



Process Engineering
Division

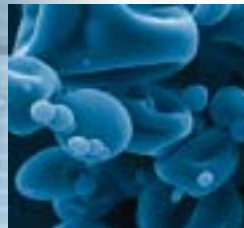
Niro Pharma Systems

AEROMATIC
BUCK
COLLETTE
COURTOY
FIELDER
NICA
NIRO

Niro Spray Dryers

for the
Pharmaceutical
Industry

- Flexible
- Scalable
- Reliable
- Controllable





For over half a century, 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 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.

Among the large number of variations are: The right size to meet the customer's output requirements, the drying principle to be used, atomisation configuration, and open or closed cycle operation.

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.

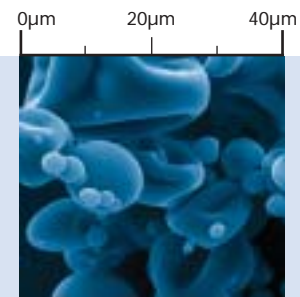
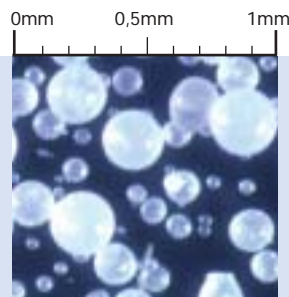
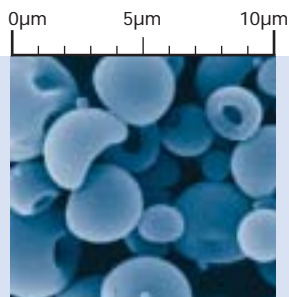


Primary *Pharmaceuticals*

Active Pharmaceutical Ingredients (API) 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,

which not only allows the customer to control the moisture or residual solvent content in the powder but also to create materials with a tailor-made particle size distribution, morphology, and nature.

Secondary *Pharmaceuticals*



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 fine particle collection.

Encapsulation

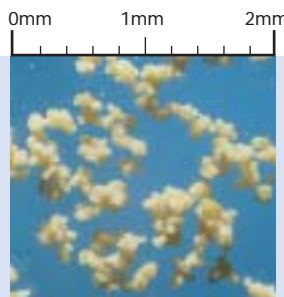
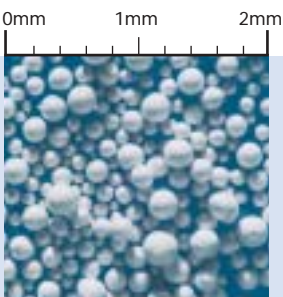
One way to achieve a constant drug level in a patient's body is to encapsulate the API in a biodegradable polymer. Controlled by diffusion, the drug is released at a constant rate over a prolonged period of time. To prepare such particles by spray drying, API and polymer are brought into solution and spray dried. Alternatively, spray congealing techniques can be used.

Increased Bioavailability

Some modern molecules can have a poor solubility in water or body fluids. Thus 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 using a polymer.



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



Spray Congealing

As an alternative to "classic" pharmaceutical production, it is possible to melt the active together with a polymer to enhance bio-availability. As an alternative only the polymer is molten and the active is incorporated just before atomization. The mix is then sprayed into cold process gas. This process can form a matrix in which the release can be easily controlled by the selection of the process conditions without the need for an additional coating step.

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 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.

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...

