GEA

Process Engineering Division

Niro Pharma Systems

AEROMATIC BUCK COLLETTE COURTOY FIELDER NICA NIRO

Technology Guide

Inspiration
Development
Know-How
Productivity
Security

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Technology Guide

Niro Pharma Systems is world leader in providing advanced processing solutions for solid dosage forms to the pharmaceutical industry. Based on a dedication to research and durable quality, Niro Pharma Systems offers a wide range of solutions, from individual pieces of equipment to complete integrated plants, by uniting the state-of-the-art technologies of Aeromatic, Buck, Collette, Courtoy, Fielder, Nica and Niro.

This brief guide is designed as an introduction to the complete range of process technologies, R&D and product testing services and training facilities available from Niro Pharma Systems. For further information on any of the processes and equipment mentioned in this brochure, please contact your nearest Niro Pharma Systems technology centre.

Aeromatic-Fielder AG
Switzerland

Aeromatic-Fielder
United Kingdom

Buck Systems
United Kingdom

Collette nv
Belgium

Courtoy nv
Belgium

GEA Buck Valve GmbH
Germany

Niro A/S
Denmark

Niro Inc.
United States

NPS Technology Centre
Switzerland

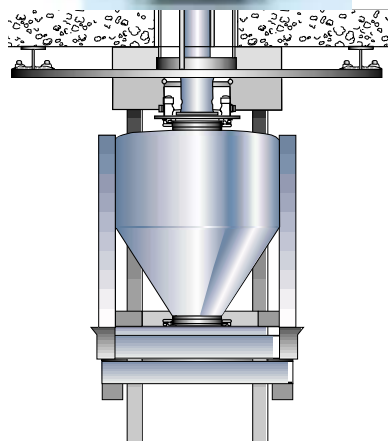
Index

Materials Handling

Niro Pharma Systems offers customised dispensing systems to optimise one of the most vital operations in the production of solid dosage forms.

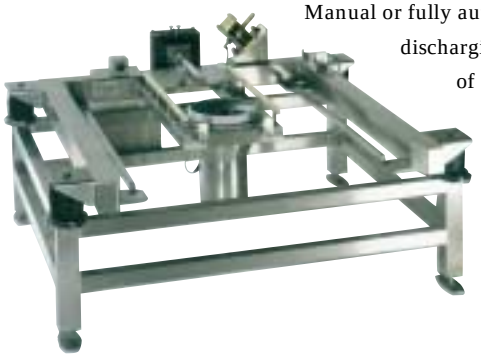
Dispensing room

The equipment features the following functions: accurate raw material weighing for transfer to mixer, precise dosage of all material to standards far beyond recognised pharmaceutical practise, containers fitted with Buck docking systems for dust-free transfer and container monitoring and check weighing. Formulation management feature incorporating materials management, over-dosing cut-off function, customised weighing log and material batch / pallet tracking system with number identification in weighing log.



Discharge station

Dust free product transfer from container to downstream equipment.



Manual or fully automatic Buck Systems charging and discharging stations can incorporate a number of different options including vibration for difficult flowing products, air-blast of the valve face and dust extract, weighing and dosing options for accurate filling and discharging, product deceleration systems to prevent segregation and product breakage during discharge.

Bridge free discharging

The Buck discharge system, in combination with the BUCK® docking system, prevents bridging in the container. The product flow maintains a constant speed without hindrance. The introduction of the Buck patented **VIBROFLOW®** discharger ensures the even flow of sticky or wet products. The **VIBROFLOW®** further eliminates segregation, damage to the material and vacuum in the IBC during discharging.

Sizes: 100, 150, 200, 250, 300mm nominal widths

High containment (HC) split valve

During charging and discharging in production processes the requirements to avoid cross contamination are very high. The patented BUCK® split disc valve which consists of an active and passive valve, each independent from the other, closes off two different container systems dust-tight.

Sizes: 100, 150, 200, 250, 300mm nominal widths

Total containment (TC) split valve

Increasing demands for clean operation during handling of highly sensitive or potent powders, require innovative solutions. The BUCK® High Containment docking system has been very successful over the years, thanks to its split valve principle. The BUCK® Total Containment System was developed to meet even more advanced demands.

