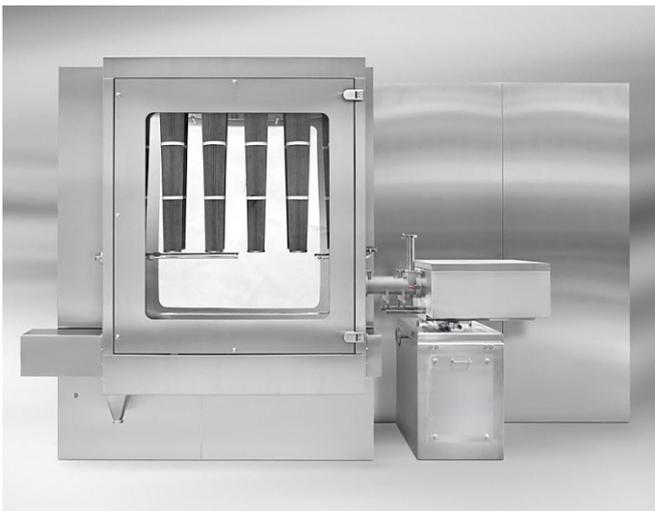


Lödige as partner for continuous manufacturing of solid dosage forms

In an extremely competitive pharmaceutical market the establishment of highly efficient production processes of solid dosage forms has become a fundamental meaning for economic success. One result from this development is the trend of replacing traditional batch processes by continuous production lines which are characterized by significant savings in running costs due to requiring less labour, cleaning efforts, quality control costs and a higher product yield. A high variability in production capacity, which can be directly controlled by system runtime, is another major benefit of continuous operating systems.

Having more than 60 years' experience in continuous mixing and granulation in various industries, Lödige reacted to the needs of pharmaceutical industry by scaling down the established systems to appropriate smaller outputs. Furthermore the Lödige product portfolio was enhanced by an innovative continuous fluid bed system. For the continuous manufacturing of solid dosage forms in principle two alternative concepts are available, direct compression and wet granulation / drying.

