



Process Engineering
Division

Niro Pharma Systems

AEROMATIC
BUCK
COLLETTE
COURTOY
FIELDER
LYOPHIL
NICA
NIRO

Niro Spray Dryers

for the
Pharmaceutical
Industry

- Flexible
- Scalable
- Reliable
- Controllable





For over 70 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.

Product Know-How

- Process Expertise



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 manufacturing industry.



Delivering the Right Solutions

Every Niro plant begins with the customer's desire to create 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.

Plants 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 as described in this brochure.

A Partnership in Every Perspective

Working with Niro means entering a solid partnership every step of the way, from process testing and design to specification of the software controlling your new plant. And our comprehensive after sales program ensures that your return on investment is optimised throughout the lifetime of the plant.



Primary *Pharmaceuticals*

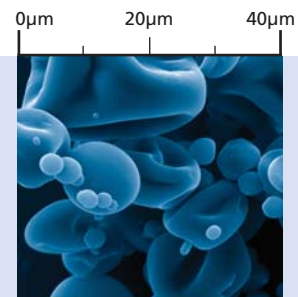
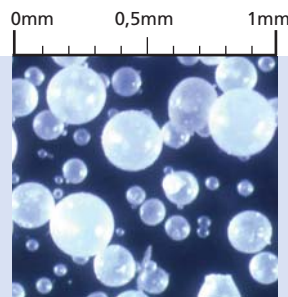
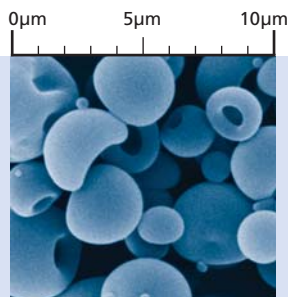
Active Pharmaceutical Ingredients (API) as well as excipients are typically produced by extraction or chemical syntheses. In most cases, the material is subsequently crystallised, mechanically separated, and dried. These steps can often be replaced by

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 materials with a tailor-made particle size distribution, morphology, and nature.

Secondary *Pharmaceuticals*

Final drug forms have traditionally been manufactured by routes other than spray drying, but now, many leading companies enjoy the

advantages that spray drying technology offers, including unique possibilities of powder engineering and process optimisation.



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 special atomisation device to produce the very fine droplets and a device for collection of the resulting fine particles.

Sustained Release

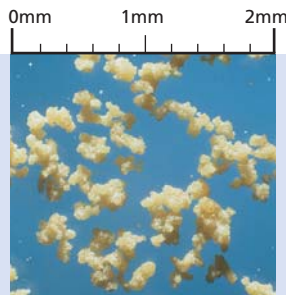
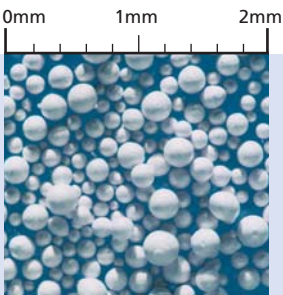
One way to achieve a constant drug concentration in blood plasma is to encapsulate the API in a biodegradable excipient. Controlled by slowly dissolution of the spray dried particles, the drug is released at a constant rate over a prolonged period of time. To prepare such particles by spray drying, excipients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

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 product is given orally, the dissolution rate may be increased effectively by keeping the spray dried API in amorphous form supported by an excipient polymer.



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



Taste Masking

As an alternative to "classic" pharmaceutical production, it is 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. This process forms a matrix in which the release can be controlled to a certain degree.

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 dyes 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.

Sterile Excipients

Production of dry sterile dosage forms often involves large-scale 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 of the excipient into sterile particles of the required size with no risk of introducing impurities – a well-known problem if milling is used.



Spray Drying

Standardised Customisation...