The docking system not only covers mechanical safety aspects, but also excludes incorrect operation and precludes contamination for both product and personnel.

With this system, the dust emission values lie in the nanogramm range in all phases of product transfer, including the docking on and off processes. A level that was only previously achieved with the additional use of isolator technology.

Sizes: 50, 100, 200mm nominal width

High containment flexible coupling

Performing a variety of functions simultaneously the HiCoFlex® coupling, is the optimal solution for material handling with flexible transport containers. It unites a reliable means of secure transportation, an ergonomic docking system, a contamination-free means of transferring media and a reliable sealing system for transport containers – making it overall a high productivity system.

Materials Handling

The efficient and effective handling of materials and powders is the key link between each process stage in the production of pharmaceuticals. Niro Pharma Systems supplies containers for transporting, storing and processing powders, granules and tablets.

Intermediate bulk containers (IBC)

Containers for powders, liquids and tablets

Many pharmaceutical manufacturers are operating with discrete batches utilising intermediate bulk containers (IBC) for handling, storage and tumble blending. Buck Systems IBCs are custom designed to suit customers' specific needs with charging and discharging valves in a variety of sizes and styles.

Capacity: 3 to 3000 litres

Pharma-charge drums

Material handling of small quantities

Pharma-charge drums are the essential link in the high-containment material handling chain. Buck offers a range of containers for transporting and handling material in small and very small batches. Applications range from laboratory and production uses to sampling under closed conditions.

Capacity: from 2 to 50 litres

IBC wash stations

An extensive selection of washing systems is available to clean the IBC with valves in place, thus minimising production downtime. IBC Wash Stations range from simple internal wash systems to fully automatic validated washing, drying and cooling booths.

Mixing / Blending

Mixing and blending is an important unit operation for pharmaceutical production. To fulfil these requirements Niro Pharma Systems offers a wide range of equipment for blending and mixing.

High shear mixing

The bottom-driven **PHARMA MATRIX™** from Aeromatic-Fielder and the top-driven **ULTIMAGRAL™** from Collette are stand-alone blender mixers.

Capacity: from 1 kg to several hundred kg/batch

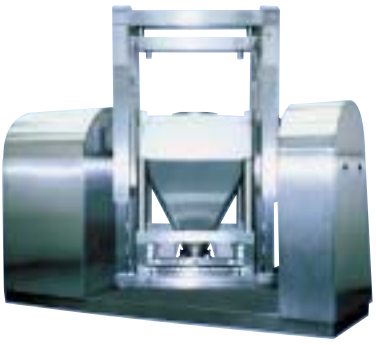
IBC tumble blenders

In-container Blending

Buck Systems produces a range of IBC tumble blenders, utilising the advantages of IBCs in the production of pharmaceuticals.

Blending within the IBC offers dramatic efficiency gains compared with conventional technology such as 'V' Blenders.

Capacity: for IBCs from 3 to 3000 litres



Post hoists and blenders

A range of post hoists and compatible blenders have been created by Buck Systems. These are suitable for the full range of IBCs and can be used in any number of applications, from dispensary to packaging lines. Post hoists allow the IBC to be inverted, and therefore filled through the outlet valve.

Capacity: for IBCs from 30 to 3000 litres

Granulation

Granulation is an important unit operation in solid dosage form production. Niro Pharma Systems is able to offer all the typically used granulation processes and also assist it's customers with the selection of the process that best meets their needs.

Spray granulation

Single-step granulation from an active powder

The powder to be granulated is suspended in the heated air of a fluid bed, and a liquid binder sprayed from nozzles positioned above (**Top Spray Granulator™**) or below (**Bottom Spray Granulator™**).

Capacity: from 20g to several ton/batch or several ton/hour

Spray fluidized granulation

Continuous granulation from an active powder

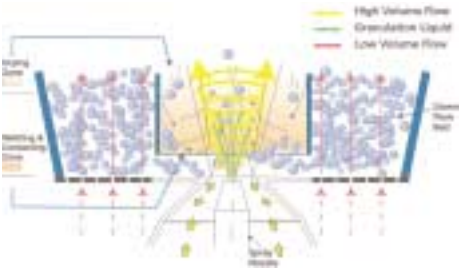
The powder to be granulated passes through the fluidized bed of the **Conti Pharm™** as a continuous stream. The liquid binder is introduced as a fine mist through spray nozzles.

