

Niro Pharmaceutical Spray Dryers



Niro Technologies

Process Expertise

For 75 years, Niro has supplied drying plants for powders and particulates to the pharmaceutical industry. This includes small capacity dryers designed for R & D as well as industrial size plants for continuous production of pharmaceutical compounds under cGMP conditions.

Our plant and process expertise is based on experience and R & D. With plants installed around the world and literally thousands of tests performed, we have established a solid base of expertise related to the needs of the pharmaceutical and biopharmaceutical manufacturing industries.

Delivering the Right Solutions

Every Niro plant begins with the customer's desire to develop a product that will succeed in the market. In Niro, the customer finds a partner who will assist him to meet that goal. Our expertise includes primary as well as secondary pharmaceuticals, including technologies for processing Active Pharmaceutical Ingredients (API) using spray drying, agglomeration, encapsulation, and spray congealing.



Niro Pharmaceutical Spray Dryers .

A Partnership in Every Perspective

Working with Niro means entering a solid partnership every step of the way, from process development and design to installation, commissioning and qualification of the new plant.



Design



1. Spray dryer chamber
2. Swirl cone
3. Gas/air disperser
4. Cyclone
5. Bag filter
6. Filter bag cages



Customised for Success

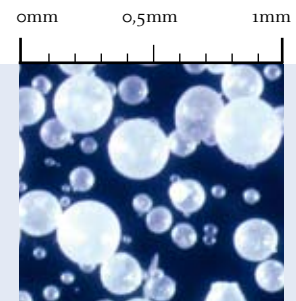
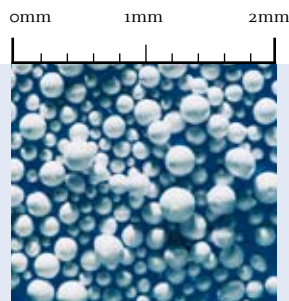
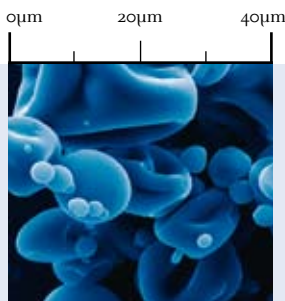
Every pharmaceutical plant and system from Niro is a unique union of proven technology and individual solutions. Based on standard components, we supply plants for cGMP production configured to meet the customer's specific requirements. cGMP requirements to equipment used for spray drying of API may in some situations be less than those for final drugs.



Primary Pharmaceuticals .

Active Pharmaceutical Ingredients (API) as well as excipients are typically produced by extraction or chemical syntheses. In most cases, the material is subsequently crystallised, mechanically separated, and dried. These steps can often be replaced by spray drying. Spray drying does not only offer

control of the moisture or residual solvent content in the powder, but also enables the creation of powders with a tailor-made particle size distribution, morphology, and nature.



Increased Bioavailability

Many modern molecules have a poor solubility in water or body fluids. It takes an extremely long time for the API crystals to dissolve and for the drug concentration to reach the required level. If the drug is given orally, the dissolution rate may be increased effectively by keeping the spray dried API in amorphous form supported by an excipient polymer.

Modified Release

One way to achieve a therapeutic drug concentration in blood plasma is to encapsulate the API in a biodegradable excipient. Controlled by slowly dissolution of the spray dried particles, the drug is released at a constant rate over a prolonged period of time. To prepare such particles by spray drying, excipients are brought into solution, mixed with API and subsequently spray dried. Alternatively, spray congealing techniques can be used.

As an alternative to “classic” spray drying, it is for some products possible to melt the API together with a meltable excipient encapsulate. As an alternative only the excipient is molten and the API is added just before atomization. The mix is then sprayed into cold process gas. Spray drying as well as spray cooling can be used to modify the release pattern eg. taste masking.

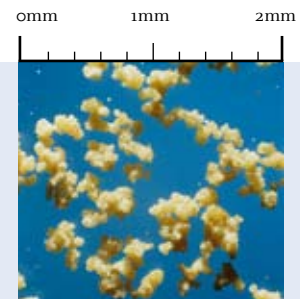
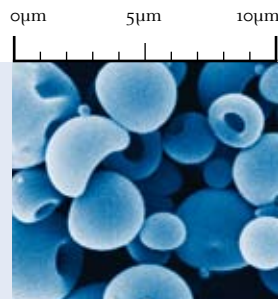
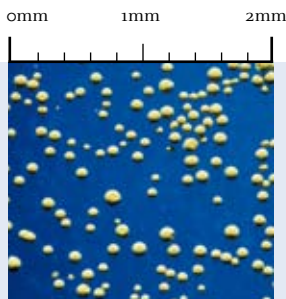
Applications

Secondary Pharmaceuticals

Final drug forms have traditionally been manufactured by routes other than spray drying, but in the last decades many leading companies enjoy the advantages that spray drying technology offers, including unique possibilities of powder engineering and process optimisation.