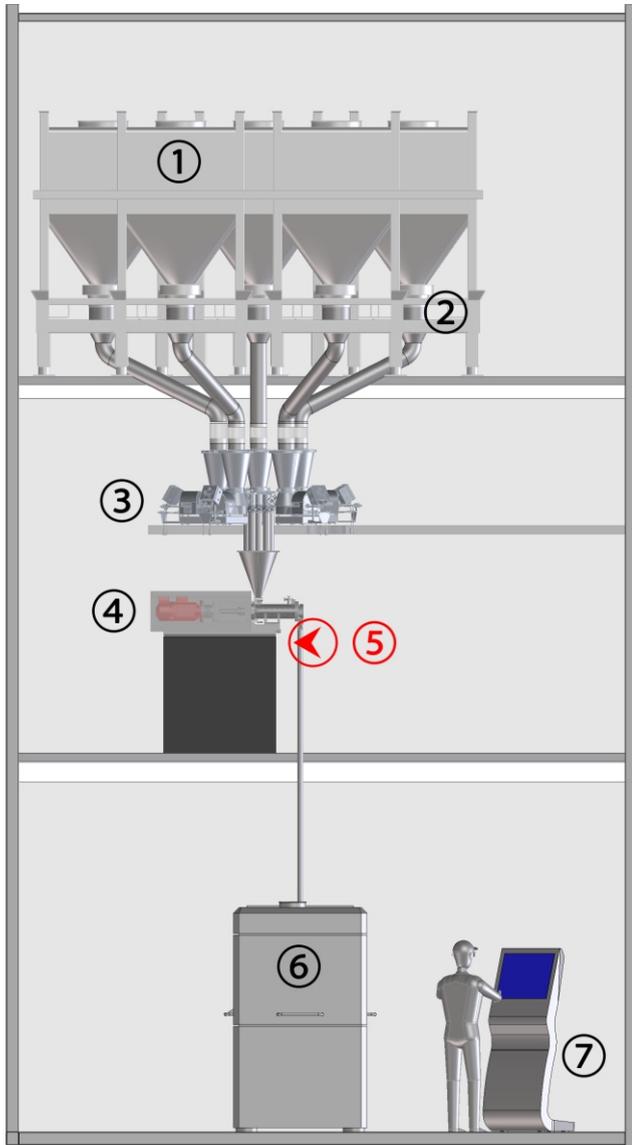


Sample installation CM 5 with continuous Fluid Bed Dryer LCF 5



Sample installation KM 5 with 2 loss-in-weight feeders

Direct compression with continuous Ploughshare® - Mixer type KM



- ① Raw materials
- ② Rotary valves
- ③ Loss-in-weight feeders
- ④ Continuous mixer type KM
- ⑤ NIR probe
- ⑥ Tablet press
- ⑦ Control system

◀ The direct compression with the continuous Ploughshare® Mixer KM as core equipment is one possibility for the continuous manufacturing. Raw materials are discharged from containers or big-bags automatically into feeding hoppers from loss-in-weight feeders by using rotary valves or vacuum conveyors. The loss-in-weight feeders dose all main ingredients into the inlet funnel from the KM.

The product is rapidly mixed and conveyed through the horizontal mixing drum by the optimized mixing elements and leaves the mixer through an open outlet. The lubricant is usually added through a separate feeding port which is located close to the machine's outlet in order to achieve the lubricant covering only the product surface. The product stream leaving the machine is inspected by a NIR-probe for detecting mixing homogeneity, particle size distribution, etc. online. The NIR controls a quick acting junction, which automatically ejects product which does not meet the defined specification into a waste product bin (not displayed at the model). The proper mixed product is gravimetrically or pneumatically transported to the tablet press and pressed.