Capacity: 150 kg/hr

High-shear granulation

The high-shear granulation process combines the active powder and other excipients with a binder solution using a high-speed mixing blade and chopper. The bottom-driven **Pharma Matrix™** from Aeromatic-Fielder and the top-driven **UltimaGral™** from Collette are stand-alone blender mixer / granulators. The **Ultima™** system is a modular BUILDING BLOCK SYSTEM offering user selectable options for mixing, high-shear granulating, melt granulation and pelletizing.

Capacity: from 1 kg to several hundred kg/batch



Precison Granulation™

To wet, agglomerate and dry particles in a fraction of a second

A rotating high velocity air stream is established in the central agglomeration tube. Particles are picked up at the base of the tube and accelerated by the air stream. The particles come into contact with liquid droplets produced from the spray nozzle at the base of the tube \ the relative velocity of air, liquid droplets and particles are high so wetting is efficient and drying begins almost immediately.

Most of the feed material is in the outer “holding area”, where the gas velocity is very low. Attrition is greatly reduced. The gas humidity is also low in the holding area so the material is dry not sticky.

Individual particles may make repeated cycles (typically from 10 to 1,000) through the tube, allowing very large agglomerates to be built up.

Capacity: 50g to several hundred kg/batch

Spray Drying

Single-step continuous granulation

Spray drying in **FSD™-mode** - Fluidized Spray Dryer or **IFD™-mode** - Integrated Filter Dryer - can be used for production of dry, free-flowing dustless granules from a suspension or solution. Spray drying combined with vigorous fluidization of moist powder in the fluid bed located at the chamber base, plus recycle of fines from the cylone / bag filter, results in spray drying taking place in a powder-laden atmosphere.

Capacity: customer specific

Turbine granulation

Continuous granulation

Pre-blended powders are dispersed in a high-speed turbine and mixed with an atomized granulating fluid. Performed in the mixer / granulator module of the **Nica System™**, processing is fast and continuous.

Capacity: up to 300 kg/hr

Drying

In the production of solid dosage forms wet granulation is a typical unit operation. After this step it is necessary to dry the material to allow further processes. Niro Pharma Systems offers a variety of drying technologies and is happy to assist in the process selection that best suits it's customers needs.

Fluid bed drying

Gentle, rapid drying of powders and particles

The product to be dried is fluidized by passing hot air through it. The process achieves fast heat transfer making it very efficient, yet gentle on the product.

Capacity: from 20g to several ton/batch or several ton/hour

One-pot vacuum / microwave drying

Gentle drying of powders

The **ULTIMAPRO™** from Collette incorporates high-shear granulation with vacuum and microwave drying options in a one-pot processor. It is ideally suited for all containment projects, facilities with space limitations or multi-product facilities.

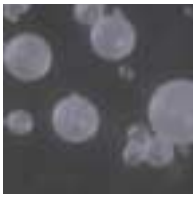
Vacuum drying can be gas assisted to improve heat and mass transfer. Microwave drying is used to achieve times equal to conventional drying processes and precise scale up of drying time periods. The swinging bowl of the **ULTIMAPRO™** offers very gentle mixing during drying which is especially of interest for mechanically sensitive materials or formulae.

Capacity: from 1 kg to several hundred kg/batch

Spray drying

Spray drying is the most important continuous drying technique for converting liquid into powders. Through design selection and dryer operation it is possible to control particle shape, size, distribution and to achieve agglomeration.

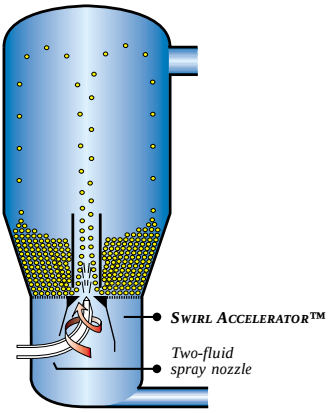
With Niro's **PHARMASD™** line of spray dryers a number of formulation processes can be accomplished: micro-encapsulation, complex formulation, modification of biopharmaceutical properties, dry powder for inhalation.