*SDMicro™ mounted in glove box.
Spray dryer for drying very small quantities
of feeds containing organic solvents*



Aseptic Production

Production of dry sterile dosage forms often involves mixing of the API with one or more excipients. To achieve a homogeneous mixture, the particle size distribution of the excipient(s) must match that of the API. In a one-step-operation, spray drying can turn a sterile solution into sterile particles of the required size with no risk of introducing impurities – a well-known problem if milling is used.

Powders for Inhalation

Spray drying has become the method of choice for the preparation of fine particles for inhalation. The spray dryer must be equipped with a dedicated atomisation device to produce the very fine droplets and a system for collection of the resulting fine particles.

Directly Compressible

Until now, a separate granulation step has often been required in the production of solid dosage forms. The granulate is needed to avoid segregation and to assure good flow properties so the dies of a high-speed tablet press can be filled accurately. With the Fluidized Spray Dryer - FSD™ or IFD™ - concept the granulation step can be an integrated part of the continuous drying process. The FSD™ technology can also be used to achieve a low residual volatiles content in the final spray dried powder.

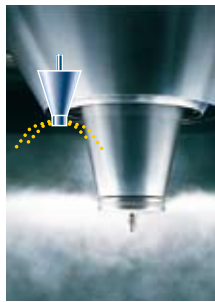
Standardised Customisation

Today's increased demands for customised design, special materials of construction, special surface treatment, advanced control systems, GMP production, and process validation have resulted in continuous improvement in spray dryer design for the pharmaceutical industry.

Atomization and Powder Discharge

One of the most important choices in a plant configuration is choosing the right atomization and powder discharge method. We offer a wide range of solutions as illustrated.

Atomizer/
Nozzle Options



Rotary atomizer



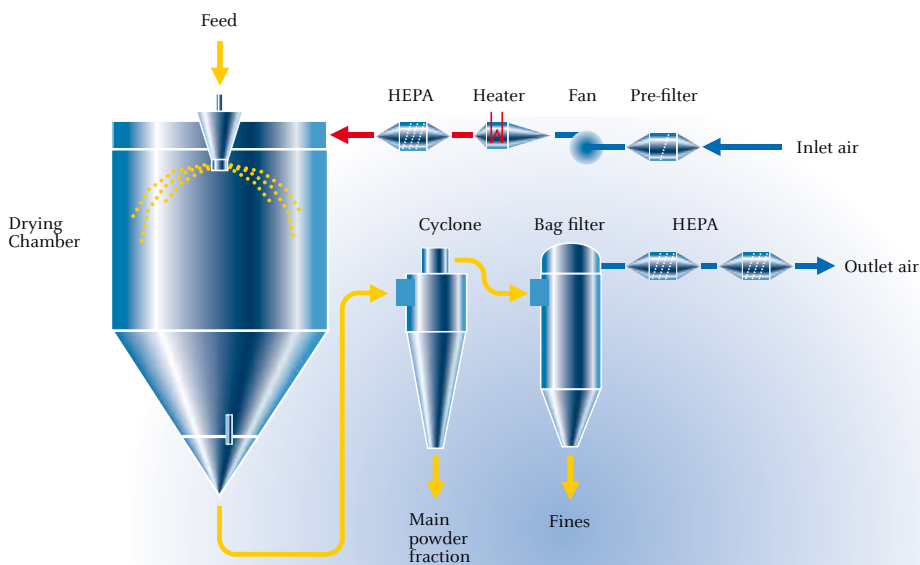
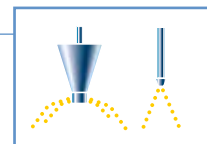
Pressure or two-fluid nozzle,
co-current mode