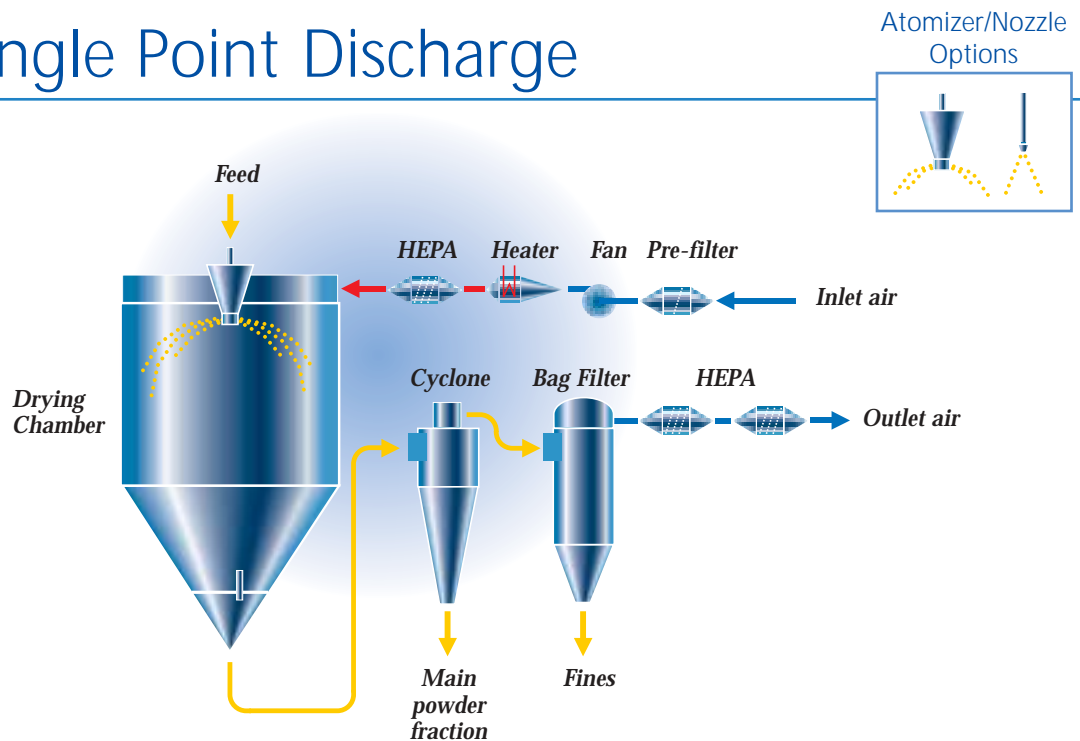
Today's increased demands for customised design, special materials of construction, special surface treatment, advanced control systems, GMP production, and process validation have resulted in continuous improvement in spray dryer design for the pharmaceutical industry.

Atomization and Powder Discharge

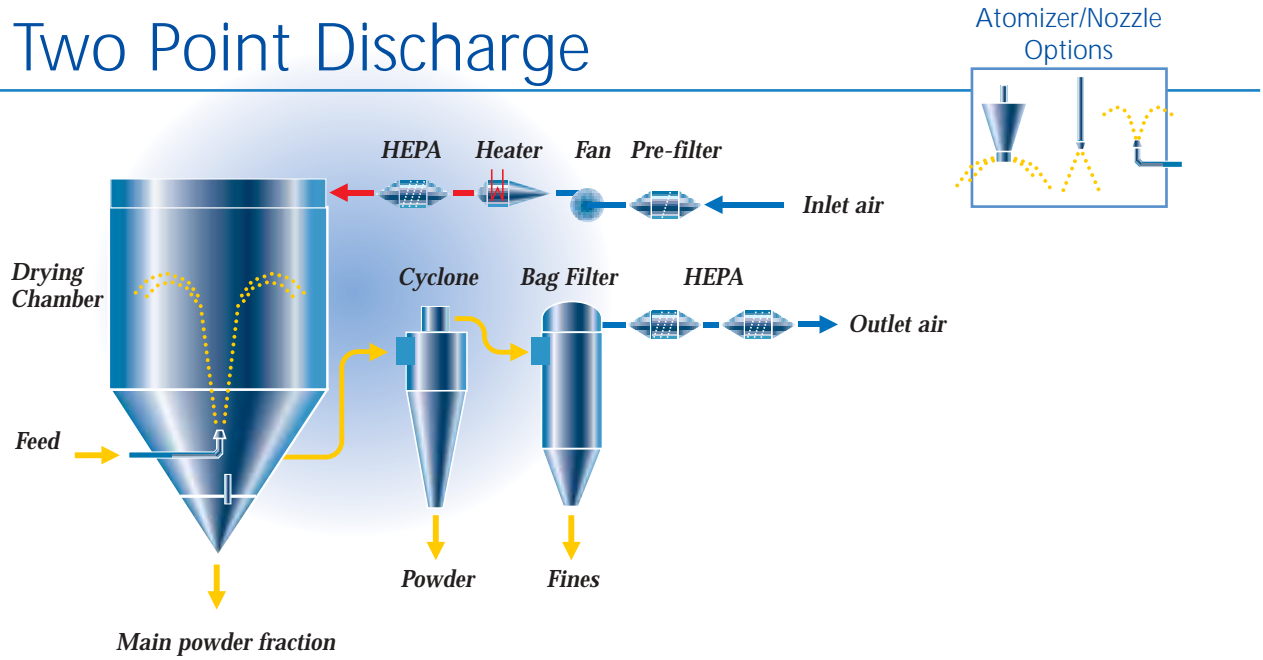
One of the most important choices in a plant configuration is choosing the right atomization and powder discharge method. We offer a wide range of solutions as illustrated below and to the right.

