

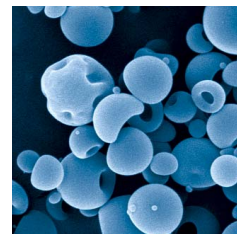


Process Engineering  
Division

Niro Pharma Systems

AEROMATIC  
BUCK  
COLLETTE  
COURTOY  
FIELDER  
LYOPHIL  
NICA  
NIRO

# NIRO PHARMA TEST STATION SPRAY DRYING



GET TO MARKET FASTER  
AND MORE EFFECTIVELY



# THE WORLD'S MOST ADVANCED GMP TEST STATION FOR SPRAY DRYING

If you're committed to turning your new discoveries into commercial drugs quickly and cost-effectively, the Niro Pharma Test Station can help you take an important step in the right direction.

The Niro Pharma Test Station is an addition to the well-established Niro Test Center, which is the world's major competence center for spray drying technology. No one knows more about engineering high-performance powders than the experienced process technologists at Niro.

The Niro Pharma Test Station is the world's most advanced GMP test station for spray drying. It not only helps you refine products and processes under GMP conditions – with minimum development time and maximum security of outcome. It also enables you to limit your upfront investment in spray drying equipment until you're sure you have a viable commercial product.

Whether you're at the early stages of product development or in the final phases of process refinement, Niro offers you unparalleled spray drying know-how.

## 70 YEARS EXPERIENCE AT YOUR SERVICE

As the world's leading supplier of spray dryers, Niro has more than 70 years experience in spray drying. Furthermore, we've spent more than a decade refining our technology specifically for use within the area of final solid dosage drug forms.

Niro spray drying offers a number of unique advantages for pharmaceutical companies: Bioavailability, encapsulation, aseptic production and inhalation.



*The Niro Pharma Test Station is built according to GMP standards for final drug production with a cleanroom for powder collection and process control that is 21 CFR part 11 compliant. It includes two fully equipped spray dryers, a PSD-1 and a PSD-4, both in closed-cycle execution. This allows for realistic full-size testing or generation of data for safe scale-up.*

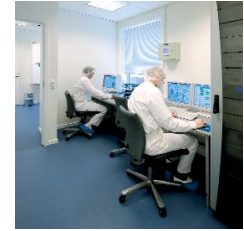


PSD-4 powder collection

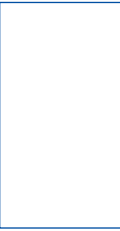
The Niro Pharma Test Station meets the EU's requirements for the production of Investigational Medicinal Products (IMP) and exists exclusively to aid Niro customers in drug development projects. It is approved by the Danish Medicines Agency.



Air lock to PSD-4 cleanroom



Main control room



### BIOAVAILABILITY

Now you can open the door for new, important treatments that are currently shelved due to low bioavailability. With spray drying you can co-precipitate an API with a polymer in a stable amorphous solid dispersion, thereby greatly improving the dissolution rate of the spray-dried powder. Likewise, nano-particles can be transformed into easy-to-handle powders.

### ENCAPSULATION

Spray drying as well as spray congealing make it possible to create particles that can fashion specific controlled release patterns and other properties – giving you a variety of commercial and pharmacological advantages. These include prevention of drug concentration peaks, reduced side effects and effective taste masking.