Pressure or two-fluid nozzle,
fountain mode

Single Point Discharge

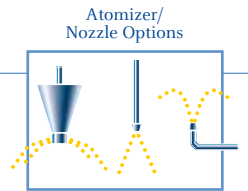
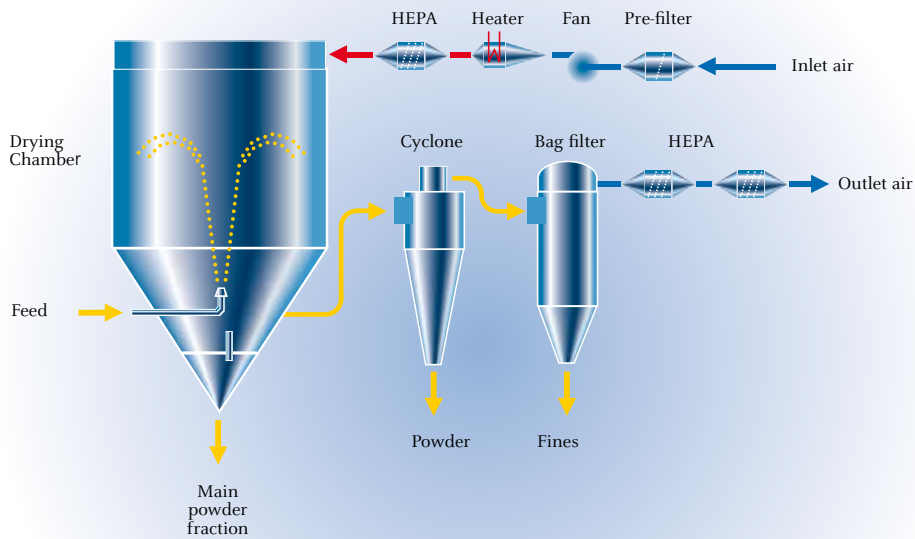
Atomizer/
Nozzle Options



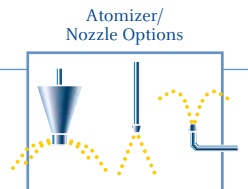
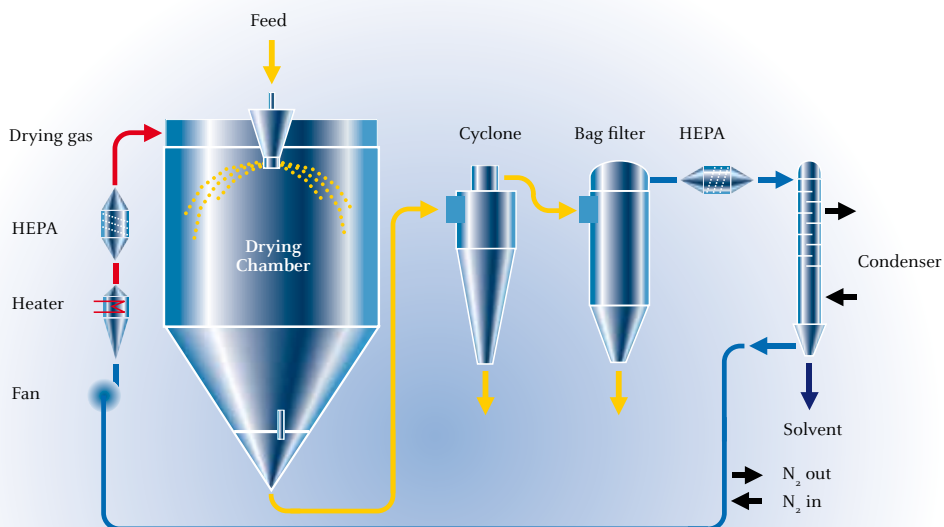


Spray Drying Concepts

Two Point Discharge



Closed Cycle Design



Meeting Every Requirement

To meet the high requirements from the pharmaceutical industry, Niro has developed a series of spray dryers, the PHARMASD™ (PSD).

Tailor-Made Solutions

The philosophy behind the design is that a combination of standardised modules are built together in order to meet the requirement for a specific duty. Therefore, dryers of equal capacity may be completely different with respect to design, configuration and physical size.

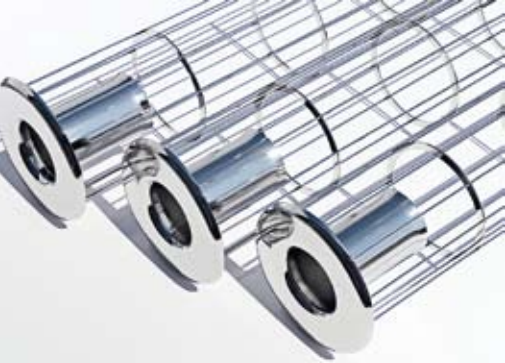
Spray Drying Organic Solvents

The use of solvents when preparing pharmaceutical ingredients poses a challenge in the drying process and has resulted in the use of nitrogen as a drying gas. Our spray dryers are configured for drying of compounds that are based on acetone, methylene chloride, ethanol, and other organic solvents.