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

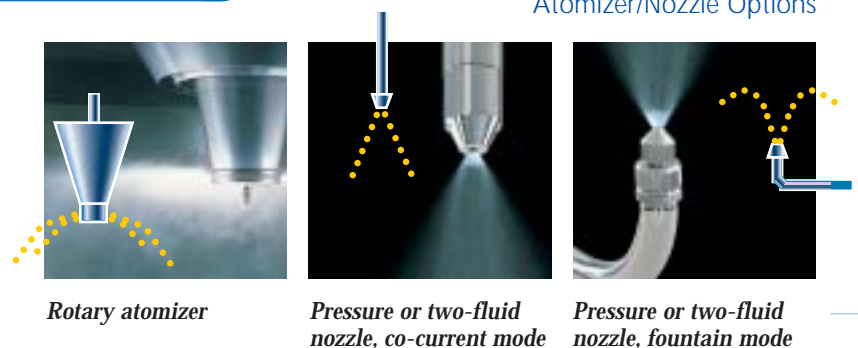
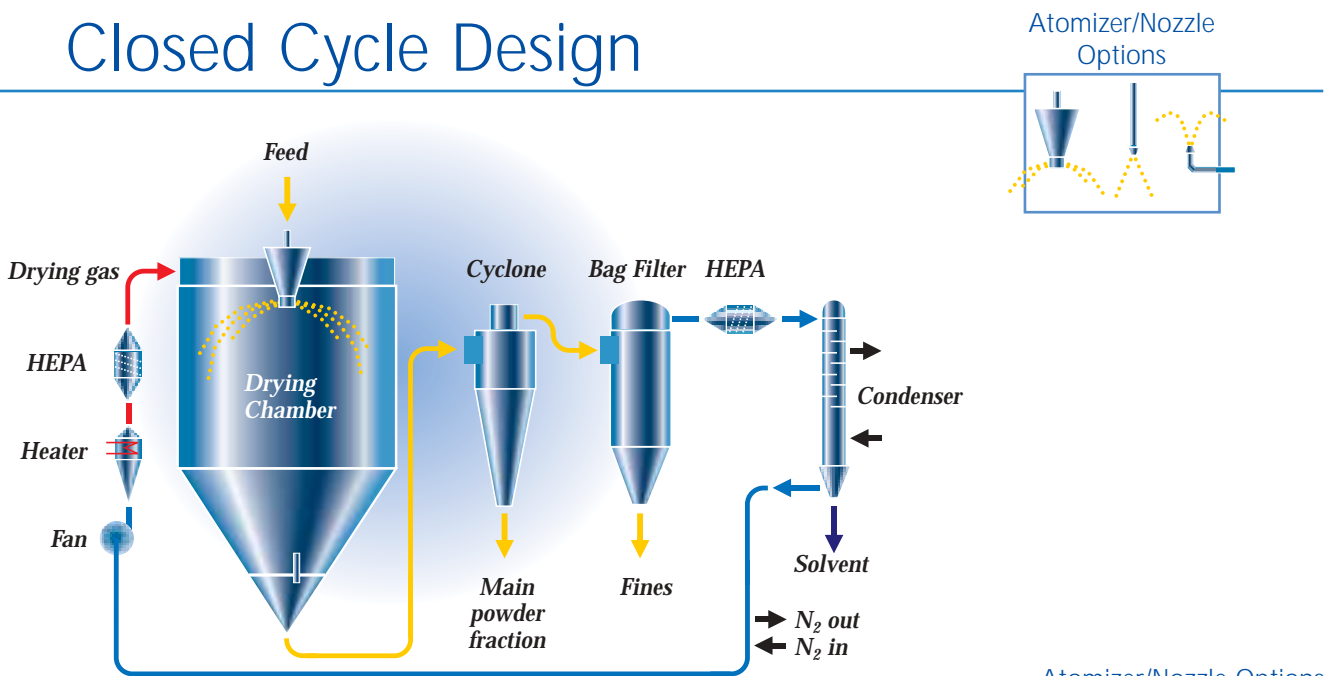
Single Point Discharge



Two Point Discharge



Closed Cycle Design



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



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



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

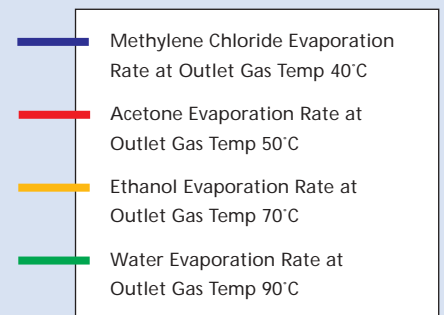
The philosophy behind the design is that a combination of standardised modules are built together in order to meet the requirement for a specific duty. Therefore, dryers of equal capacity may be completely different with respect to design, configuration and physical size.

