

# SYSTEM SOLUTIONS FOR THE PHARMACEUTICAL INDUSTRY



**ALWAYS THE RIGHT MIX**

# PHARMACEUTICAL INDUSTRY – HIGH-TECH MADE BY PEOPLE FOR PEOPLE





# PRODUCT-SPECIFIC PROCESS DESIGN

## GUARANTEES THAT THE DETERMINED QUALITATIVE PROPERTIES OF SENSITIVE PRODUCTS ARE MET

### SOLUTIONS PROVIDED BY LÖDIGE

- Mixing / Granulating
  - Basic pharmaceutical materials
  - Excipients / Active agents
- Drying
  - Active agents
  - Moist product
- Coating
  - Tablets
  - Capsules
  - Pellets
  - Granules
  - Particles / Crystals



#### Medicines are high-tech products

What matters is the dosage – especially when it comes to pharmaceutical products. Because modern medicines are truly high-tech products. Cutting edge technology is also necessary to research and develop them: using the latest analysis and synthesis techniques, genetic laboratories, powerful IT systems, analysis robots and much more.

Nowadays, medicines are manufactured exclusively using state-of-the-art technology. From the raw materials to the package, the products produced must meet the most rigorous standards for quality.

It goes without saying that during production all criteria which could influence the quality and effectiveness of the product must be guaranteed. The safety of the patients depends on it.

#### Lödige provides the solution

For this reason, medicine productions worldwide are subject to the absolute highest standards regarding safety, purity and reproducibility. Our products and services are subject to these same internationally valid quality standards.

This means: all our systems for versatile applications in the field of solid dosage forms are developed and implemented entirely in accordance with the complex body of rules and regulations governing laboratories and production lines. Our specific processing know-how for mixing, drying and coating systems forms the basis for the development of innovative system solutions in the pharmaceutical industry. Lödige adapts perfectly to the production conditions on site and helps in this way the customers to cope successfully with the current challenges in manufacturing plants. High-quality machines, service from an experienced professional and a competitive price: this makes Lödige a valuable partner in the pharmaceutical industry. A close cooperation with well-known manufacturers of pharmaceutical products for decades proves this competence: as a result more than 1,000 systems have been supplied.

You will find detailed descriptions of our systems in our brochures and flyers.

# MIXING AND GRANULATING IN A HORIZONTAL SYSTEM

**By inventing the Ploughshare® mixer, Lödige revolutionised mixing and treatment technology. Numerous patented innovations based on this system are proof of the technology's incredible potential. The quality of Lödige Ploughshare® mixers has been proven repeatedly for many years in the pharmaceutical industry.**

The heart of the mixer is a special arrangement of Ploughshare® shovels on a horizontal shaft. They rotate in a horizontally fitted, cylindrical mixing vessel. The size, number, positioning, geometric shape and peripheral speed of the mixing elements are coordinated for three-dimensional movement of the components inside the mixing drum. During this process, the mixture is continuously gripped by the mixing tools.

This reliably prevents dead space or low-movement zones, while guaranteeing quick, precise mixing action. This process is highly suitable for mixing processes whereby the components have widely differing bulk densities, particle sizes, rheological features and highly different mass fractions.

Some mixing tasks – for instance the addition of fluids or granulation tasks – make it necessary to support the mixing effect of the mixing elements. For this purpose, separately driven choppers rotating at high speed are installed. The mixing process can also be carried out continuously in Ploughshare® Mixers of type KM.



Ploughshare®-Mixer type FKM



Ploughshare®-Shovels with chopper



Ploughshare®-Mixer type FKM Hygienic Design



# MIXING AND GRANULATING IN A VERTICAL SYSTEM

**The High Shear Mixer MGT is a system for mixing, granulating and sieving of pharmaceutical powders and granules. Lödige High Shear Mixers are particularly easy to clean and are characterized by their extremely low-maintenance.**

A three-arm mixing element rotates close to the wall and with minimum clearance from the bottom of the vertical mixing container.

