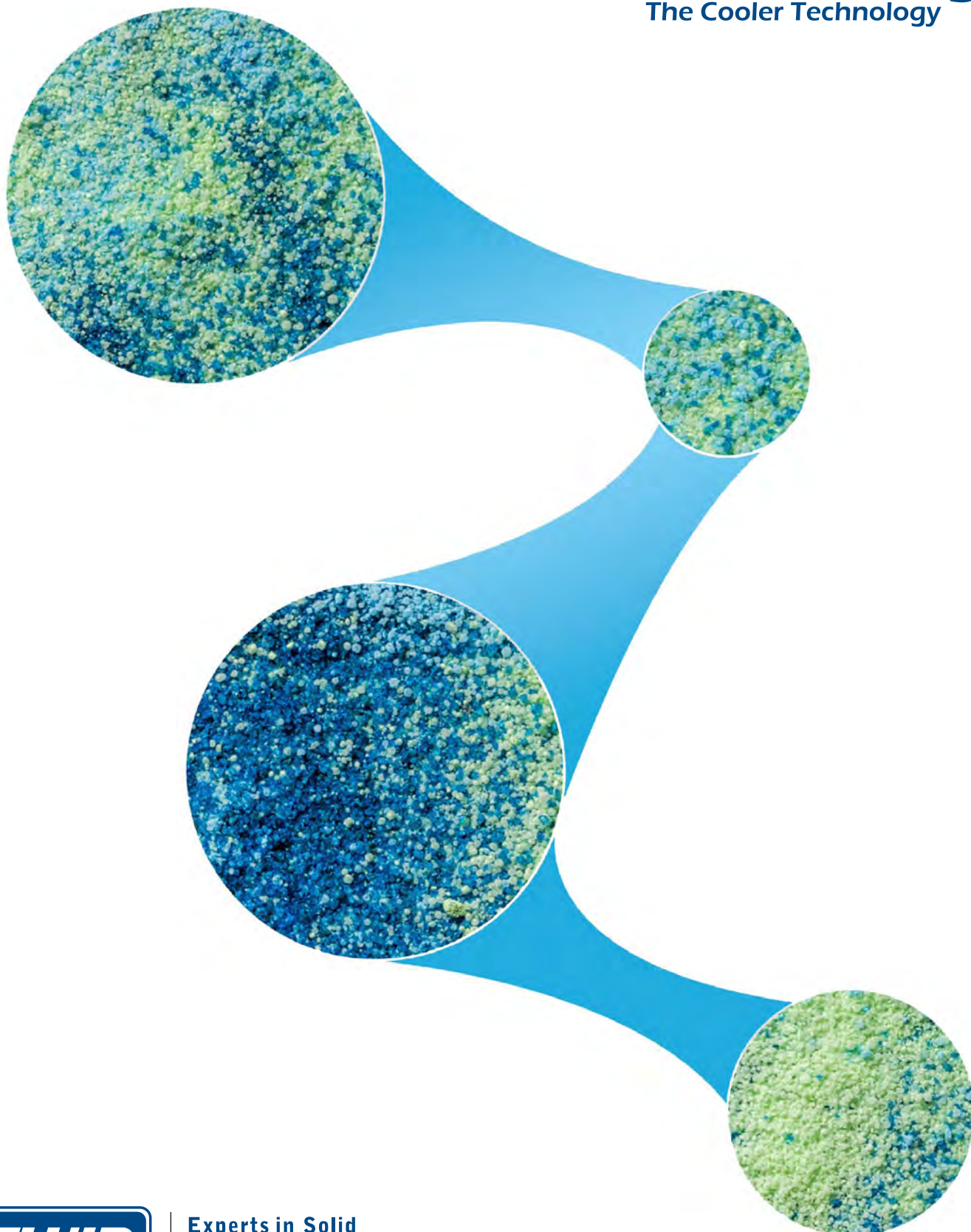


PolarDry™

The Cooler Technology



**Experts in Solid
Dosage Technology**

A Division of *Spraying Systems Co.*®

A SUSTAINABLE SOLUTION 



**YOUR MOST INNOVATIVE
POWDER DEVELOPMENT IDEA,
NOW A REALITY!**

INTRODUCTION





MAKING SPRAY DRY COOL

THE FUTURE OF SPRAY DRY & MICROENCAPSULATION

The patent-pending PolarDry® Electrostatic Spray Dryer utilizes revolutionary electrostatic technology, which drives water or solvent to the outside and solids to the inside of the atomized droplets, lowering the required evaporation temperature and eliminating active ingredient loss, degradation, or denaturalization. Harnessing the electrostatic effect, non-polar actives can be driven into the core and efficiently microencapsulated, virtually eliminating surface active, resulting in stunning encapsulation efficiency.