### ASEPTIC PRODUCTION PRE-STUDIES

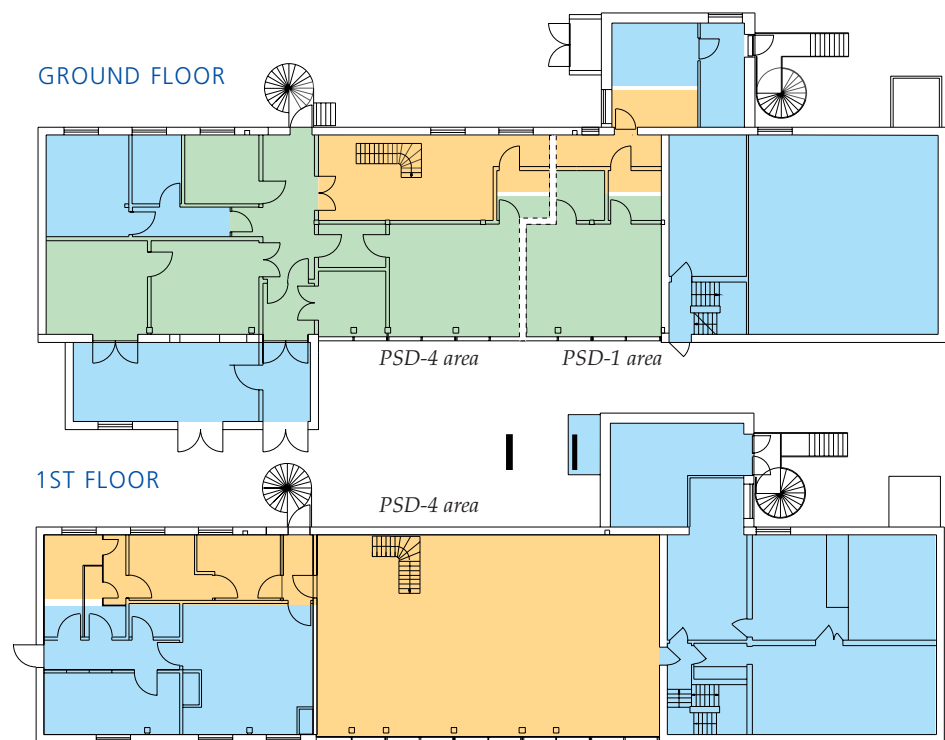
Spray drying offers a number of advantages over traditional methods of aseptic drying such as freeze drying. By providing precise control of the drying process, spray drying gives you far greater command over the shape, density and morphology of the final product. Although the Niro Pharma Test Station cannot offer actual aseptic production, valuable pre-studies can ensure proof of concept and help you decide on appropriate further steps.

### INHALATION

Niro has developed highly specialised spray drying nozzles (patent pending) that give you far greater particle engineering capabilities, even at a large scale, making it possible to accurately manipulate the aerodynamic particle size.

## FLOOR PLAN : PHARMA TEST STATION

- GMP Processing area
- GMP Non-Processing area
- Non-GMP area



# INVEST IN RELIABLE RESULTS, QUICKLY

Which characteristics are most advantageous for your product? How can a spray drying process be designed to meet your product expectations? Is the process robust? The Niro Pharma Test Station enables you to answer crucial questions about your product and processes and achieve proof of concept quickly and effectively – before you've made a significant investment in production facilities and in-house expertise.

## TOXICOLOGY STUDIES AND CLINICAL TRIALS MATERIAL

Use the Niro Pharma Test Station to produce material for safety, stability and toxicology studies and clinical trials. The production facilities are fully qualified and approved by the Danish Medicines Agency, and a comprehensive SOP system supports the activities.

## SMALL-SCALE EFFICIENCY, FULL-SCALE EXPERTISE

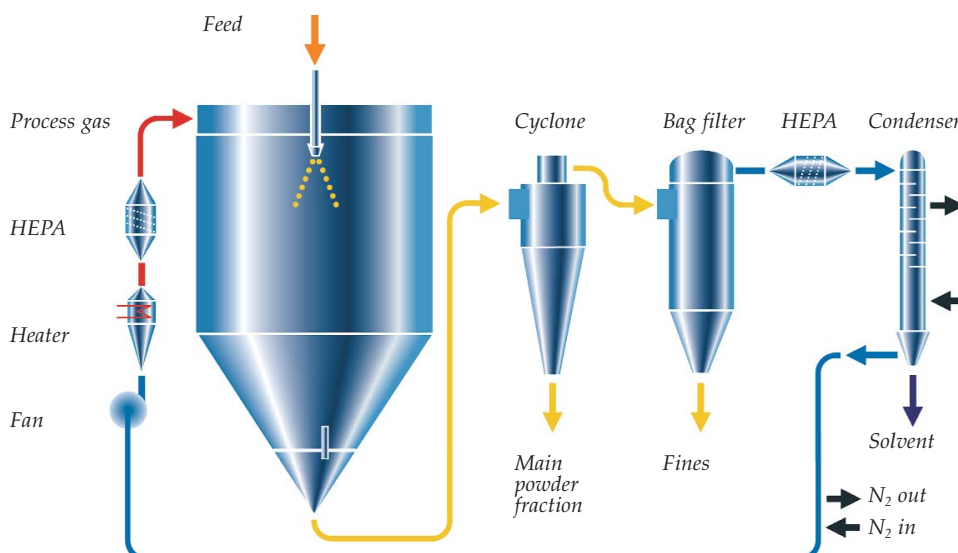
The Niro Test Center, which includes GMP as well as non-GMP facilities, encompasses resources ranging from table-top equipment to full-size spray drying plants. To minimise your costs, we conduct initial testing under non-GMP conditions, using the same type of processes as in the GMP test station. This enables us to refine product and process parameters in a flexible environment.