The special shape of this element and its peripheral speed are coordinated in such a way that the mixing product is circulated as a vortex and thereby accelerated horizontally and vertically. This product movement assures rapid, intensive mixing, bulk densities and surface condition.

High mixing precision is obtained within minimum time. If necessary, a separately driven chopper disperses lumps, distributes liquid uniformly and promotes wet granulation. In this way, the endpoint of granulation can be controlled as required. Liquid addition is carried out with a pump or by gravity.

The liquid is added into the mix right above the chopper which achieves best possible distribution. The optional wet sieve ensures the calibration of the wet granules while discharging from the mixer. Discharge can take place into a vessel or the product can be transported pneumatically to a Fluid Bed Dryer.



Vertical mixing system type MGT



Three-arm mixing element and chopper



MGT with integrated wet sieve

# DRYING, GRANULATING AND COATING IN A FLUID BED PROCESSOR

**The Lödige Fluid Bed Processor LFP is available in different sizes suitable for batches from 0.1 to 500 kg. Numerous options allow the processor to be adapted to application-specific requirements.**

The Fluid Bed technology of the LFP achieves a constant and reproducible product quality while ensuring a gentle process in short process times.

Processes ranging from powdery materials to free-flowing materials can be carried out as well as the drying of moist products (e.g. moist granulates).

Moreover, powders, granulates and other shapes can be coated in this system too. During the process, heated air – in defined quantity and speed – continuously flows through the special designed Conidur® bottom into the product vessel. The product starts to fluidize and can be moistened by means of a ternary spray nozzle and granulated, depending on the application. Tangential spray nozzles in the area of the Conidur® bottom (underfeed) or a Wurster system are used for coating pellets.

Integrated filters – selected according to the process and product – hold back the powder particles and return them into the process by continuous filter cleaning.



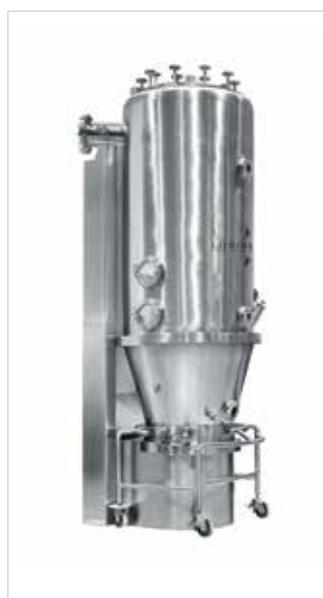
LFP filter elements



LFP Mini 1



LFP 8 for development and small production



Production unit LFP



LFP with product container in run-out position and lifting device

# COATING IN A **LÖDIGE COATER LC**



Lödige Coater type LC 130

**Lödige Coaters of type LC are used for processing different shapes of tablets, capsules and pellets and operate on the co-current, under-pressure principle. 25 – 100 % of the working capacity of the Coater can be used without modification of the system. As well as the Coater itself, the LC Coating System includes the inlet air treatment, the exhaust air system, the controls, liquid dosing, feeding and discharging and the WIP system.**

Optimal process control, fast coating speed, easy handling and easy cleaning were the top-priority for development of the Coater. The coating process can be divided into the following three sub-processes: spraying of lacquer, drying of the tablets and mixing of the tablets. The LC coater series optimizes all three sub-processes. The totally perforated drum with a free surface of more than 40 % enables a maximum air flow.

The mixing elements ensure the uniform and gentle mixing, even with variable filling degrees. These are the most important conditions for best uniformity of coating.

The optimised nozzle arm permits easy adjustment of the nozzle position to the tablet bed – making it possible to set the optimum spraying distance and angle at all times. The heated inlet air is guided into the Coater housing via a special distribution system and led through the perforation into the coating drum, thereby ensuring quick drying of the moist tablet surfaces. The air is then extracted through the tablet bed.