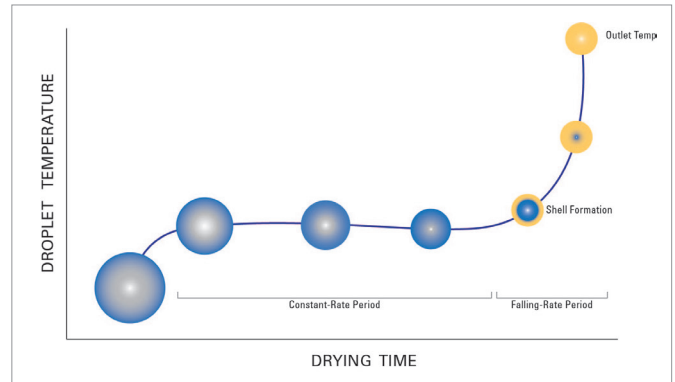
- Product drying temperatures as low as ambient to 80 °C
- Faster, continuous processing of temperature sensitive materials
- Higher bulk density
- Longer shelf life
- Safe, non-reactive processing
- Elimination of traditional secondary agglomeration operations
- Low-energy recirculating process – minimal emissions

LOW TEMPERATURE DRYING

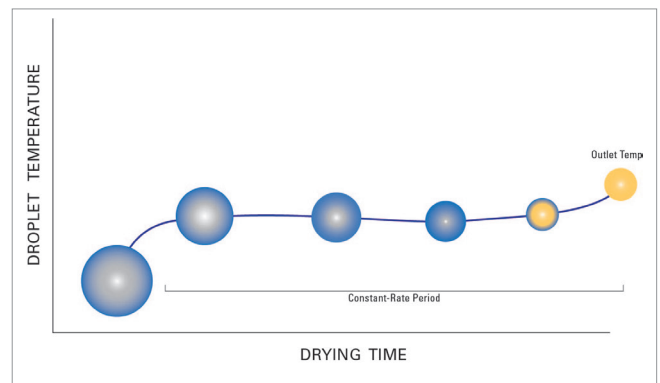
In both Traditional Spray Drying and in the PolarDry® process, liquid droplets are atomized and sprayed into a stream of drying gas. Then, heat is transferred from the drying gas to the liquid and powers the evaporation of the solvent. Once all the solvent has been evaporated, the result is a dry, powdered material.

In Traditional Spray Drying, there are two distinct phases of drying: a Constant-Rate drying phase, and a Falling-Rate drying phase. During the Constant-Rate phase, the majority of heat transferred to the droplet is latent, and used to drive the evaporation of the solvent. The solvent evaporation cools the

surrounding drying gas, and the droplet temperature remains constant. As more and more of the solvent evaporates from the droplet, the solid content of its outer layer increases to the point where it forms a shell. Now, there is a particle with a solid shell surrounding a wet core and the drying phase switches to the Falling-Rate phase. During this phase, heat is transferred to the particle from the drying gas as sensible heat. The temperature of the particle is raised to fully evaporate the remaining solvent from the core of the particle.



In the PolarDry® Process, the electrostatic effect is used to stratify the components of the droplet during atomization, based on the polarities of the materials. With a feedstock based on a polar solvent, the solid materials are driven to the inside of the droplet, and the solvent is driven to the outside. This prevents shell formation, and eliminates the need for the Falling-Rate drying period. A considerable amount of thermal energy from the drying gas is used for latent heat, while less is used for sensible heat. This allows for fast, efficient drying without the need to raise the temperature of the product.