Spray drying is suitable for drying heat-sensitive pharmaceuticals such as proteins and peptides with a minimal loss of activity. The dryers can be designed for aseptic and sterile production in open or closed cycle operation.

Pelletizing

Pellets have many additional benefits compared to conventional tablets. Niro Pharma Systems is able to offer all the typically used pelletization processes and assist with the selection of the process that best suits its customers' needs.



Liquid layering of pellets

Layering a drug onto starter pellets

The multi-functional **Precision Coater™** and **Top Spray Coater™** systems can all be used to make pellets by layering the active material on to an inert core. Non-pareil starter pellets are sprayed with a solution or suspension of the active material, and dried simultaneously.

Capacity: from 500g to several 100 kg/batch

Powder layering of pellets

Layering a drug onto starter pellets

When the active ingredient is in powder form, pelletization can be achieved by spraying starter pellets with the active powder and, at the same time, a liquid binder solution. The layered pellets are then dried.

Capacity: 500g to several 100 kg/batch

Melt granulation pelletization

Pelletization by heating and massing a powder mixture

Melt pelletization is performed in the **Pellet-Processor™** or the **UltimaPro™**. The active and binder powders are mixed and heated to a temperature above the melting point of the binder. Granulation and pelletization are then carried out in a single operation.

Capacity: 500g to several 100 kg/batch

Wet granulation pelletization

Granulating and spheronizing a powder mixture

The active substance is mixed with 5-30% microcrystalline cellulose and the mixture granulated with water or an organic solvent. During the process the granules are compacted and spheronized. This operation can be performed using the **Pellet-Processor™** or the **UltimaPro™**.

Capacity: 500g to several 100 kg/batch

Extrusion and spheronization

Pelletization by forming and spheronizing extrudates

The **Nica System™** is a turnkey pellet production plant, which combines mixer / granulator, extruder and spheronizer in a single, integrated process.

Continuously wet powders pass through a low-shear radial extruder. The extrusions are fragmented and formed into pellets in the spheronizer.

Capacity: up to 300 kg/hr

Coating

Coating is an important unit operation used mainly to modify the colour, give protection, for taste masking or to create a modified release form. In pharmaceutical production Niro Pharma Systems is able to offer all the typically used coating technologies and assist with the selection of the process that best suits its customers' needs.

Bottom spray fluid bed coating

Precision coating of small particles such as powders, granules, crystals, pellets and small tablets

The **PRECISION-COATER™** offers precise particle coating from 50-5000µ. The coating liquid is sprayed up into a fluidized bed. Advanced fluid dynamics controls the flow, and achieves a high degree of coating uniformity.

Capacity: 50g to several 100 kg/batch

Top-spray fluid bed coating

Cost-effective pellet coating

In the **TOP SPRAY COATER™**, particles to be coated are suspended in the fluidized bed and a coating liquid is sprayed down from above.

Capacity: 50g to some tons per batch

Spray congealing / cooling

Spray congealing carried out in spray coolers is ideal for the cooling of dispersions of drugs in a melted carrier. The hot melt is sprayed into cold process gas where it solidifies into coarse, solid and spherical particles.

Tabletting

Niro Pharma Systems offers a range of extremely reliable and flexible tablet presses.

Rotary tablet presses

Precise, rapid pressing of tablets

The revolutionary **MODUL™** has a patented, fully exchangeable compression module, which allows change over between products in less than 30 minutes.

Capacity: from 10,000 to 1,000,000 tablets per hour

Bi-layer tablet presses

Automatic double-sided rotary tablet press for single- and double-layer tablets

This double-sided tablet press has been specifically designed and developed for the production of quality bi-layer tablets and provides:

- Displacement weight monitoring / control for accurate and independent weight control of the individual layers
- Low compression force exerted on the first layer to avoid capping and separation of the two individual layers
- Increased dwell time at pre-compression of both first and second layer to provide sufficient hardness at maximum turret speed
- Maximum prevention of cross-contamination between the two layers and a clear visual separation between the two layers and maximised yield

Inspecting

Video inspection system

Automated video inspection systems

Courtoy is the exclusive European distributor for the KANEBO automated video inspection systems. These Japanese build systems use state-of-the-art video technology to provide the most accurate and fastest inspection of tablets, capsules, vials and granules, while at the same time guaranteeing high repeatability and detailed batch reporting.