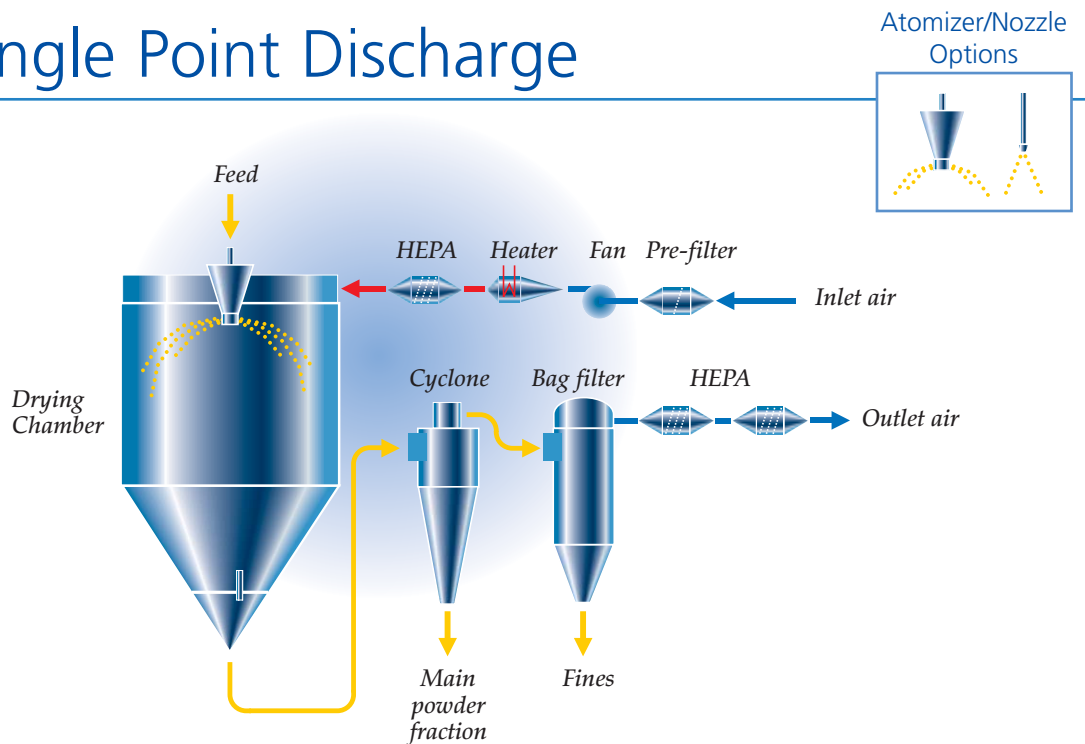
Today's increased demands for customised design, special materials of construction, special surface treatment, advanced control systems, GMP production, and process validation have resulted in continuous improvement in spray dryer design for the pharmaceutical industry.

Atomization and Powder Discharge

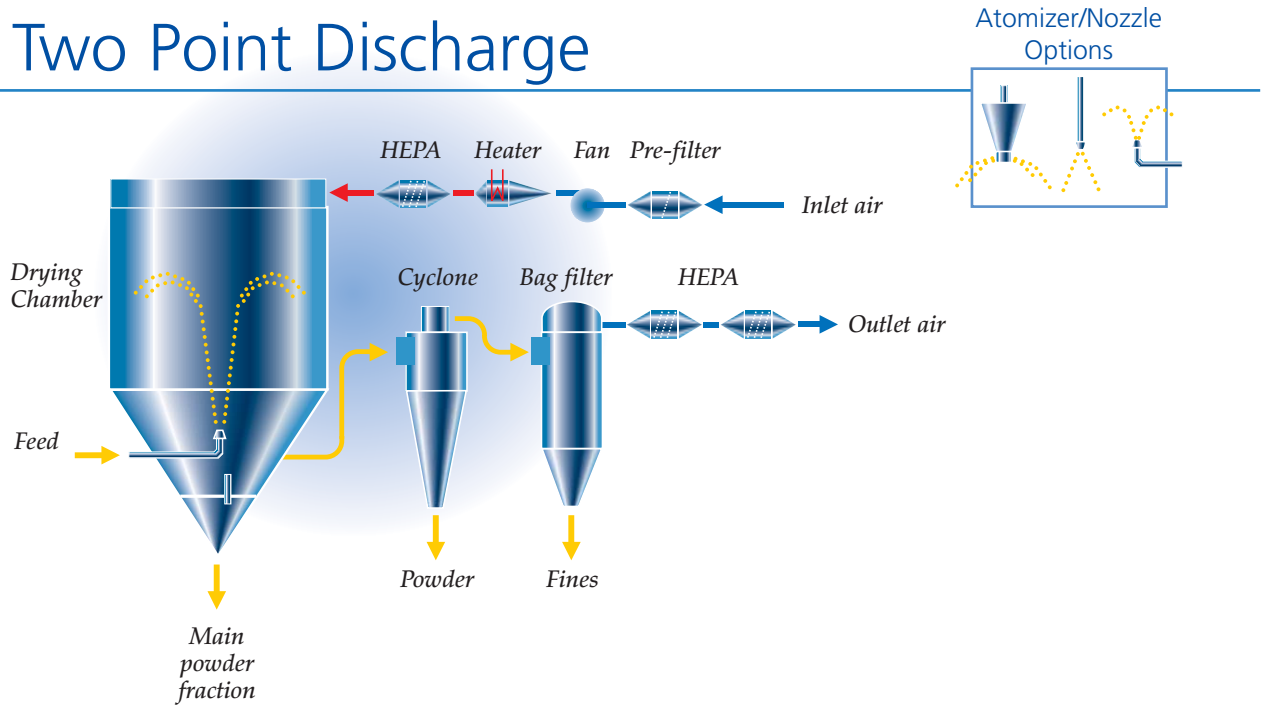
One of the most important choices in a plant configuration is choosing the right atomization and powder discharge method. We offer a wide range of solutions as illustrated below and to the right.