Because you are able to run full-scale tests, you can also train key personnel and qualify processes while establishing a commercial production unit. This substantially compresses the time used in the "tech transfer" and the switch to commercial production.

*Feed characteristics and final product requirements determine selection of the atomizing device and process parameters.*



## CLOSED CYCLE SPRAY DRYING PROCESS



*The spray drying process consists of four basic stages:*

- atomization
- contact with drying gas
- particle formation
- powder recovery

*Instant drying and, consequently, fast stabilisation of feed material at moderate temperatures means spray drying is also suitable for heat-sensitive materials.*



Raw material reception



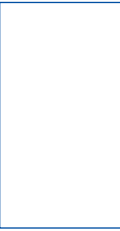
Feed preparation



PSD-4 chamber and HVAC ducts



PSD-4 chamber cone in cleanroom



## PSD-1

### PLANT CONFIGURATION

- Main components: Chamber, cyclone, bag filter, HEPA-filters, condenser, electrical heater
- Nitrogen as drying gas
- Closed-cycle loop
- Powder collection under cyclone. Bag filter for collecting fines
- Atomization methods:
  - Pressure nozzle, co-current
  - Two-fluid nozzle, co-current

### FEED

- Mixing of various solvents possible
- Dosing and mixing of various raw materials possible
- Filtration of feed possible

### SOLVENTS

- Water
- Ethanol
- Methanol
- Isopropyl alcohol
- Acetone
- Methylene chloride
- Ethyl acetate

### OPERATING PARAMETERS

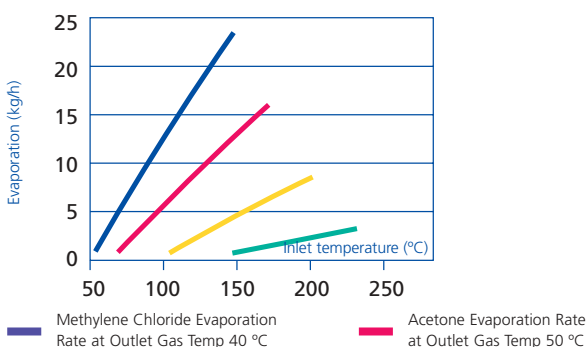
|   |   |
|---|---|
| Inlet temperature                             | up to 220 °C                              |
| Outlet temperature                            | up to 150 °C                              |
| Condenser temperature                         | down to -18 °C                            |
| Feed rate                                     | up to 10 kg/h (depending on solvent type) |
| Feed temperature                              | 5 °C to 80 °C                             |
| Pressure nozzle, atomization pressure         | 10 bar to 100 bar                         |
| Two-fluid nozzle, gas pressure                | 0,5 bar to 14 bar                         |
| Two-fluid nozzle, atomization gas temperature | 18 °C to 100 °C                           |

### CIP

- CIP liquid temperature: Up to 80 °C

### PSD-1 CO-CURRENT ATOMIZATION

Nominal drying gas rate: 80 Kg/h



## PSD-4

### PLANT CONFIGURATION

- Main components: Chamber, cyclone, bag filter, HEPA-filters, condenser, electrical heater
- Nitrogen as drying gas
- Closed-cycle loop
- Powder collection under cyclone. Bag filter for collecting fines
- Atomization methods:
  - Pressure nozzle, co-current
  - Two-fluid nozzle, co-current

### FEED

- Mixing of various solvents possible
- Dosing and mixing of various raw materials possible
- Filtration of feed possible