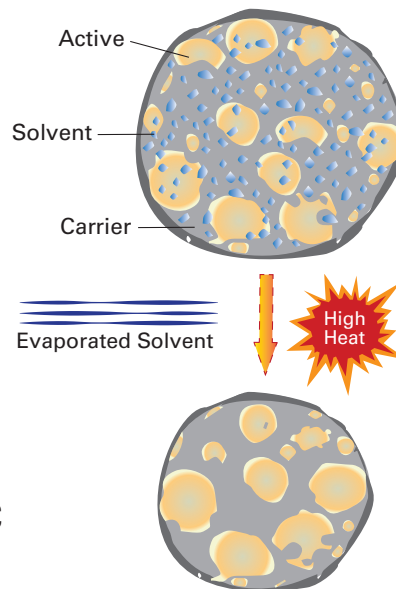


TRADITIONAL MICROENCAPSULATION

Since the late 19th century, Spray Drying Technology has seen use on an industrial-level scale. In that time, the technology has evolved only incrementally with the fundamentals remaining very much the same still today.

Typically, the encapsulation in a traditional spray dryer uses an emulsion made up of three components; a solvent (water or solvent), a carrier (starch), and a core/active (oil or vitamin). The object of Spray Drying is microencapsulation - forming the carrier around the active and drying off the solvent with a heated drying gas. Ideally, the carrier remains as a protective layer around the active keeping it from oxidizing. Traditionally, the emulsion is atomized using a nozzle or rotary atomizer, and heated drying gas (200 °C or higher) is introduced to the atomized emulsion.

Some major drawbacks of traditional spray dry include intense heat that can degrade the end product, and a dried particle that has the active trapped both inside the droplet and on the surface, partially defeating the intention of microencapsulation.

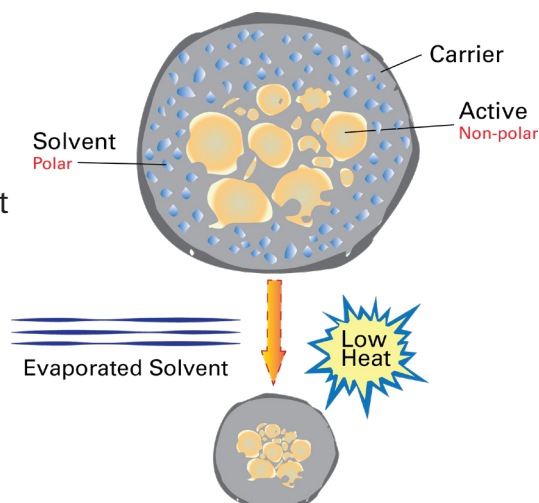


ELECTROSTATIC MICROENCAPSULATION

The PolarDry® technology is the latest innovation in spray drying. The difference is the use of electrostatic technology.

In microencapsulation, each emulsion component has differing polarities. The solvent and carrier, being the most polar of the group, will have the largest electric dipole moment. The active, being less polar, will have a smaller dipole. The solvent molecules will repel each other and the solid particles. This will force the solvent and carrier to migrate to the outer surface of the droplet, while the active will remain at the center.

Driving the solvent to the outer surface creates the ideal drying condition, leading to a near perfect encapsulation of the active without the use of high evaporation temperatures.



BENEFITS

THE POLARDRY® DIFFERENCE

PROCESS BENEFITS

- Low operating temperature allows for efficient drying of heat sensitive materials
- Greater encapsulation efficiency for high-volatile components
- SAFE - Nitrogen Inerted
- “All-in-one” modular equipment design features a small footprint which reduces maintenance and installation costs
- Complete product line is scalable from R&D to production-size models
- Contained, robust processing
- Inner liner makes for easy clean-up/changeover
- Process products with low glass transition temperature (Tg)
- Recycled process gas with negligible emissions virtually eliminates regulatory issues
- Substantially shorter process time than freeze drying

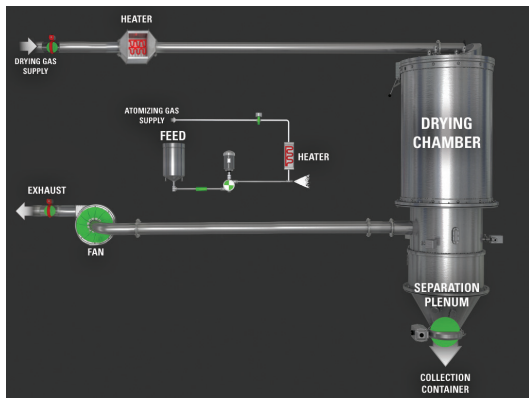
PRODUCT BENEFITS

- Superior morphology
- No oxidation
- Superior flowability
- Lower heat degradation of molecules/components
- Controlled agglomeration reduces post-processing and creates a larger particle size which allows for a higher bulk density
- Superior microencapsulation increases potency, stability and product shelf life and provides superior dissolution