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

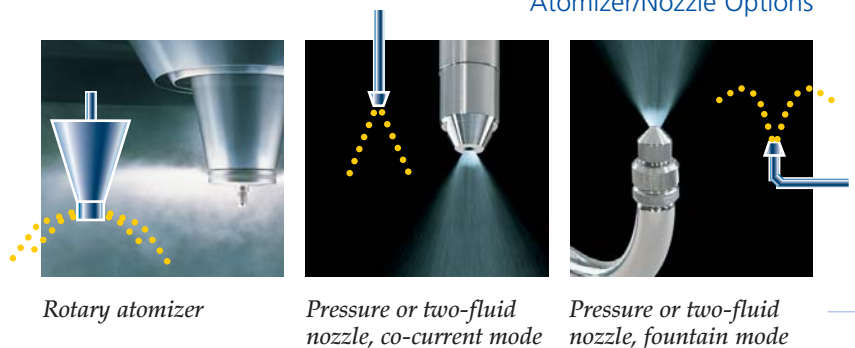
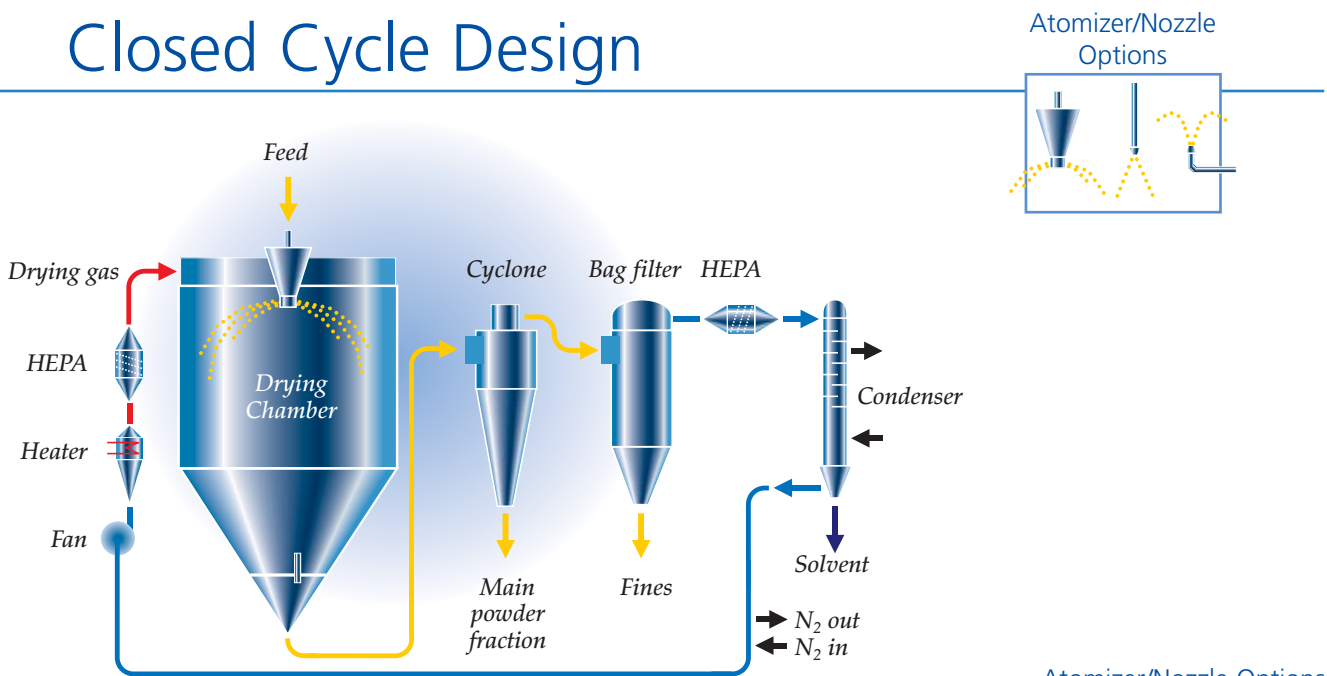
Single Point Discharge