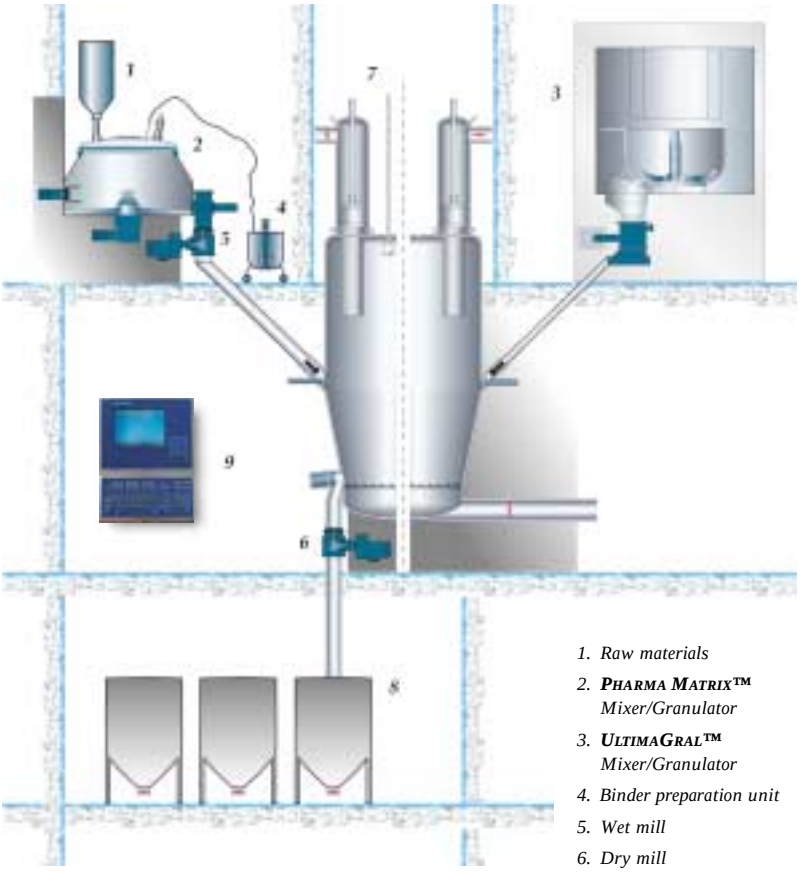
Capacity: from 48,000 to 216,000 tablets per hour

Integration

Current Good Manufacturing Practices increasingly require that product is fully contained during processing to protect operators and environment. Integrated process systems not only offer containment but improved productivity through automation, increased yield and efficient cleaning procedures.

System integration

Niro Pharma Systems specialises in the design and manufacture of fluid bed and high-shear granulation technology and is uniquely qualified to provide state-of-the-art integrated high shear mixer-granulator and fluid bed drying technology. Drawing on its world-class expertise, Niro Pharma Systems offers fully integrated turnkey installations. The service includes: design, installation assistance, commissioning, process validation, as well as training, and technical support. Installation, operation qualification and documentation are carried out according to FDA / GAMP guidelines.



1. *Raw materials*
2. ***Pharma Matrix™*** *Mixer/Granulator*
3. ***UltimaGral™*** *Mixer/Granulator*
4. *Binder preparation unit*
5. *Wet mill*
6. *Dry mill*
7. *Fluid bed dryer*
8. *Finished product*
9. *Control system*

Integration by design

Niro Pharma Systems' entire range of process equipment is designed with system integration in mind. A modular approach allows customers to select standard processes modules to suit project needs. High-shear granulators in both top- and bottom-drive design are available, enhancing flexibility towards customers' processes, product flow and building requirements. Specific fluid bed dryers, coaters and pelletizers can be combined with wet and dry milling facilities, handling systems and binder preparation units in fully contained integrated systems for optimum process efficiency.