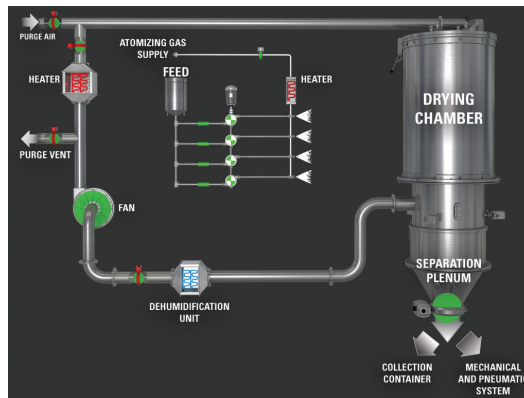
SYSTEM COMPONENTS

PolarDry® Electrostatic Spray Dryer systems consist of a spray chamber with an accompanying lid, a separation plenum, feed delivery, a drying gas recirculation system, and a discharge cone for collection of the finished product. There are also secondary fixtures such as valves and associated process controls. Furthermore, The PolarDry® product line operates as an “All-In-One” system, meaning that every system component necessary for its operation is encompassed in a single structure.

MODEL 001



MODEL 004 - MODEL 50+

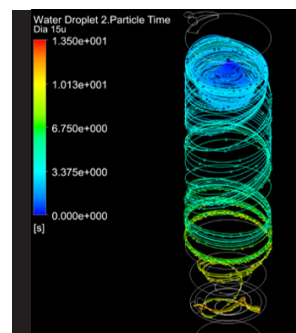


OPERATION OVERVIEW

The feedstock is pumped through the nozzle(s) located at the top of the chamber where the electrostatic charge is induced at the nozzle tip and the heated, pressurized gas atomizes the feedstock. The electrostatic forces within the droplet drive the water molecules/solvent to the outside of the droplet, optimizing the evaporation process. In some cases, insoluble molecules can be encapsulated by other solids present in the feedstock. This process is further accelerated by the drying gas flowing through the spray chamber in a spiral flow pattern.

During suspension, and partially during collection, moisture is transferred from the droplet to the atomizing and drying gas streams. The transfer of moisture results in an electrically charged solid powder which is collected and neutralized in an electrically grounded collection system.

After leaving the separation plenum, the combined drying and atomizing gas immediately pass over a HEPA filter and condensing coil propelled with the assistance of a gas blower, where the moisture is removed from the gas stream before it is reheated, HEPA filtered, and returned to the top of the tower. A bleed system assures that the extra gas introduced by the nozzle does not over-pressure the system. When the system needs to be accessed by the operator, a fresh air intake evacuates the system of nitrogen making it safe to open the system.



FULL PRODUCT LINE

Process Scalability is one of your key success factors. To address this requirement, PolarDry® was designed around a complete line of patent-pending machines that share similar process characteristics so you can easily scale up through the life cycle of your products.

Each PolarDry® machine shares the following key features:

- HEPA filtration
- Integrated feedstock delivery pump
- Removable disposable chamber liner for easy clean-up
- Patented reverse pulsing filter system*
- Optional split butterfly valve for high potency containment and processing
- Wash-in-place nozzle(s)

MODEL 0.1: SMALL-SCALE FEASIBILITY

A table-top PLC controlled once-through design intended for small-scale feasibility tests. This GMP designed machine is specifically sized to fit in most lab & fume hoods.

Additional features include:

- Autoclavable for sterile applications
- Batch Architect™ with data logging
- Produces small-scale samples with minimum product loss



MODEL 001: FEASIBILITY

A portable PLC controlled once-through design intended for laboratory environments. This GMP designed machine is the best option for feasibility checks.

Additional features include:

- Clear spray chamber for easy viewing
- Batch Architect™ with data logging
- 1 liter collection chamber with isolation valve



*Patent Number: 8,876,928 B2 (Models 001 & 004)

MODEL 004: R&D

A semi-portable PLC controlled recirculating system for R&D Environments. This unit uses the same nozzle as Models 032 and 050+ for easy scale-up. This model includes portable access stairs with a work platform.

