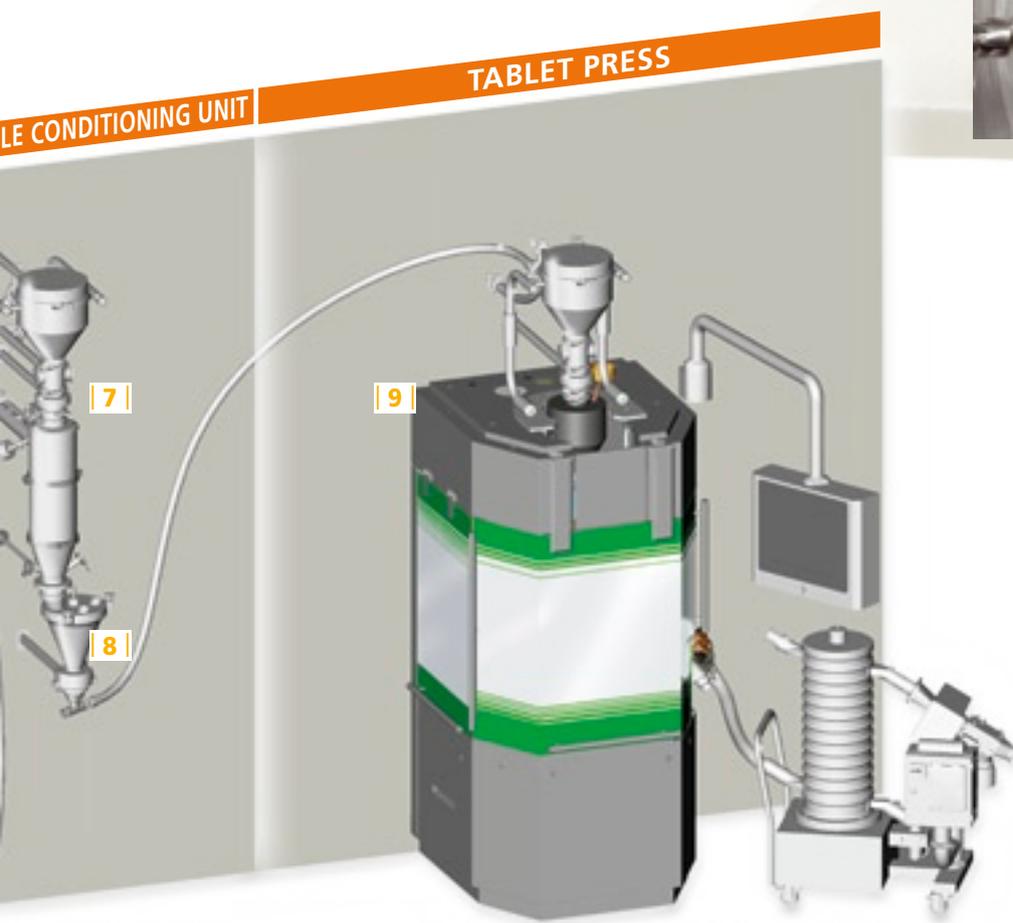
Featuring 6 compression modes (a.o. compression to equal porosity), the innovative Exchangeable Compression Module (ECM) concept with Wash-Off-Line capability and advanced in-line PAT sensors and control system.

PAT options

The critical quality attributes of the product, such as particle size, homogeneity and moisture content, can be measured on-line at different points in the continuous process.

Controls

An advanced control system ensures the smooth running of the continuous process line and synchronizes the heartbeat of each component. Critical parameters are continuously tracked and deviations outside set boundaries automatically lead to correction of the relevant parameters via a closed-loop feedback control in order to keep the CQA's within specifications.



Cleaning

Wash-In-Place or Wash-Off-Line available

Capacity

| | |
|-------------------|------------------------------|
| Nominal capacity* | 10 - 100 kg/h |
| Campaign size* | 500 g to 14,4 tons (or more) |

* product dependent

Innovation

GEA Pharma Systems – Collette™ introduces ConsiGma™

GEA Pharma Systems nv - Collette™, manufacturer of the state-of-the-art batch high shear granulation and drying systems, UltimaGral™ and UltimaPro™, introduces ConsiGma™, a revolutionary continuous high shear granulation and drying system.

The system satisfies the pharmaceutical industry's demand for continuous production to provide improved quality, flexibility and consistency for pharmaceutical processes. ConsiGma™ allows you to bring your products to the market faster, in a more flexible and environmentally conscious way.

It's main advantages are:

- Flexible batch size: One ConsiGma™ can run 500g in R&D, but can also run clinical trial, launch size, and any production size batches. There is no need for scale-up and fast product development is possible
- Compact, modular construction with very short installation time : fast deployment, full flexibility, no influence on building design
- Consistent granule quality with improved compressibility characteristics : parametric release possible, reduced quality cost
- Reduced investment and running costs: reduced space requirements, reduced use of utilities





Central know-how on a global Scale

Based on a strong commitment to research and development, pharmaceutical technology centres in Belgium, Denmark, Switzerland, the UK, Singapore, and USA provide global technical support and know-how to the pharmaceutical industry.

These centres of excellence give customers

access to a range of test facilities and expert teams with technical and process know-how. Our teams work closely with our customers to optimise processes and evaluate their products, enabling them to achieve their process and production goals.



Contracting profitable Experience

A world leader in supplying pharmaceutical equipment, GEA Pharma Systems offers manufacturers all over the world the opportunity to enter into a profitable partnership for development and contract. GPS combine advanced in-house technology with a thorough

understanding of the pharmaceutical industry to help customers maximize their development results.

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