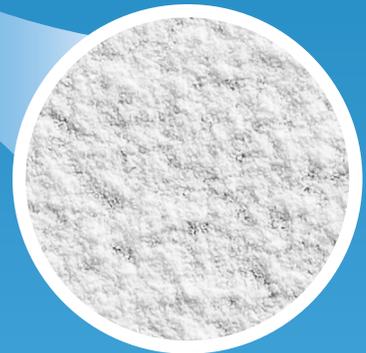


PolarDry®



A Division of *Spraying Systems Co.*®

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FREEZE DRYING / TRAY DRYING

-30°C 0°C 35°C

- Post-processing required for desired particle and powder morphology
- Batch process leads to increased downtime
- Extensive drying time is costly

POLARDRY® ELECTROSTATIC DRYING

35°C 100°C

- + Continuous process
- + Wide range of scale
- + Particle size control
- + Lower cost of production/ low utility cost
- + Ambient storage and transportation

CONVENTIONAL SPRAY DRYING

100°C 230°C

- High temperature leads to product degradation
- Granulation needed, requiring post-processing
- High heat is less energy efficient and more costly

PolarDry®

THE FUTURE OF DRYING AND POWDER PRODUCTION

The patented PolarDry® electrostatic dryer utilizes a unique electrostatic technology that increases the diffusion rate of water and solvent—allowing for faster evaporation of liquids from the atomized droplets while driving the active components inward to the core. This unique electrostatic drying technology prevents loss of activity, degradation or denaturation of the active components while ensuring superior drying efficiency.

- Faster processing to match supply with demand
- Modular design to fit into your continuous manufacturing or batch production line
- Save processing time by eliminating evaporation and concentration steps
- Available for both aqueous and solvent applications

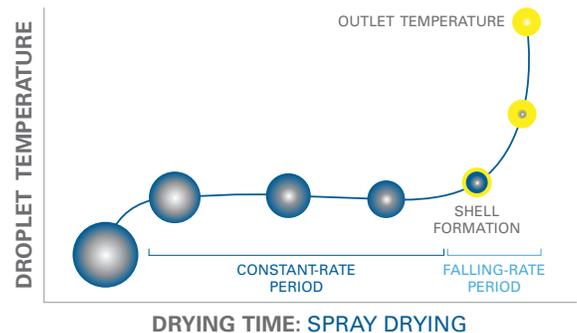
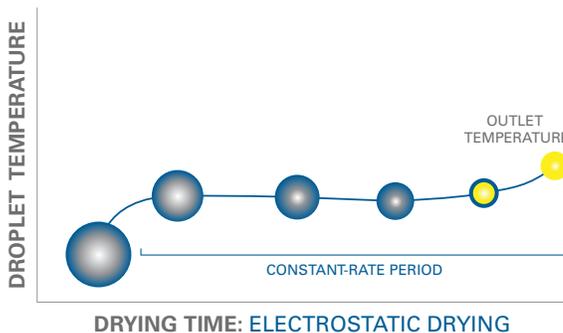
DRYING OF PHARMACEUTICALS

For decades, pharmaceuticals have been dried using batch production processes such as freeze-drying or lyophilization. As the world of pharmaceuticals moves towards advanced and continuous manufacturing, drying technologies that can provide a solution to the lengthy, complex and slow batch processes are in demand. Although conventional spray drying is a continuous process, it is not an ideal replacement due to the high temperatures at which drying occurs. The higher temperatures can degrade and damage the active pharmaceutical ingredients, affecting the quality of the dried product and sometimes contaminate with impurities that can affect the treatment.