The drying parameters and capacity vary greatly, depending on the solvent used, as shown in the tables on page 12-13.



From Niro Pharma Test Station in Copenhagen: GMP facility including a PSD-4 spray dryer operating in closed cycle mode



PHARMA^{SD}™

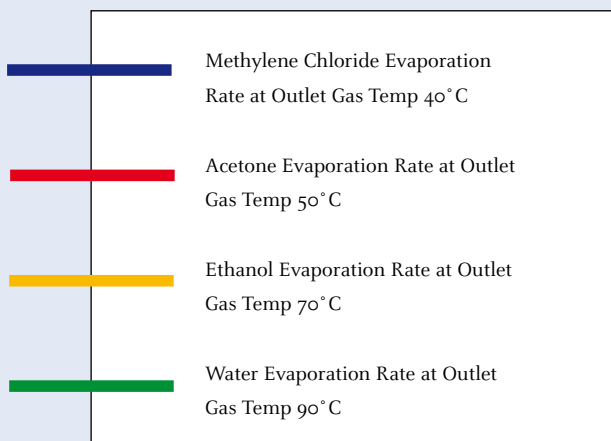


From Niro Pharma Test Station in Copenhagen: GMP suite with a PSD-1 spray dryer in closed cycle mode



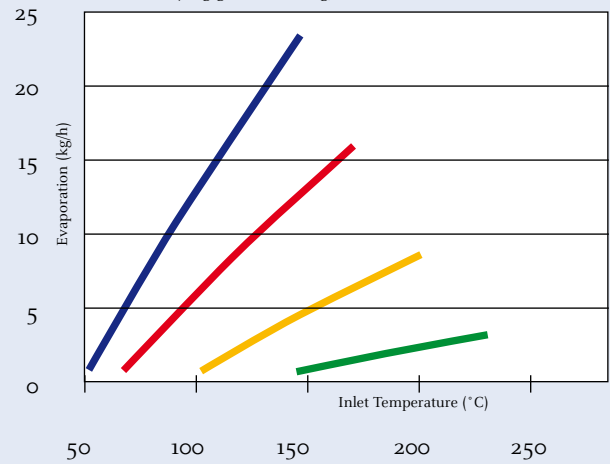
SDMicro™ R&D and laboratory spray dryer. Nominal drying gas rate: 30 kg/h