Two Point Discharge



Closed Cycle Design



PHARMASD™

- 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 Standard

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



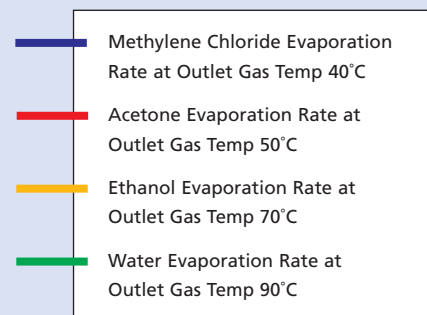
GMP facility including a PSD-4 spray dryer operating in closed cycle mode



Table top aseptic spray dryer - ASEPTICSD™
Nominal drying gas rate: 30 kg/h

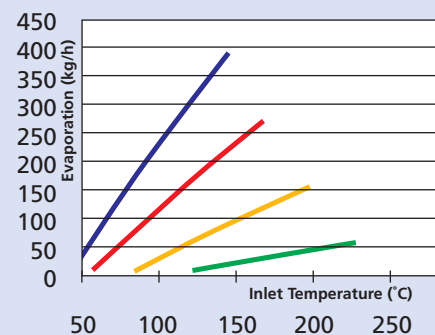
has resulted in the use of nitrogen as a drying gas. Our spray dryers are configured for drying of compounds that are based on acetone, methylene chloro-

The PHARMASD™ Series



PSD-4 co-current atomization

Nominal drying gas rate: 1250 kg/h





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

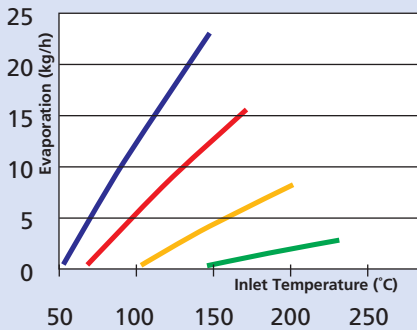
ride, ethanol, and other organic solvents.
The drying parameters and capacity vary greatly, depending on the solvent used, as shown in the tables below.