ELECTROSTATIC DRYING

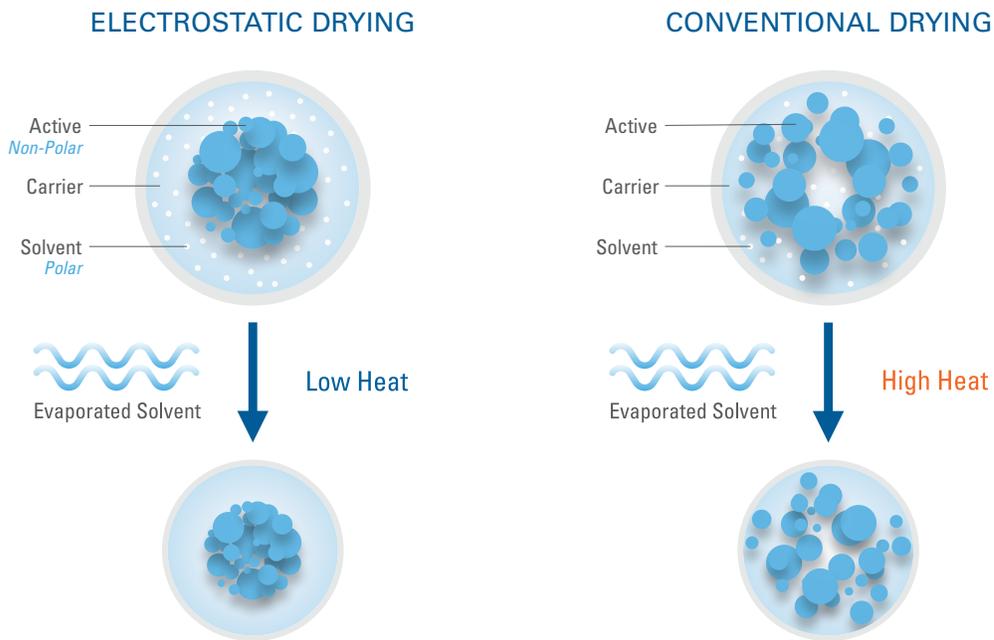
Fluid Air's PolarDry® electrostatic dryer enables continuous drying of pharmaceuticals at significantly lower temperatures than conventional spray drying. In the PolarDry® process, liquid droplets of the starting material containing the active ingredient and possible carriers are atomized and sprayed into a drying gas stream. Before drying, the droplets are electrostatically charged, allowing liquids to evaporate more quickly. When the liquids evaporate, a solid particle is created that flows cyclonically to the bottom of the dryer. The product is a powder with the desired powder properties that does not require any further downstream processing to reduce particle size.

During the drying process, electrostatic charge on the droplet's surface increases the rate of diffusion of liquids to the outside of the droplet, allowing all liquids to evaporate more quickly and forcing any solids in the droplet inward. This means that drying can be achieved at moderately lower inlet temperatures compared to conventional spray drying. This also results in lower outlet or product temperatures and protects the heat sensitive active components.



PARTICLE AND POWDER FORMATION

The unique electrostatic effect in the PolarDry® process is used to stratify or layer the components of the droplets during drying. During the drying process, as the droplet travels to the bottom of the dryer and particle formation occurs, the solids in the droplet are pushed inward while the liquids diffuse to the outside of the droplet. Two phenomena occur simultaneously: efficient drying is achieved by forcing the liquids outward, and the liquid layer protects the active components from the physical stress of the temperatures in the drying chamber. As the particles flow through the chamber, the vaporized liquids cool the chamber, resulting in lower outlet and product temperatures and further protecting the dry active components.



BENEFITS

THE POLARDRY® DIFFERENCE

PROCESS BENEFITS

- Low operating temperature allows for efficient drying of heat-sensitive materials
- Gentler drying for thermosensitive materials
- 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 in production scale models makes for easy clean-up/changeover
- Process products with low glass transition temperature (Tg)
- Recirculation of drying gases in production-scale models
- Substantially shorter process time than lyophilization and eliminates post processing for particle size modification