### SOLVENTS

- Water
- Ethanol
- Methanol
- Isopropyl alcohol
- Acetone
- Methylene chloride

### OPERATING PARAMETERS

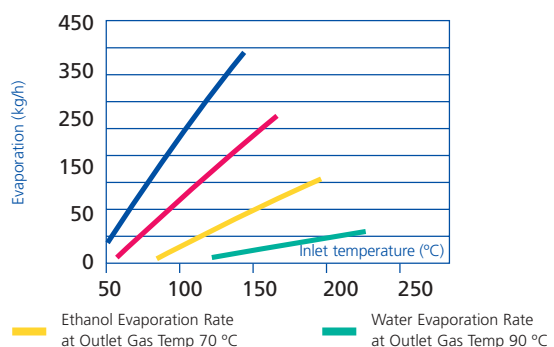
|   |   |
|---|---|
| Inlet temperature                             | up to 220 °C                                  |
| Outlet temperature                            | up to 150 °C                                  |
| Condenser temperature                         | down to -18 °C                                |
| Feed rate                                     | 15 kg/h to 400 kg/h depending on solvent type |
| Feed temperature                              | 5 °C to 80 °C                                 |
| Pressure nozzle, atomization pressure         | 10 bar to 300 bar                             |
| Two-fluid nozzle, gas pressure                | 0,5 bar to 14 bar                             |
| Two-fluid nozzle, atomization gas temperature | 18 °C to 100 °C                               |