Dispensing

Granulating & Drying

Blending

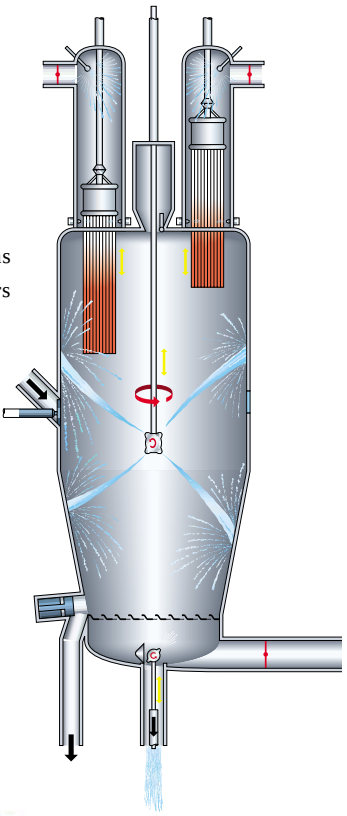
Tabletting, Inspecting & Cleaning

Cleaning

Niro Pharma Systems has the strongest track record and the largest number of proven references for CIP in the industry.

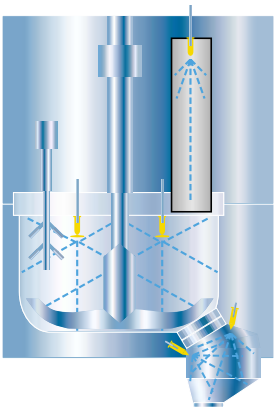
Designed for cleaning

Process optimisation depends on efficient, effective cleaning. Automation of the cleaning process ensures repeatability, allows validation and minimises down-time. In recognition of the fundamental role played in today's advanced powder processing industry by automated clean-in-place procedures Niro Pharma Systems has developed a unique approach to CIP.



WIP / CIP

All process plant can be supplied with a basic wash-in-place (WIP) system or with fully automated cleaning-in-place system. CIP options for the fluid bed processor include process filters that do not have to be removed for cleaning.



CIP Kitchen

Complete Services

Control systems

System control options range from simple, manual push-button control to full programmable logic controller (PLC) - based and state of the art PC - based SCADA options offering a wide range of recipe handling, data acquisition and networking functions. The systems comply with all current industry standards like 21 CFR part 11 and standard communications ensure full compatibility with existing control strategies and plant-wide supervisory systems.

Small-scale equipment

Niro Pharma Systems' expertise has been channelled into a specialist department dedicated to the development and manufacture of mobile small-scale laboratory equipment.

Bench-top equipment is ideally suited to R&D projects, low volume production requirements, and development work on process optimisation.

The small-scale product division offers customers a service tailored to meet their specific needs: blending, granulation, pelletizing, drying and coating, coupled with the benefits provided by Niro Pharma Systems technical knowledge and experience.

Safety and the environment

Niro Pharma Systems is committed to maintaining the highest possible safety and environmental standards.

With a range of emission control options - including solvent recovery systems, outlet filters, and full containment plant - granting full compliance with national, regional, local, and in-house regulations.

Equipment can also be supplied to meet explosion-proof and pressure shock standards as required.

Complete Services

Engineering

The expertise of the Niro Pharma Systems engineering team is available to help customers find the optimum solution for their individual processing needs. The company assists with single phases of a project, or takes full responsibility for design and installation of a complete turnkey plant.

Equipment services

Niro Pharma Systems customers benefit from a comprehensive assistance package to help them maximise their potential.

Customers can **rent equipment** to aid the further development of ideas and products. Niro Pharma Systems is able to transport its process equipment anywhere in the world to meet the development trial requirements of individual companies.

Regular maintenance is essential to ensure equipment operates to maximum efficiency. Fully trained engineers can carry out on-site **servicing and calibration** of equipment, either as part of a **planned maintenance programme** or in response to customer need. **Replacement parts** can be supplied from stock or manufactured to order.