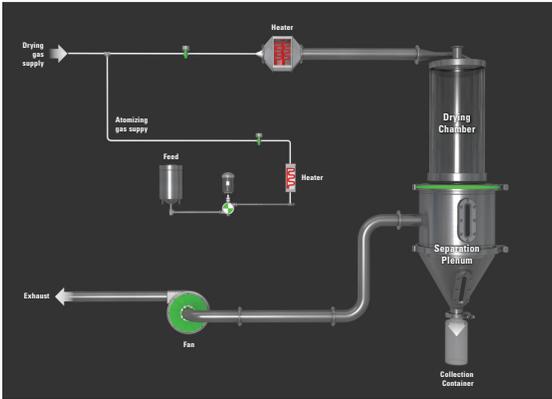
PRODUCT BENEFITS

- Superior morphology
- No oxidation
- Superior flowability
- Lower heat degradation of molecules/components
- Lower retention of harmful solvents in final dried powder
- Lower drying temperatures prevents reactions and formation of impurities

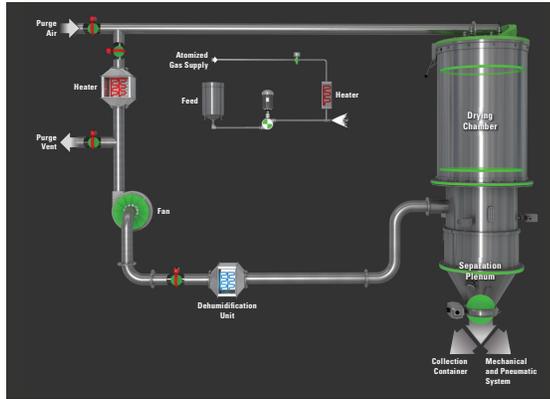
SYSTEM COMPONENTS

PolarDry® electrostatic 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. 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 050+

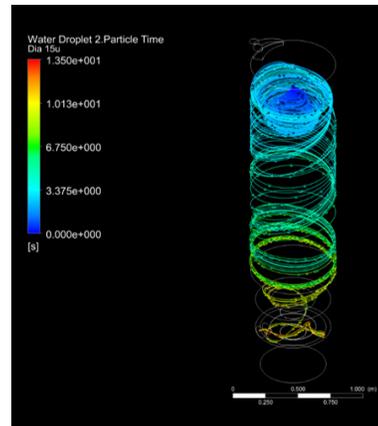


OPERATION OVERVIEW

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 improve the diffusion of water out 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.

After leaving the separation plenum, the combined drying and atomizing gas immediately pass through a HEPA filter and a 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 overpressure 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 patented 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 on Model 004, 032, 050 for easy cleanup
- MAGNAFLO® patented reverse-pulsing filter system*
- Optional split butterfly valve for high potency batch containment and processing
- Wash-in-place nozzle(s)
- Solvent-based feedstock capability and solvent-rated systems available

MODEL 0.1

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

Additional features include:

- Batch Architect™ with data logging
- Produces small-scale samples
- Autoclavable options are available



0.1

MODEL 001

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



001

*Patent Number: 8,876,928 B2
(Models 001, 004, 032, 050)

MODEL 004

A PLC-controlled recirculating system for R&D and/or production environments. 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



004

*Patent Number: 8,876,928 B2
(Models 001, 004, 032, 050)

MODEL 032

Modular-designed, PLC-controlled systems for pilot environments. Choose Batch Architect™ or Batch Architect Pro™ with 21 CFR PART 11 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
- Swing-out separation plenum
- Optional wash-in-place skid
- Optional pneumatic conveyor
- Quiet operation



032

*Patent Number: 8,876,928 B2
(Models 001, 004, 032, 050)

MODEL 050, 050+

Production models are modular-designed, PLC-controlled systems having 50+ kg/hr of evaporative capacity at maximum drying conditions. Choose from Batch Architect™ or Batch Architect Pro™ with 21 CFR PART 11 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
- Swing-out separation plenum
- Optional wash-in-place lance
- Pneumatic conveyor for continuous operation
- Quiet operation