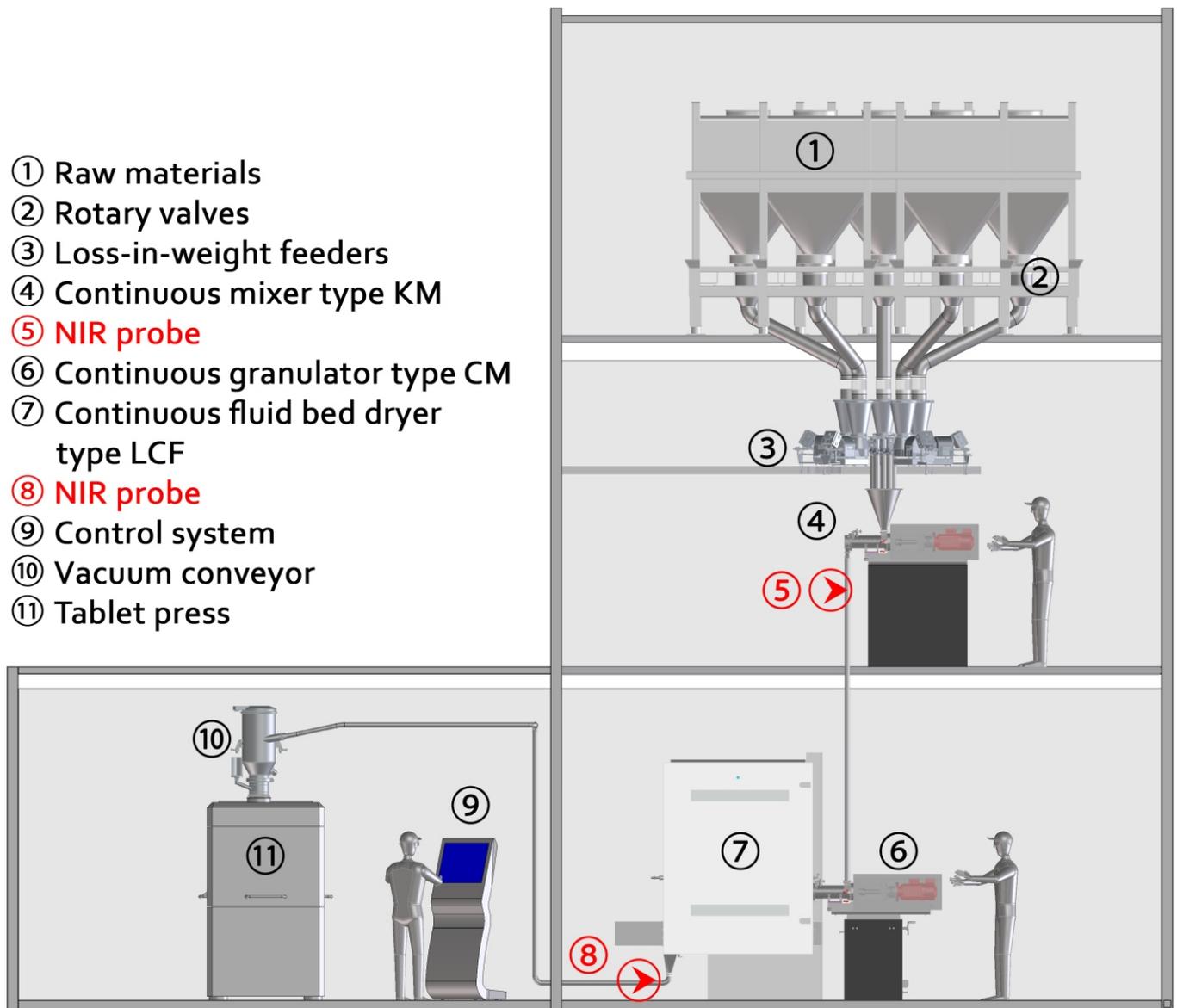
Continuous wet granulation and drying

The continuous wet granulation is a concept with several ► process steps in sequence. Raw materials are discharged from containers or big-bags automatically into feeding hoppers from loss-in-weight feeders by using rotary valves or vacuum conveyors. The loss-in-weight feeders dose all main ingredients into the inlet funnel from the KM. The product is rapidly mixed and conveyed through the horizontal mixing drum by the optimized mixing elements and leaves the mixer through an open outlet. The product stream leaving the machine is inspected by a NIR-probe for detecting mixing homogeneity, particle size distribution, etc. online. The NIR controls a quick acting junction, which automatically ejects product which does not meet the defined specification into a waste product bin (not displayed at the model).

The proper mixed product is gravimetrically discharged into the feeding port from a Continuous Granulator CoriMix® CM. The high speed rotating mixing elements in the granulator create a ring layer of product in the machine's drum and move the product forward through the machine. By addition of a liquid binder a high shear granulation takes place in the ring layer. The granules leave the machine through an open discharge straight into the continuous Fluid Bed Dryer LCF. Drying is carried out by fluidizing the product with conditioned warm air while the product is conveyed through the dryer using a screw, which rotates close to the half rounded sieve bottom. By adjusting the rotation speed of the screw, the retention time of product in the dryer and hereby the drying time can be controlled exactly. The LCF is designed with 3 independent inlet air chambers.

For each chamber air flow and temperature can be adjusted individually in order to carry out the drying process with the highest accuracies. The dry granules are discharged from the dryer by gravity into a discharge funnel. Optionally a dry sieve can be installed directly on the dryer outlet for final granule size calibration (not displayed at the model). Before the granules are conveyed to the tablet press an additional quality check for particle size, moisture, etc. is carried out by a NIR probe. Product which does not meet the defined specification is ejected into a waste product bin according to the same principle as previous described. The dry and size calibrated granules are pneumatically conveyed to a tablet press. The lubricant is added into the feeding hopper of the tablet press before pressing.

- ① Raw materials
- ② Rotary valves
- ③ Loss-in-weight feeders
- ④ Continuous mixer type KM
- ⑤ NIR probe
- ⑥ Continuous granulator type CM
- ⑦ Continuous fluid bed dryer type LCF
- ⑧ NIR probe
- ⑨ Control system
- ⑩ Vacuum conveyor
- ⑪ Tablet press



**Gebrüder Lödige
Maschinenbau GmbH**

Postfach / P.O.Box 2050
33050 Paderborn

Elsener Strasse 7 - 9
33102 Paderborn
Germany

Telefon / Phone: +49 5251 309-0
Telefax / Fax: +49 5251 309-123
E-Mail: info@loedige.de

Kundendienst / Customer Service:
Telefon / Phone: +49 5251 309-222

www.loedige.de