### CIP

- CIP liquid temperature: Up to 80 °C

### PSD-4 CO-CURRENT ATOMIZATION

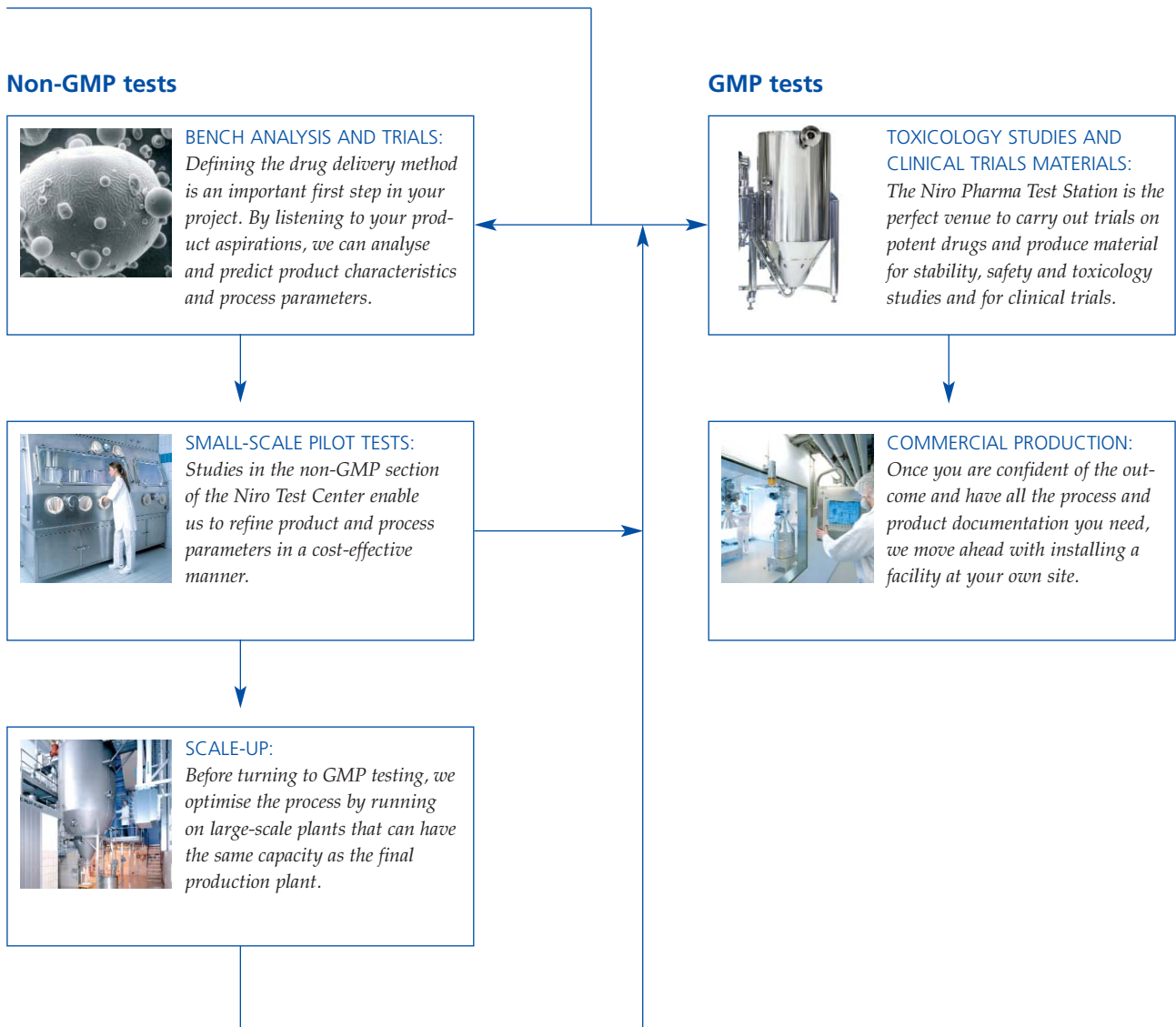
Nominal drying gas rate: 1250 Kg/h



# SHORTEN YOUR DRUG DEVELOPMENT CYCLE

The Niro Test Center includes GMP as well as non-GMP facilities. These facilities allow you to go from the early stages of product development, where only a few hundreds of millilitres of liquid product are available, to the final phases of process refinement, where full-scale testing is possible.

## DEVELOPMENT ROUTE





PSD-4 chamber roof with gas dispenser and top of bag filter



CIP tanks



PSD-1 drying chamber



Solvent vapour adsorption and waste water tanks

## Communication is critical

At the early stages of a project, the involved parties will sign a confidentiality agreement. Before any testing begins, we work with you to clearly define your project and its goals. Both the customer's and Niro's responsibilities are spelled out, the level of documentation is agreed upon, and basic documentation is established for the development phases. Formal protocols are prepared and approved by both parties before GMP production begins. A typical protocol includes the following:

- **INTRODUCTION AND TIME SCHEDULE**

A short introduction to the project.

- **OBJECTIVE**

A clear description of the purpose of the trial, leaving no doubt about what to investigate.

- **SAFETY**

Material safety data sheets (MSDS) are required before any production can be planned.

- **RESPONSIBILITY**

A description of the responsibilities of Niro A/S and of the customer. Who is responsible for equipment, analysis, provision of materials including excipients and solvents, operation methods, decontamination procedure, swab analysis, safety issues, etc.

- **EQUIPMENT**

A description of the selected spray drying system.

- **METHODS**

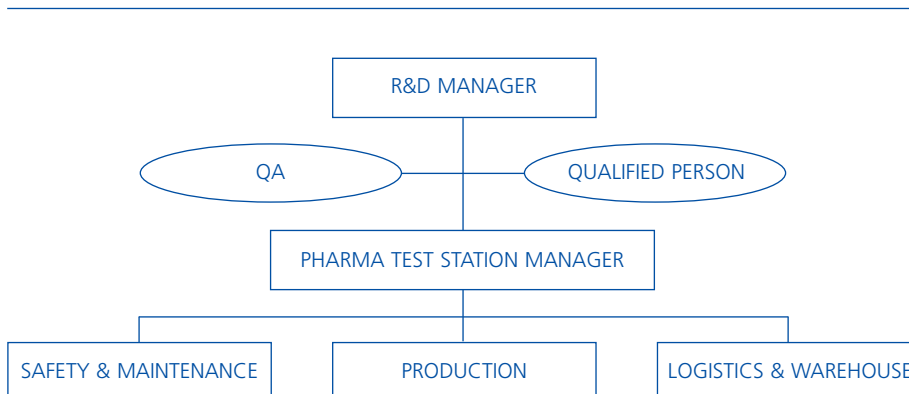
Batch records, feed preparation, drying conditions, test plan, SOPs.

- **DEVIATIONS PROCEDURE**

For reporting deviations from the protocol.



The Niro Pharma Test Station includes a validated purified water production and distribution system. The PW production unit supplies the spray dryer CIP and feed systems with water meeting the pharmacopoeial quality standard.



The organisation of the Niro Pharma Test Station is established to meet the requirements from the authorities and the customers as well as the organisation's operational requirements.



# Niro Pharma Systems

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.



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Niro A/S · Gladsaxevej 305 · PO Box 45 · DK-2860 Soeborg · Denmark  
Tel +45 39 54 54 54 · Fax +45 39 54 58 00 · E-mail: [pharma@niro.dk](mailto:pharma@niro.dk) · Website: [www.niro.com](http://www.niro.com)