To avoid the expense of equipment replacement, Niro Pharma Systems can **upgrade** existing systems and plant to meet different operational parameters, to comply with changing regulations, or to modify for use at another location.

Finally, operators of Niro Pharma Systems equipment can undergo **training** to help them maximise efficiency, either at the time of installation or periodically as required.

A Partnership in Pharmaceutical R & D

Niro Pharma Systems offers a complete range of R & D and product testing services. Customers can test and optimise existing processes, develop new procedures, and perform pilot scale productions of any aqueous- or solvent-based pharmaceutical product. Furthermore, full demonstration and training facilities make Niro Pharma Systems your obvious choice of pharmaceutical process partner.

Process selection

Niro Pharma Systems is in the unique position of having in-house experience with all commonly used wet granulation methods. The company can, therefore, test your material in a fluid bed spray granulator, top- or bottom-drive high-shear granulator with fluid bed drying, with all tests being made in lab or pilot scale plant, depending on your needs. There is also an extruder / spheronizer combination for pelletizing. Coating facilities are available to coat fine powders up to tablets.

All processes can be demonstrated and tested with product supplied by the customer or with placebo formulations.

Formulation

Niro Pharma Systems has the experience and know-how to help you find the optimal formulation for your new active and thereby achieve the required pharmacological characteristics for the final dosage form. It can also help optimise your formulation for existing processes, including screening different excipients, optimising excipient amounts, adjusting or changing release profiles, taste masking of actives, improving compressibility, and replacing organic solvents by changing excipients.

A Partnership in Pharmaceutical R & D

Process development

Finding the best process is one of the first steps towards a profitable result. Sometimes closely linked to formulation development, process development can be done at lab or at pilot scale.

The process development service includes identifying the optimal process parameters as well as crucial parameters for product validation in the production plant.

Process optimisation

For existing products, installing new equipment or using new excipients often brings up the question of process optimisation. Rather than tying up your in-house R & D department, Niro Pharma Systems can use its own experience in excipient behaviour to help review your production processes.

Clinical scale production

Thanks to a highly trained staff and the installation of all equipment in a modern GMP-environment, Niro Pharma Systems can produce oral solid dosage forms to Swiss health authority standards. Quality control can either be performed in-house by the customer or with a local specialist company.

Pilot scale production

Niro Pharma Systems offers pilot-scale production to ensure 'fast-track' success of a new product in the market. This will also allow pharmaceutical companies to achieve security of outcome through better understanding of processes and the easier selection of the most appropriate technology for full-scale production.

Process integration

When designing a modern production facility, integrating the various unit operations - and therefore the various pieces of equipment - into a single process train is of major importance. The NPS Technology Centre demonstrates the individual steps in the production to help customers fully understand the processes involved.

Training

Authorities around the world make increasingly strict demands on security on pharmaceutical production plants.

At the same time, plants reach increasing levels of complexity making proper training a crucial issue. The NPS Technology Centre offers process training with special emphasis on your specific processes and procedures. Training can cover unit operations, e.g. mixing / blending, granulation, drying, pelletizing, tablet compression, or coating. It also provides practical training in equipment use and maintenance, either at the centre or at your own facility.

GEA-Diessel Pharma Biotech

Liquid Process Systems for the Pharma Biotech Industry

GEA-Diessel is known as a world leader in design and integration of process lines for the pharma-biotech industry. With more than 70 years of experience in hygienic design, GEA-Diessel is the perfect partner for plants manufacturing liquid products for the pharma biotech industry; clean utilities and CIP/SIP are also a part of GEA-Diessel's scope of supply to the complete process line.

GEA-Diessel offers project support from conceptual design phase to OQ, including support for PQ.