Additional features include:

- Batch Architect™ with data-logging
- 20 liter collection chamber with isolation valve
- Optional 5-ton (17,5 kW) chiller (required)
- Optional Wash-in-Place skid
- Quiet Operation



MODEL 032: PILOT

Modular designed, PLC controlled systems for Pilot Environments. Choose Batch Architect™ or Batch Architect Pro™ with CFR21 PART11 Compliant Data Logging to control this system. Includes access stairs with a work platform.

Additional features include:

- 15 liter collection chamber with isolation valve
- Optional 30-ton (105 kW) chiller (required)
- Feedstock handling system with nozzle clog detection and optional feedstock scale
- Swing out separation plenum
- Optional Wash-in-Place skid
- Optional pneumatic or cable conveyor
- Quiet Operation



MODEL 050, 050+, 100, 200: PRODUCTION

Production models are modular designed, PLC controlled systems producing up to 200kg/hr. Choose from Batch Architect™ or Batch Architect Pro™ with CFR21 PART11 Compliant Data Logging to control these systems. Models include access stairs with a work platform.

Additional features include:

- Model 050+ can easily increase capacity by adding modules
- Feedstock handling system with nozzle clog detection and optional feedstock scale
- Swing out separation plenum
- Optional Wash-in-Place skid
- Optional pneumatic or cable conveyor for Continuous Operation
- Quiet Operation



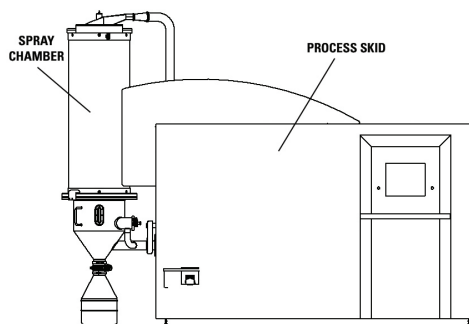
MODEL 050



MODEL 100

PROCESS SKID

Model		Height	Width	Length
0.1	ft	1.9	1.3	1.6
	m	0.6	0.4	0.5
001	ft	5.7	1.7	3.3
	m	1.7	0.5	1.0
004	ft	6.0	2.5	9.5
	m	1.8	0.8	2.9
032	ft	6.5	4.0	13.8
	m	2.0	1.2	4.2
50+	ft	7.0	5.0	16.0
	m	2.1	1.5	4.9



SPRAY CHAMBER

Model		Nominal Diameter	Elevation Off Floor	Recommended Room Height
0.1	ft	0.3	1.9	3.0
	m	0.1	0.6	0.9
001	ft	0.7	6.0	8.0
	m	0.2	1.8	2.4
004	ft	1.9	9.3	12.0
	m	0.6	2.8	3.7
032	ft	3.7	15.5	18.0
	m	1.1	4.7	5.5
50+	ft	5.0	16.0	20.0
	m	1.5	4.9	6.1

OVERALL

Model		Height	Width	Length	Access Stairs/Platform
0.1	ft	2.2	2.4	1.7	Not required
	m	0.7	0.7	0.5	
001	ft	6.0	1.7	5.0	Not required
	m	1.8	0.5	1.5	
004	ft	9.3	2.5	12.3	Portable
	m	2.8	0.8	3.8	
032	ft	15.5	11.0	16.0	Integral to Skid & Chamber
	m	4.7	3.4	4.9	
50+	ft	16.0	16.0	16.0	Integral to Skid & Chamber
	m	4.9	4.9	4.9	

SPECIFICATIONS*

*Dimensions are subject to change. Please consult Fluid Air for the most current outline drawings.