Spray Drying Organic Solvents

The use of solvents when preparing pharmaceutical ingredients poses a challenge in the drying process and 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

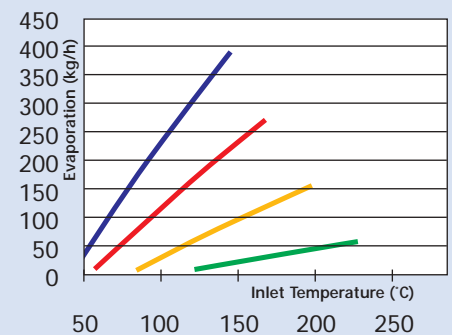
solvents. The drying parameters and capacity vary greatly, depending on the solvent used, as shown in the tables below.

The PHARMASD™ Series



PSD-4 co-current atomization

Nominal drying gas rate: 1250 kg/h



PSD-4 closed cycle spray dryer



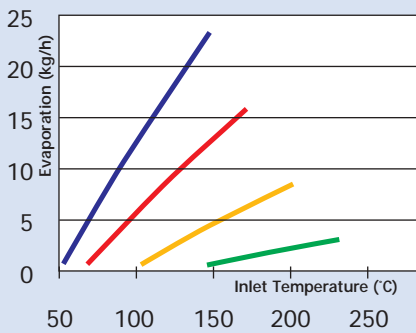
PSD-1
 Spray dryer with
 cyclone and bag filter



PSD-2
 Spray dryer equipped for steam sterilisation

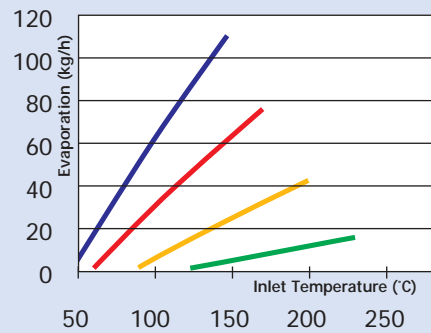
PSD-1 co-current atomization

Nominal drying gas rate: 80 kg/h



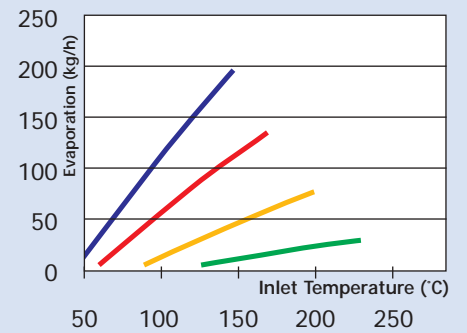
PSD-2 co-current atomization

Nominal drying gas rate: 360 kg/h



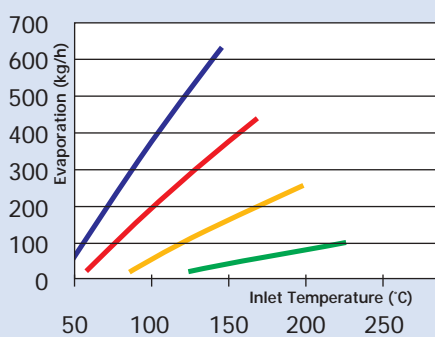
PSD-3 co-current atomization

Nominal drying gas rate: 630 kg/h



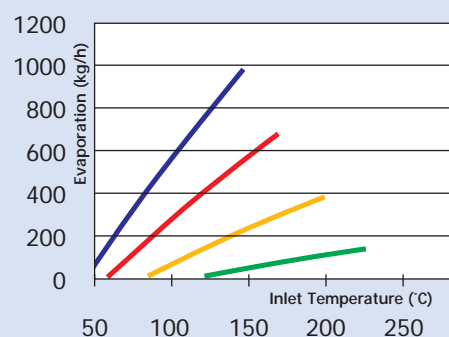
PSD-5 co-current atomization

Nominal drying gas rate: 2000 kg/h



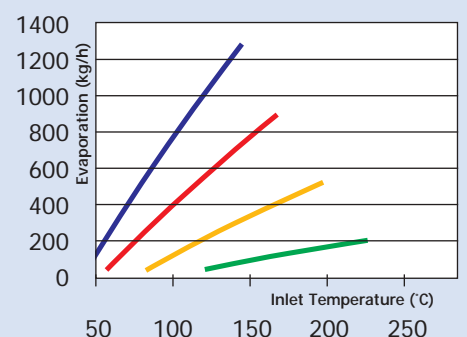
PSD-6 co-current atomization

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 plants 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.