Process Integration, Hygienic Design/Aseptic Design

Always an integrated part of GEA-Diessel supplies

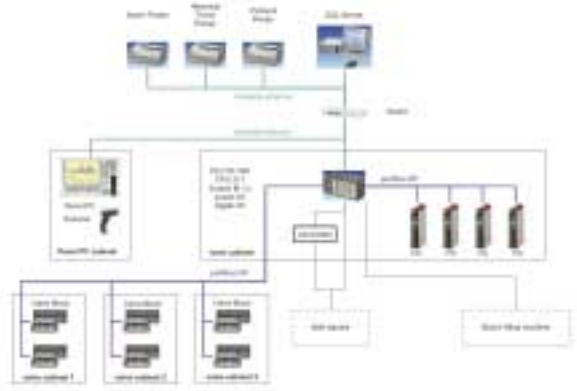
GEA-Diessel attaches great weight to hygienic design. Today, advanced process lines for the pharma biotech industry are built with integrated CIP / SIP. For many years, GEA-Diessel has been a leading supplier of turn-key pharmaceutical production plants and consequently we know how to design process lines suitable for CIP / SIP.

Complying with the rules of GMP and the FDA is a question of choosing the appropriate components.

Automation

GEA-Diessel can supply all types and levels of automation, from simple plc solutions to very sophisticated DCS solutions with interface to superior MES / MIS systems.

A common feature for all systems is that they are developed in accordance with the applicable rules and regulations (at present GAMP 4).



Qualification Services

GEA-Diessel offers services during the project from CD to OQ, and assistance in connection with PQ and final validation.

Also, GEA-Diessel will willingly take responsibility for the complete project, from CD to OQ, meaning that the client will have only one point of contact and one responsible during the entire project.

Process Technologies

Formulation

GEA-Diessel is a well-reputed supplier of all types of liquid formulation processes, eg:

- Coating Solutions
- Suspensions
- Infusion Liquids
- Injection Liquids
- Syrups
- Drop Solutions
- Special Solutions

The systems can be supplied as Built-In-Place or as ready-to-use process modules.

Ready-to-use process modules can be supplied pre-tested incl. *FAT, pre-IQ* and *pre-OQ*. This type of pre-tested modules give the client great advantages, reducing the total construction time of green field projects considerably, and minimising down times during installation of new modules in existing process lines.

Fermentation

GEA-Diessel is an experienced supplier of complete fermentation lines from *pre-fermentation* to *purification* and *fractionation*.

Fermentation skid modules can also be supplied pre-qualified to minimise construction time on site.

Process Technologies

Blood Fractionation

GEA-Diessel supplies complete process lines for blood fractionation.

By combining the GEA-Diessel know-how with GEA equipment from Tuchenhagen Flow Components, GEA Filtration and Westfalia Separator, GEA-Diessel is capable of supplying unique technology for the blood fractionation industry.

Clean Utilities

One of the cornerstones of any pharma biotech business is clean utilities. GEA-Diessel is an experienced supplier of all types of clean utilities systems, such as:

- Water for Injection
- Purified Water
- Clean Gasses
- Clean Steam
- Pharmaceutical Acid / Lye
- CIP / SIP
- Kill

The above-mentioned technologies are only an extract of GEA-Diessel's know-how in liquid processing. Please contact us for further information.

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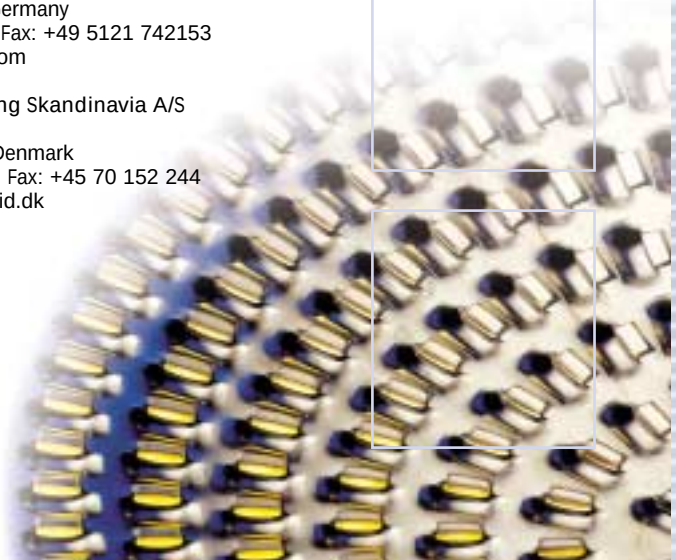

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