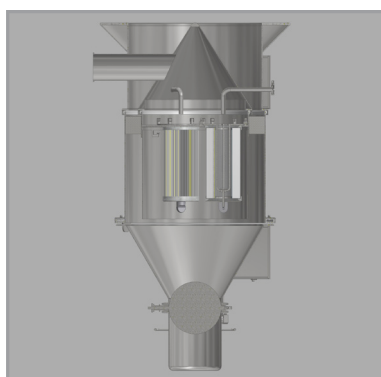
FLEXIBLE SOLUTION

Flexibility is a key consideration when developing your process. PolarDry® machines are designed to ensure:

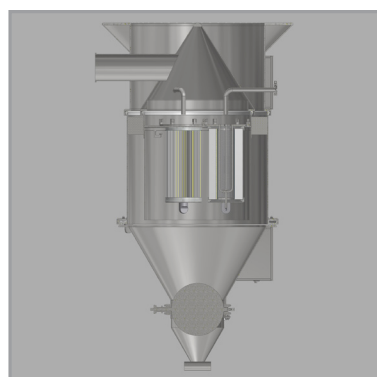
- **Quick Set Up** from one run to the next by integrating in the design a **disposable inner chamber liner** that can be changed in a matter of minutes.
- **Portable** so machines can be easily transferred from one suite to another:
 - Model 001 (Feasibility) and Model 004 (R&D) are on wheels and are fully contained, only requiring electricity, a nitrogen intake, an outside chiller (Model 004 only), with fresh air vents to operate.
 - Model 032 (Pilot) only requires electricity, a nitrogen intake, and an outside chiller to operate.
- Patent pending cartridge filter configuration that allows easy turnaround from one run to the next. The reverse pulsing feature ensures that drying gas flow remains steady.

CONFIGURABLE IN A BATCH OR CONTINUOUS PROCESS

As the FDA and other worldwide regulatory agencies push for continuous processes in pharmaceutical production of Pharmaceuticals, the PolarDry® process stands ready to meet the requirements. PolarDry® machines incorporate a unique patent pending collection/particle separation plenum which can be easily configured for batch or continuous processing by configuring the outlet as shown below.



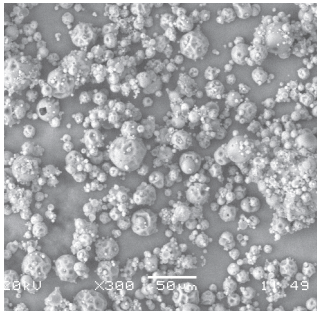
Batch Configuration



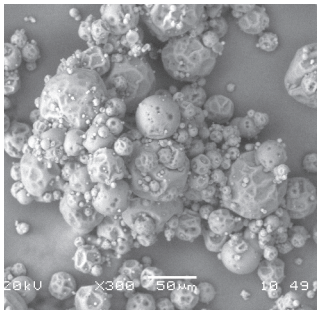
Continuous Vacuum
Transfer System

GRANULATING WHILE SPRAY DRYING

2 MACHINES IN 1



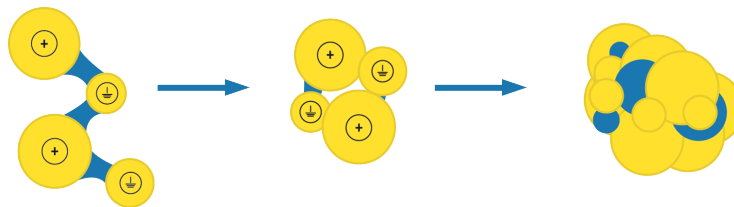
Conventional Spray Dryer
10 lbs/hr - 190°C



PolarDry® Spray Dryer
10 lbs/hr - 90°C

*Same feedstock formula used
for both examples

By controlling the electrostatic charge applied to the feed on an intermittent basis, PolarDry® Technology gives you the means of agglomerating particulates as they are being dried. This patent pending feature, PWM (Pulse Width Modulation) precludes the need for expensive secondary agglomeration operations.



By controlling the voltage applied to the spray droplet as it is being atomized, some particles form an outer shell readily, while others develop their shell gradually, resulting in a wet or tacky particle. As these two types of particles colloid, they bond forming an agglomerated particle. This results in a finished product with larger particles and fewer fines which flows freely.