050

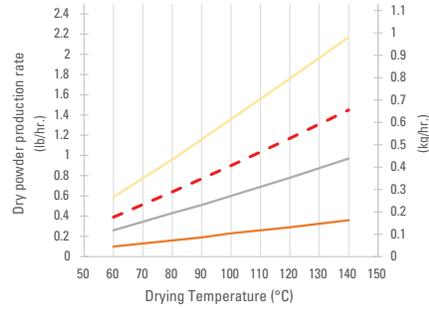
*Patent Number: 8,876,928 B2
(Models 001, 004, 032, 050)



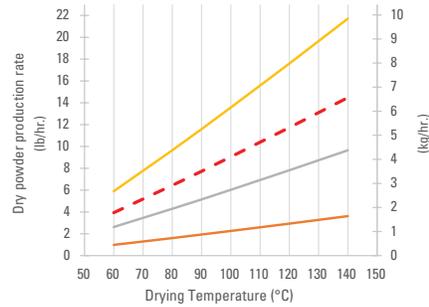
Electrostatic drying paves the way for more efficient and effective manufacturing of thermosensitive pharmaceuticals, nutraceuticals, and more, accelerating the delivery of important innovations to market.

CAPACITY

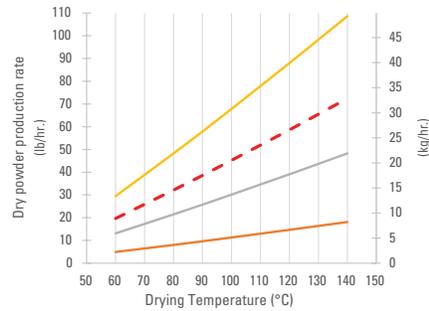
MODEL 001, 43 Nm³/h (25 SCFM) GAS FLOW



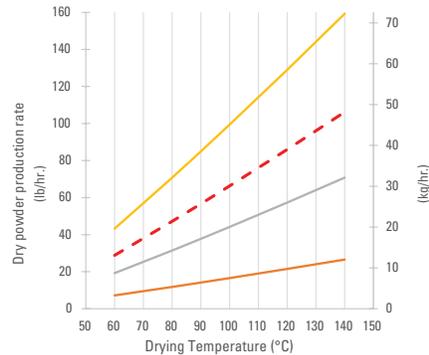
MODEL 004, 255 Nm³/h (150 SCFM) GAS FLOW



MODEL 032, 1275 Nm³/h (750 SCFM) GAS FLOW



MODEL 050+, 1870 Nm³/h (1100 SCFM) GAS FLOW



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%.

KEY	
60% EXHAUST SATURATION	
	20% Solids Solution Production Rate
	40% Solids Solution Production Rate
	50% Solids Solution Production Rate/Water Evaporation Capacity
	60% Solids Solution Production Rate
Note: All gas flows are at standard conditions	

PROCESS SKID

Model		Height	Width	Length
0.1	ft	2.6	1.8	2.6
	m	0.8	0.6	0.8
001	ft	7.0	2.4	4.8
	m	2.1	0.7	1.5
004	ft	11.5	5.8	11.6
	m	3.5	1.8	3.6
032*	ft	18.2	13.3	19.7
	m	5.6	4.1	6.0
050+*	ft	19.5	15.2	18.1
	m	6.0	4.7	5.6

*With platform stairs.

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	6.2	8.0
	m	0.2	1.9	2.4
004	ft	1.9	10.0	12.0
	m	0.6	3.1	3.7
032	ft	3.7	15.7	19.0
	m	1.1	4.8	5.8
050+	ft	5.0	16.5	20.0
	m	1.5	5.1	6.1

OVERALL

Model		Height	Width	Length	Access Stairs/Platform
0.1**	ft	3.0	3.8	4.6	Not required
	m	0.9	1.2	1.4	
001**	ft	8.0	7.2	10.3	Not required
	m	2.4	2.2	3.2	
004**	ft	12.0	16.5	19.7	Portable
	m	3.7	5.0	6.0	
032	ft	19.0	23.5	30.5	Integral to skid and chamber
	m	5.8	7.2	9.3	
050+	ft	20.0	30.9	21.7	Integral to skid and chamber with mechanical space
	m	6.1	9.5	6.7	