The PHARMA^{SD}™ Series



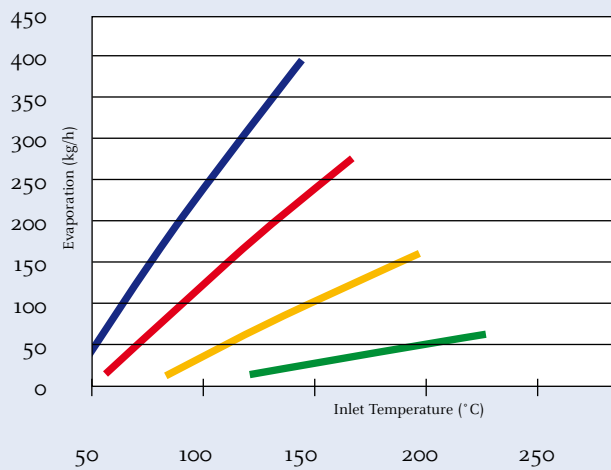
PSD-1 co-current atomization

Nominal drying gas rate: 80 kg/h



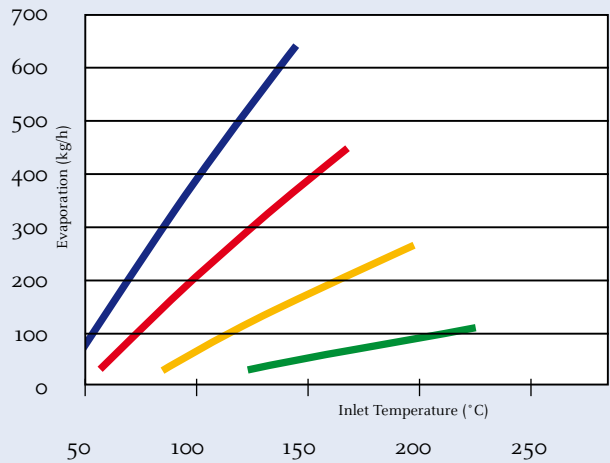
PSD-4 co-current atomization

Nominal drying gas rate: 1250 kg/h



PSD-5 co-current atomization

Nominal drying gas rate: 2000 kg/h

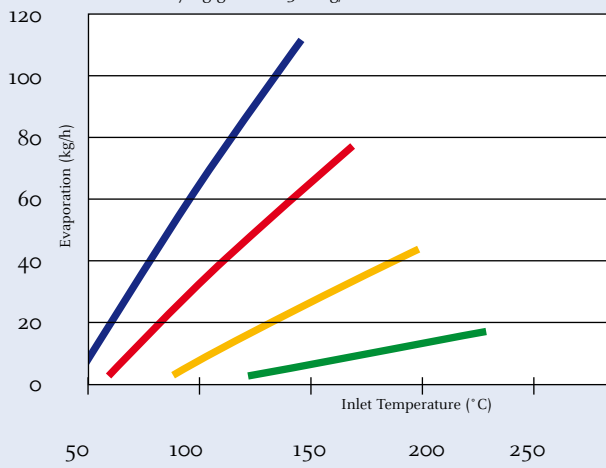




PHARMA^{SD}™

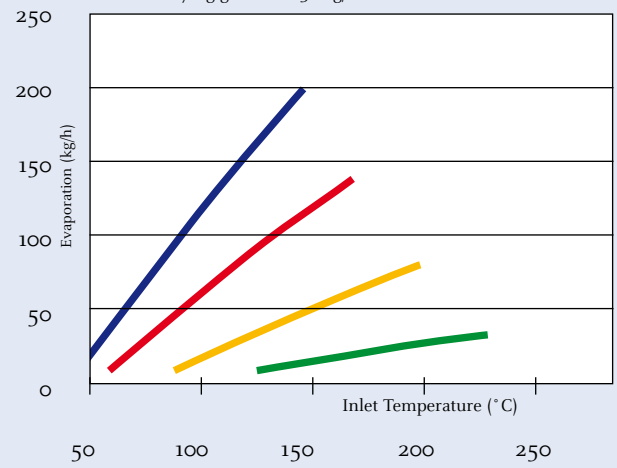
PSD-2 co-current atomization

Nominal drying gas rate: 360 kg/h



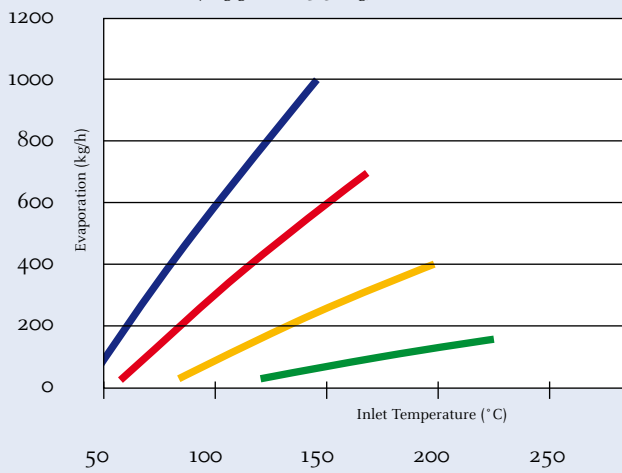
PSD-3 co-current atomization

Nominal drying gas rate: 630 kg/h



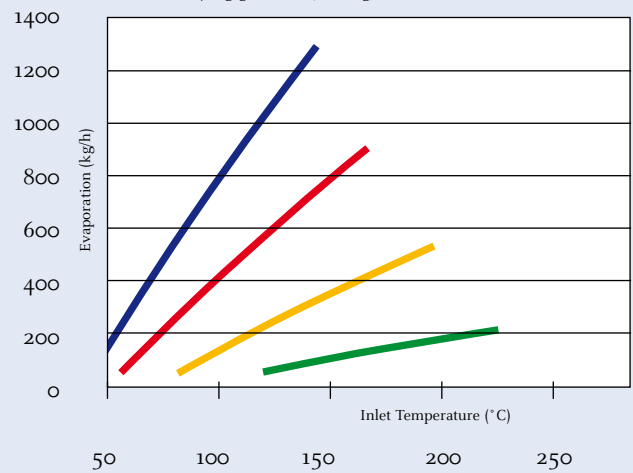
PSD-6 co-current atomization

Nominal drying gas rate: 3150 kg/h



PSD-7 co-current atomization

Nominal drying gas rate: 4000 kg/h





Plant Components .