The whole product range inside the Coater is kept below atmospheric pressure. Complete discharge is done while the drum is rotating backwards, without any additional equipment. An innovative ultrasonic generator is used during the cleaning process. It reduces the cleaning time significantly – especially in case of hardly soluble substances. The Coater is designed for through-the-wall assembly, which permits optimum separation of the technical and process areas. The technical area is always available for access by the maintenance staff.

The new control system can be operated intuitively and fulfils all the latest GMP requirements.



Lödige Coater type LC 150 with spray arm in run-out position



Lödige Coater type LC 70

# CONTINUOUS WET GRANULATION AND DRYING IN A **LÖDIGE GRANUCON®**

The GRANUCON system is a complete, continuous production line – from powder to granules ready for compression. This range comprises dosing units, mixers, sieve/rasp and a comprehensive control system.

## Continuous Granulator CoriMix® type CM and Continuous Mixer type KM

This high speed mixer is designed to intermix liquid or pasty components into dry powder. The high shear force introduced by the granulating tools generates a uniform granule structure.

## Continuous Fluid Bed Dryer type LCF

The dryer operates in accordance with the fluid bed technology. A screw installed above the exchangeable perforation continuously conveys the product through the dryer. The speed of the screw and therefore the dwell time of the product can be adjusted in a variable manner. This design ensures a closer distribution of the dwell time than in other continuous systems available in the market. Operation and cleaning of the dryer are incredibly easy. The throughput ranges from 5 to 50 kg/h.

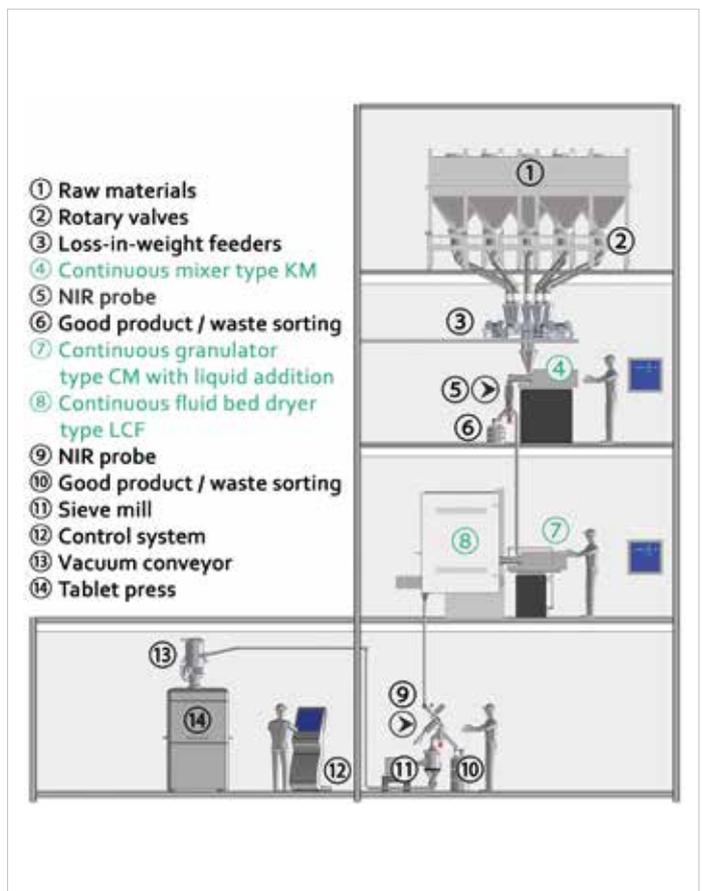


Continuous Granulator CoriMix® CM

## Continuously from Powder to Granules

Compared to a batch process, the continuous operation allows to produce the same product at much lower cost. This depends particularly on the following factors:

- Less product handling
- Plug flow, minimum product loss during starting and downtime
- Less manpower
- Smaller machines – less cleaning
- Continuous process monitoring (PAT) – less costs
- Less space required in the GMP area
- Scale-up: Increasing production is possible through mostly automated 24/7 operation