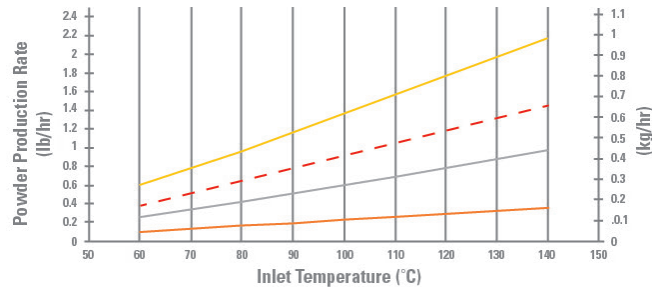
SAFETY FEATURES

- Nitrogen Inerting/Explosion Protection per NFPA654 & NFPA69
- Redundant oxygen monitor prevents operation if oxygen level is above 5%
- Rated lid safety lock & monitored inflatable seals prevent the operator from opening the vessel lid if oxygen level isn't safe (Model 004 and above)
- Over heating temperature protection
- Emergency stop buttons with safety reset
- Voltage generator resets if amperage exceeds 0.8 mA, protecting the operator

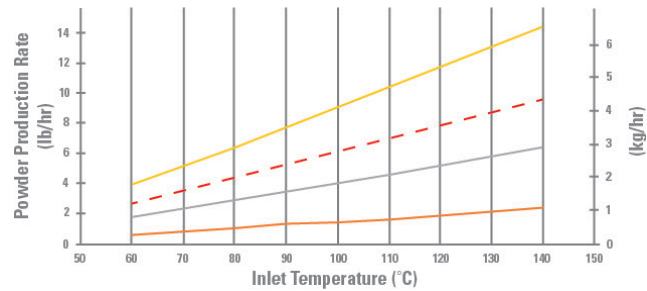
CAPACITY

The system dehumidification coil's mechanical design and chiller tonnage, as well as the particles' ability to give up moisture, determine the maximum evaporation rate of the system. The following charts show the production rate where the dryer's exhaust saturation is at a typical 60%. The red dashed lines show the maximum evaporation rate which is also the production rate when the solids content is 50%.

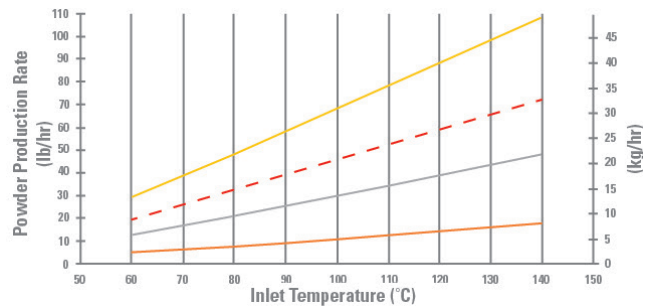
MODEL 01, 25 M³/HR (15 CFM) GAS FLOW



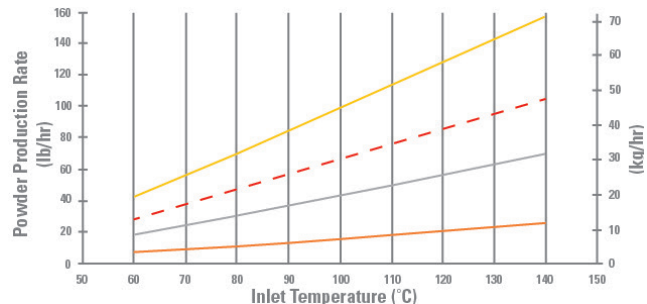
MODEL 04, 170 M³/HR (100 CFM) GAS FLOW



MODEL 32, 1275 M³/HR (750 CFM) GAS FLOW



MODEL 50+, 1870 M³/HR (1100 CFM) GAS FLOW



KEY

60% EXHAUST SATURATION

- 20% Solids Solution
- 40% Solids Solution
- - - 50% Solids Solution
- 60% Solids Solution

Note: All gas flows are at standard conditions

TESTING FACILITIES

Fluid Air has used its over three decades of experience in the Oral Solid Dosage market developing testing services capable of pilot and proof of concept studies. Let us show you how to make the most of your manufacturing process, or let us help you develop a feasible process for the manufacturing of new products. We are able to demonstrate our full range of powder processing technologies, including: particle size reduction, drying, top spray granulation, Wurster coating, high shear granulation, dry blending, and our new PolarDry® electrostatic spray drying.