PSD-1 Spray dryer with cyclone and bag filter

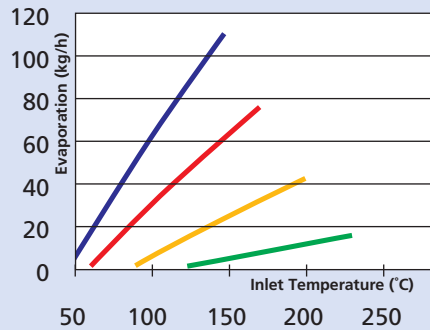
PSD-1 co-current atomization

Nominal drying gas rate: 80 kg/h



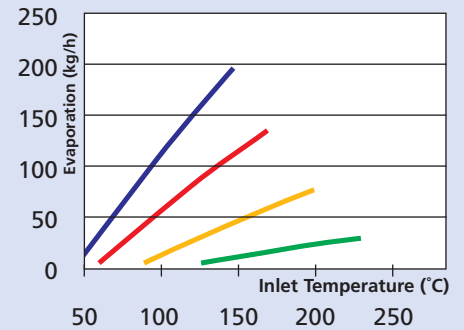
PSD-2 co-current atomization

Nominal drying gas rate: 360 kg/h



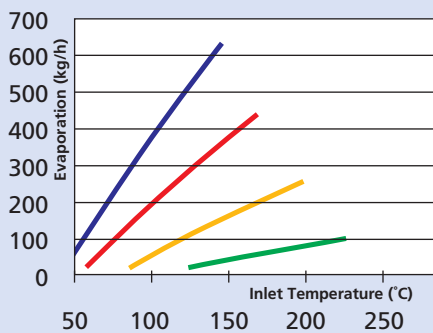
PSD-3 co-current atomization

Nominal drying gas rate: 630 kg/h



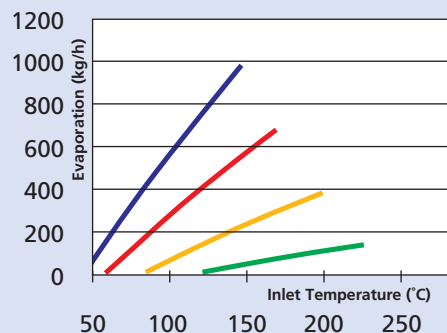
PSD-5 co-current atomization

Nominal drying gas rate: 2000 kg/h



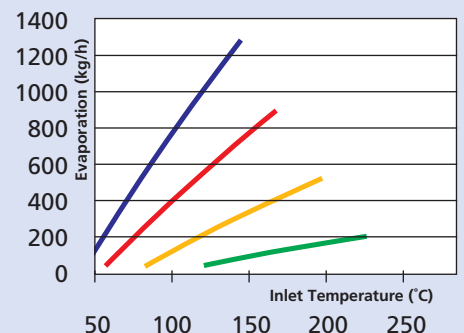
PSD-6 co-current atomization

Nominal drying gas rate: 3150 kg/h



PSD-7 co-current atomization

Nominal drying gas rate: 4000 kg/h





Plant Components

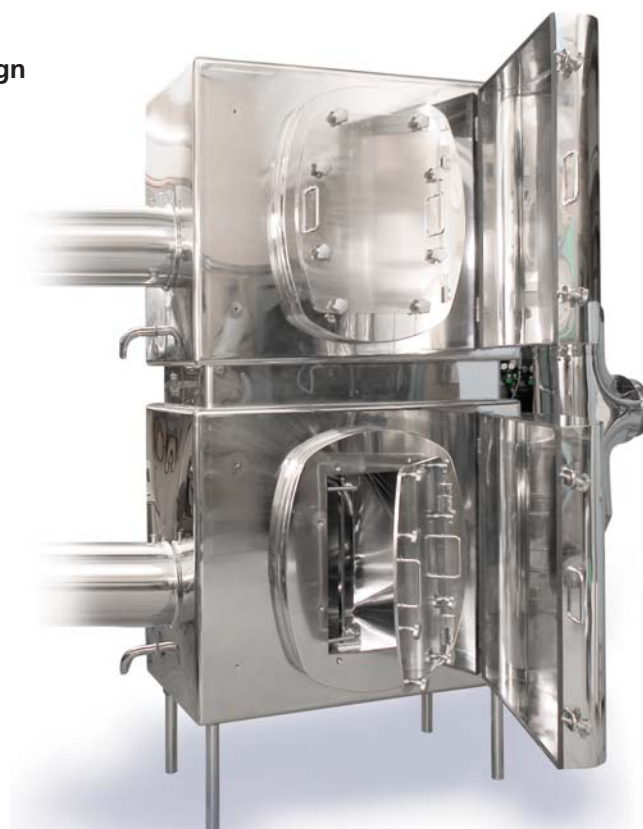
PHARMASD™ design options include:

- Equipment for closed-cycle operation
- Facilities for hot gas sanitisation
- Special sanitary duct connections
- Special 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

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.

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





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 finished plant.