Single-unit manufacturing combined with the use of standard modules has replaced serial plant production within the pharmaceutical industry, enabling truly customised solutions based on proven systems.

Each module, indeed each system component, must meet the strictest requirements and regulatory standards around the world.

PharmaSD™ design options include:

- Equipment for closed-cycle operation
- Facilities for hot gas sanitisation
- Sanitary duct connections
- Certified construction materials
- HEPA filters for gas streams
- Special process gas disperser design
- Swirl cone for chamber access
- CIP equipment
- Mirror polished surface
- Explosion protection systems



Double HEPA filter housing for safe change of filter inserts using the "Bag-in / Bag-out" principle. For PSD-5 spray dryer



Manufacturing of drying chamber and cyclone under strict quality control

The Complete Partnership .

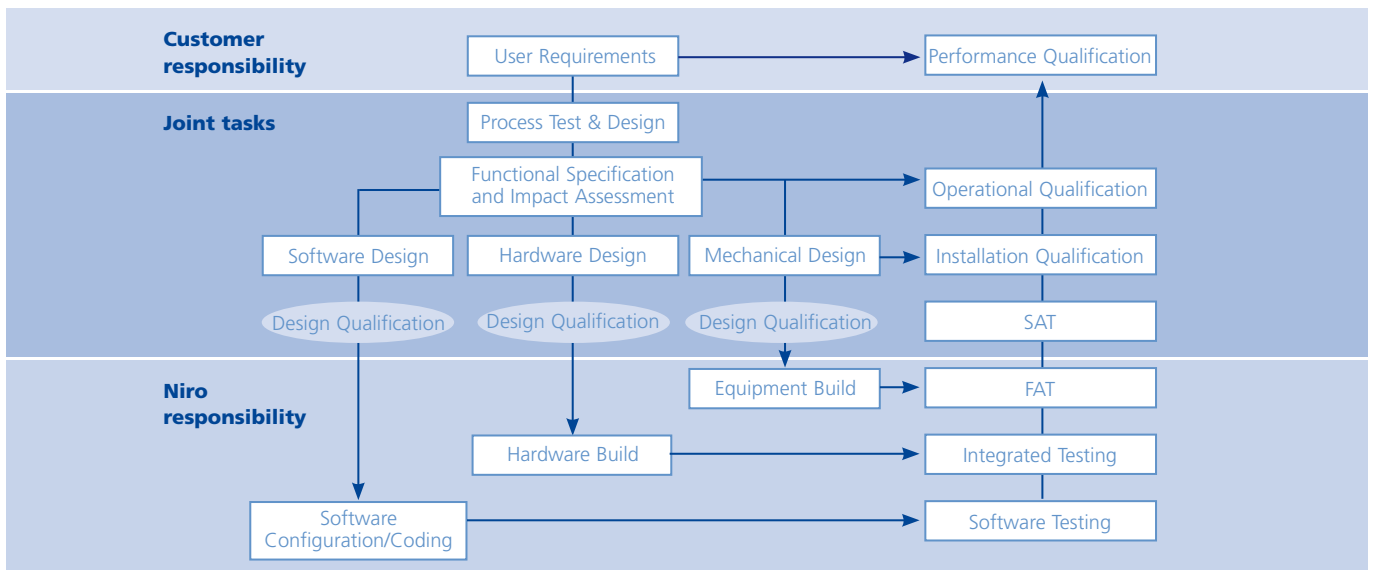
Working with You...

Entering a partnership with Niro means entering a partnership that does not end until you are completely satisfied. From the moment you have specified your user requirements and until the plant has been put into service and has been qualified, our trained staff stays with you at every step of the process, working in close co-operation with your own staff creating the components and systems that will result in a qualified plant.

...Every Step of the Way

Based on years of experience, equipment qualification will be carried out according to an agreed plan using documents prepared by Niro.

Our engineers will contribute to a successful qualification of the equipment in close co-operation with your validation staff.



Two-fluid nozzle dedicated for large scale GMP production of very fine particles (Patent pending)



Rotary atomizer F1.5 X designed to meet cGMP requirements (Patent pending)



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.



GEA Pharma Systems

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