TESTING

AURORA, ILLINOIS



NANTES, FRANCE



MERRIMACK, NEW HAMPSHIRE



SHANGHAI, CHINA



TRUGANINA, AUSTRALIA

APPLICATIONS

BIOPHARMA & PHARMA INDUSTRY

- Biologically Active Material (Bacteria, Viruses, etc.)
- Heat-sensitive Actives
- Active Pharmaceutical Ingredients
- Microencapsulation
- Small Molecules

FOOD INDUSTRY

- Probiotics
- Powder food materials - proteins, hydrocolloids and carbohydrates
- Heat-sensitive ingredients - colors
- Oxygen-sensitive components - essential fatty acid or fish oil

NUTRACEUTICAL INDUSTRY

- Heat-sensitive Components - Vitamins and Supplements
- Oxygen-sensitive Components - Antioxidants
- Protein Preservation
- Oils/Non-Polar Materials to Powders

OTHER INDUSTRIES

- Agricultural Bacteria
- Cosmetics
- Fine Chemicals
- Beverage
- Consumer Products
- Specialty Dairy
- Health/Performance Enhancement



IN-LINE, MICRO-AGGLOMERATE PROCESSING OF EXCIPIENT AND VITAMINS AT LOW TEMPERATURE

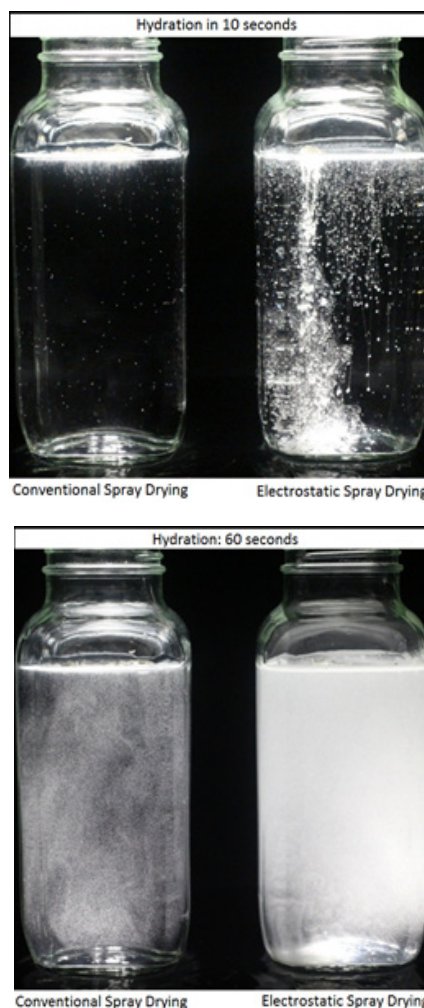
USING ELECTROSTATIC ATOMIZATION SPRAY-DRYING

GOAL

Ability to spray-dry Vitamin C with lower degradation of potency due to low temperature with electrostatic spray dry, with added benefits of superior particle size, bulk density, dissolution, and morphology.

SUMMARY OF FINDINGS

The electrostatic, spray-drying processing technology is a streamlined, one-step process that allows water evaporation at significantly lower processing temperature ($<90^{\circ}\text{C}$) and, in tandem, enables the agglomeration process to take place before particles are completely dry. The samples shown are free-flowing powders with moisture content falling within the industry acceptable range ($<8\%$). This technology provides products with superior, instant hydration for water-based applications; compared to hydration properties of conventional spray-dry products. In addition, larger particle sizes demonstrated by this technology resolve dusting issues commonly seen with smaller particle sizes. The mild processing afforded by this technology provides enhanced ingredient encapsulation and superior shelf life. Lastly, electrostatic spray-drying also provides an efficient, cost-effective, one-step unit operation that surpasses other technologies within this space.



Visit www.fluidairinc.com/spray_dryer_systems.html to request the full case study.

CASE STUDY

CHILLED TO PERFECTION

THE LATEST INNOVATION IN SPRAY CHILL & MICROENCAPSULATION

Introducing the patent-pending PolarChill™ Spray Chiller. Spray Chilling Technology has been widely studied and used in the pharmaceutical, food, cosmetic & chemical industry for many years and is gaining popularity in the healthcare industry due to increased demand for microencapsulated products.

- Ability to control particle size with PULSAJET nozzles
- Superior process control
- Easy to clean/change over chamber design with liner
- All-in-one design/modular/compact design
- Cyclonic pattern for reduced tower height and diameter



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**Experts in Solid
Dosage Technology**

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Bulletin No. FA111B

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