1. Insulated and mirror polished ducts
2. V-duct with ports for CIP nozzles
3. Removable CIP nozzle mounted in duct
4. Bag filter cages
5. Actuated damper with inflatable sealing
6. Insulated cyclone: Ø 140mm

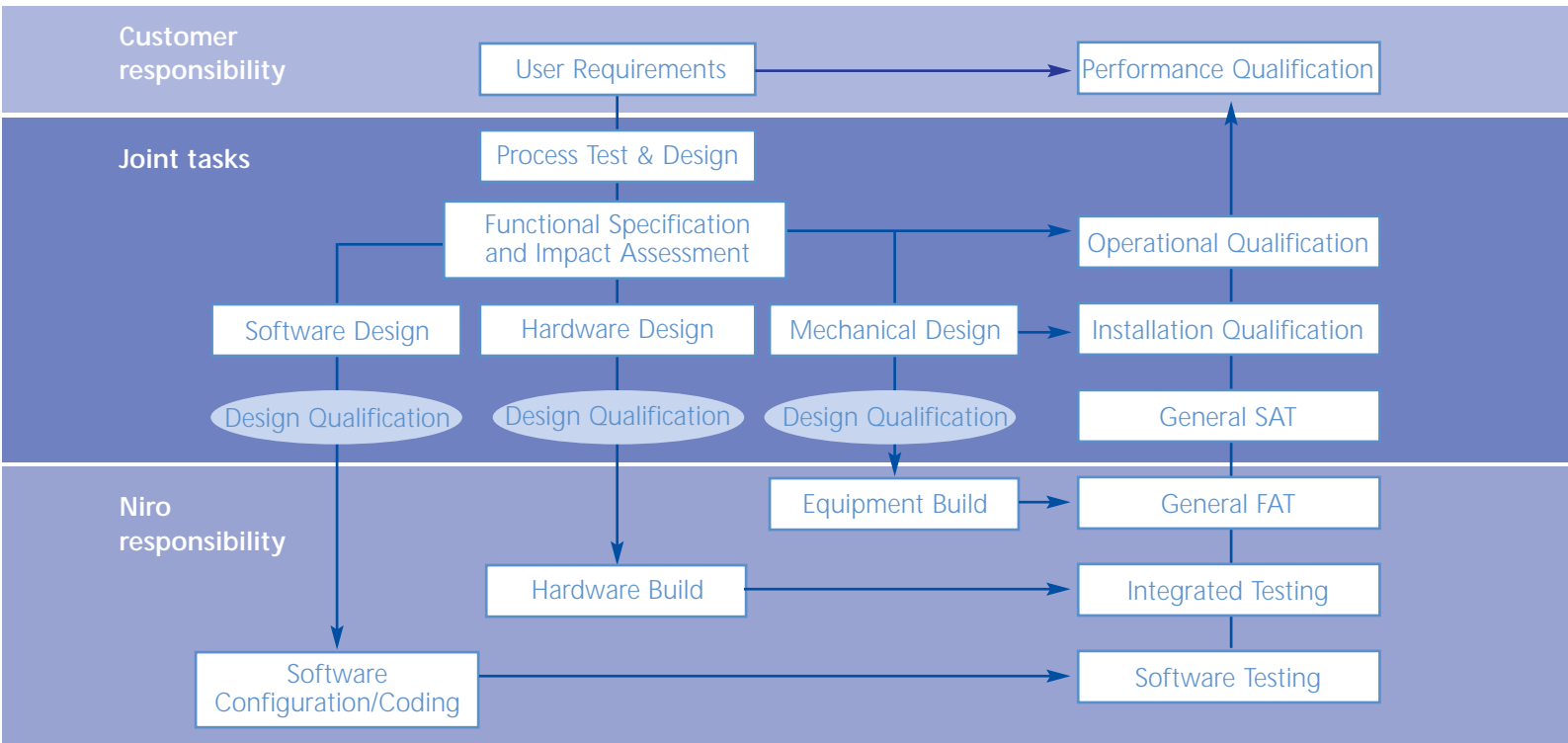


*Rotary atomizer F1.5 X
designed to meet
cGMP requirements.*

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 finished 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.



Niro Pharmaceutical Test Station

Denmark: Spray drying technology



Niro Pharmaceutical Technology Centre

USA: Coating and 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, Nica, and Niro.

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