Granucon® – Model for wet granulation and drying



# DRYING IN A **VACUUM SHOVEL DRYER SYSTEM TYPE VT**

**Compared to conventional drying processes, vacuum drying contains a number of process advantages: In particular, it is characterised by low drying temperatures that are gentle to the product and the possibility of high evaporation rates, reducing the resulting process times.**

By carrying out a vacuum drying process in a horizontal shovel dryer the advantages of vacuum drying can be combined with the process technology options of a Ploughshare® mixer. Beyond producing mixtures with an excellent mixing accuracy, the mixing elements also provide essential support for the drying process by carrying out a steady exchange between product and heat transfer surface. This ensures a very effective heat transfer into the product.

Compared to alternative vertically arranged drying systems, the horizontal dryer has a significantly higher available heat exchange surface, which also leads to shorter drying times. Moreover, the system can be equipped with several options for liquid addition and distribution and can therefore also be used as a granulator. The possibility of installing a sieve mill directly onto the machine's feeding port for material preprocessing resp. below the outlet for final granule size calibration completes the range of possible processes in the vacuum shovel dryer.

In the pharmaceutical industry, there are multiple applications and processes which can be carried out in a vacuum shovel dryer. Typical examples are drying of APIs, the combination of several process steps in "single pot applications" and effervescent products.



Vacuum Shovel Dryer type VT 2000



VT control panel



Vacuum Shovel Dryer type VT 200

# MACHINES FOR RESEARCH, PRODUCT DEVELOPMENT AND SAMPLE PRODUCTION

Lödige laboratory systems provide reliable scale-up to production size. Their function principle is identical to that of production machines, making it possible to use them for production of small batches with the same quality criteria.



Vertical Laboratory Mixing Granulator type MGT-L



Laboratory Coater LC with inlet air and exhaust air unit



Laboratory Ploughshare® Mixer and Vacuum Dryer



The Lödige Pharma Test Centre is equipped with the most modern machines for:

- Mixing
- Wet Granulating
- Sieving
- Drying
- Tableting
- Coating

in compliance with GMP and at production conditions.

### Test Centres

The Lödige Test Centres of more than 700 sqm provide trial capacity for more than 30 machines including a laboratory for physical analysis. A separate test centre is dedicated to pharma trials in compliance with GMP conditions. The pilot machines are designed for a reliable scale-up to production equipment.



Lödige Pharma Research & Test Centre

### Mixing Granulator type MGT 125



- Mixing
- Granulating
- Wet granulating
- Drying
- Batch size up to 40 kg
- Control of the point of granulation
- Dust-free feeding
- Rasp / sieve downstream

### GRANUCON®



- Material handling
- Dosing
- Continuous mixing
- Continuous granulation
- Continuous drying
- Integrated WIP cleaning
- Variable air quantity in 3 chambers

### Coating System type LC 70



- Film Coating
- Totally perforated drums
- Filling degree 25 - 100 %
- Batch size up to 40 kg



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Lödige offers high-quality partial systems and service for process engineering applications in various industries in the fields of mixing, granulation, coating, drying, reaction and related processes. Our motivated employees and their expertise in processes, development and production are the key to our success and the success of our partners all over the world. Focusing on core industries and proximity to our customers through local presence is a crucial component of the positive development of our company.

Lödige, which was founded in 1938, is a family-run business in its third generation now. With the invention of the Ploughshare® Mixer, Lödige created a mixing unit that can cover a wide range of different processing tasks. This unit forms the basis for numerous innovations in the area of mixing and processing technology. Industrial mixing and processing technology has been significantly influenced by Lödige and will continue to be so in the future.

Over 500 patents and more than 35,000 machines and systems demonstrate our experience with customer-oriented system solutions. Lödige operates with more than 500 employees worldwide and supports its customers with a network of subsidiaries, technical offices and agencies.