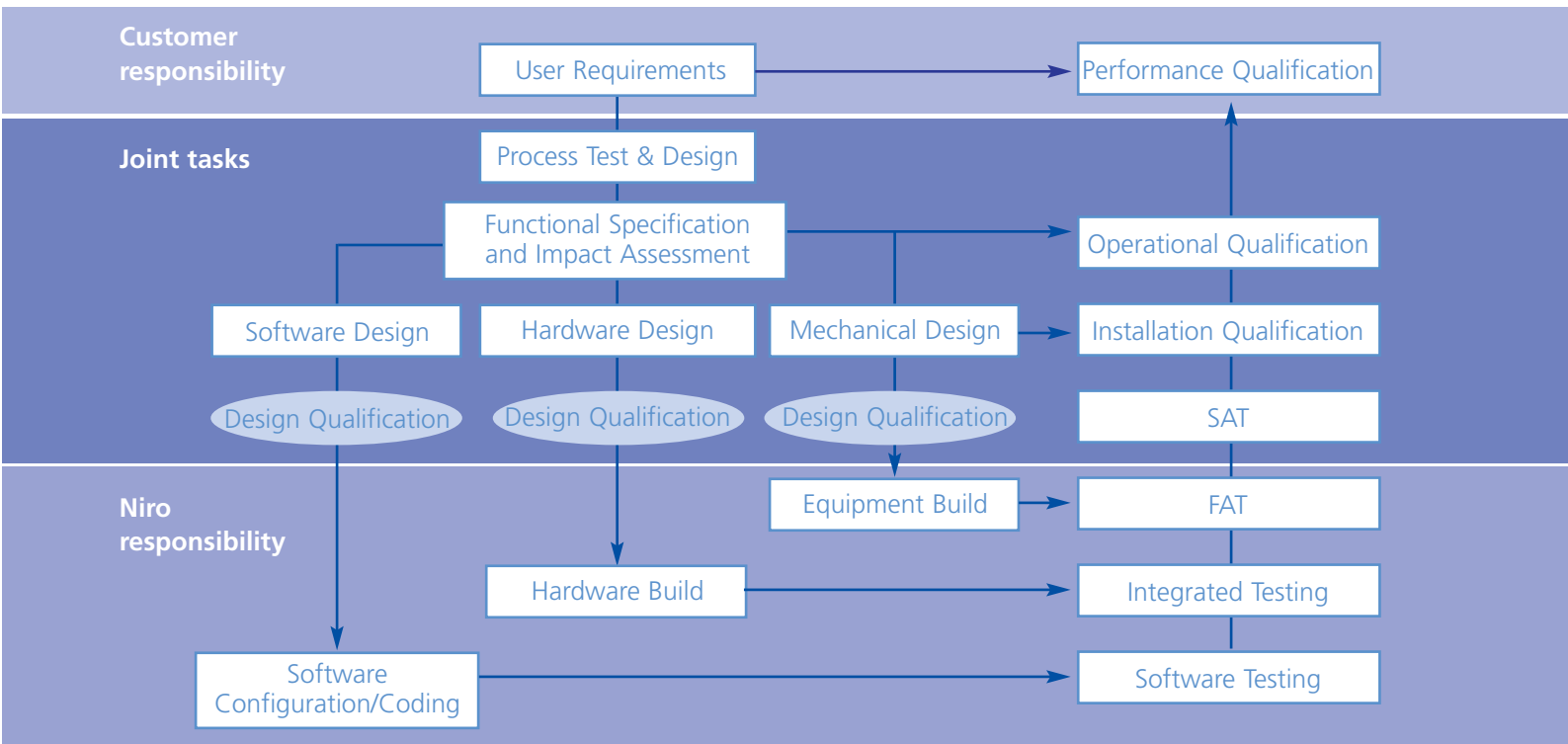


Two-fluid nozzle dedicated for large scale GMP production of very fine particles (Patent pending)



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

The Complete Partnership



...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.



Niro Pharmaceutical Test Station

Denmark: Spray drying technology



NPS Technology Centre

Switzerland: Solid dosage technology



Niro A/S

Denmark

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, Lyophil, Nica, and Niro.

Niro A/S

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