**Solvent Duty (SD) available.
Contact Fluid Air for dimensions.

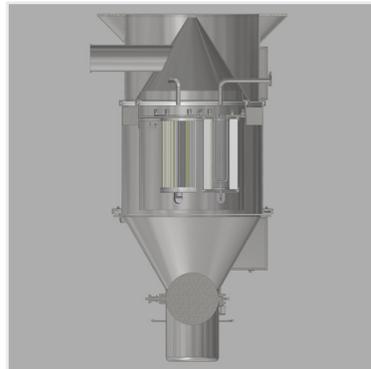
FLEXIBLE SOLUTION

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

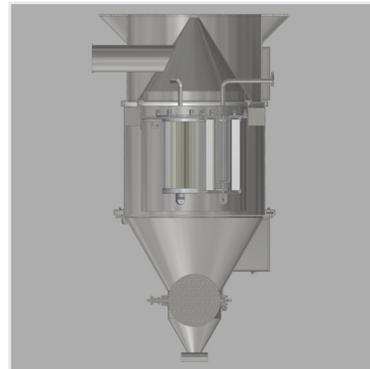
- Quick set up from one run to the next by integrating an inner chamber liner that can be changed.
- Portable so machines can be easily transferred from one suite to another:
 - Model 001 is portable with wheels, fully contained, only requiring electricity, a nitrogen intake, and fresh air vents to operate.
 - Model 004 only requires electricity, a nitrogen intake, compressed air, and an outside chiller to operate.
- Patented 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 production of pharmaceuticals, the PolarDry® process stands ready to meet the requirements. PolarDry® machines incorporate a unique patented collection/particle separation plenum which can be easily configured for batch or continuous processing by configuring the outlet as shown:



Batch Configuration



Continuous Vacuum Transfer System

SAFETY FEATURES

- Nitrogen-inerting explosion protection per NFPA 654, NFPA 69, and ATEX
- Redundant oxygen monitor prevents operation if oxygen level is above 5% (above 1% on Model 001)
- Rated lid safety lock and monitored inflatable seals prevent the operator from opening the vessel lid if oxygen level isn't safe (Model 004 and above)
- Overheating temperature protection
- Emergency stop buttons with safety reset
- Voltage generator resets if amperage exceeds 0.8 mA, protecting the operator

PHARMACEUTICAL

- Peptides and proteins
- Oligonucleotides
- Cell and gene therapy products
- Inhalable and injectables
- Thermosensitive active pharmaceutical ingredients
- Small molecules
- Microbiome therapeutics

OTHER INDUSTRIES

- Agricultural bacteria
- Energy storage
- Cosmetics
- Fine chemicals
- Beverage
- Consumer products
- Health/performance enhancement

FOOD & DAIRY

- Probiotics
- Powder food materials: proteins; hydrocolloids; and carbohydrates
- Heat-sensitive ingredients: colors and flavors
- Oxygen-sensitive components: essential fatty acid or fish oil
- Vitamins and supplements
- Oxygen-sensitive components: protein preservation
- Oils/non-polar materials to powders



TESTING FACILITIES

Fluid Air has used its over four 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 PolarDry® electrostatic drying.

Lab Capabilities—Process Development

- Help customers with process development on their products
- Process development includes:
 - Feedstock formulation and optimization
 - Drying process development
 - Optimizing for moisture content, residual solvent retention, particle size, throughput, etc.
 - Optimizing process for yield
 - Analyses conducted on feedstock and powders through all steps
- Knowledge transfer to customer

Dedicated Field and Process Service

- Fluid Air provides phone support, in-person service and product training. This includes:
 - Construction supervision and on-site project management
 - Process and equipment training
 - Software and process support
 - Optimizing process for yield
 - Replacement parts
 - Equipment upgrades and retrofits

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