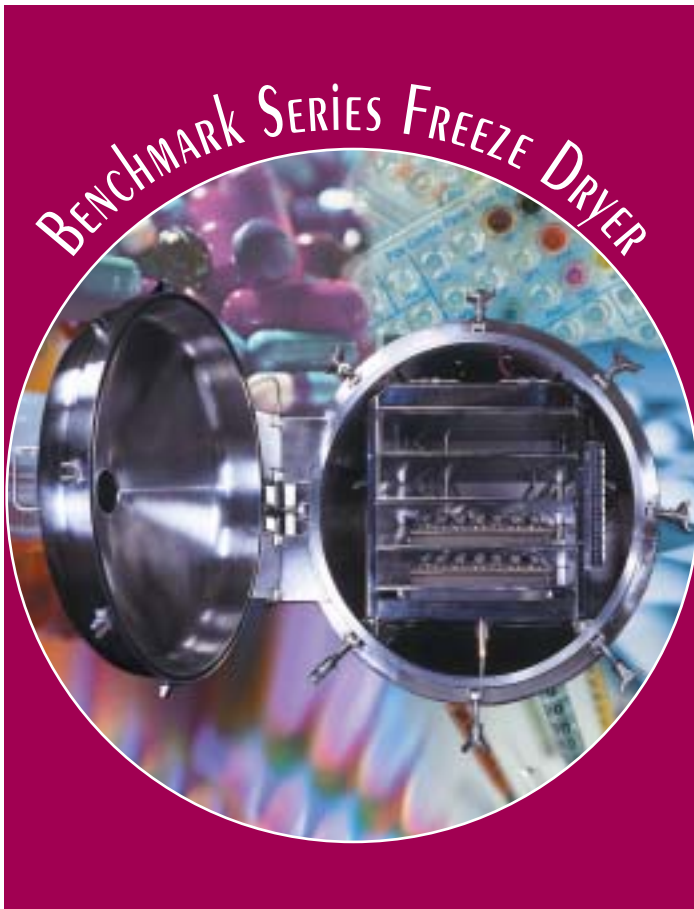


BENCHMARK 1000 - 3000 FREEZE DRYERS



MANY CONFIGURATIONS TO CHOOSE FROM





The Benchmark Series Freeze Dryers are engineered to process pilot to production scale batches of pharmaceutical and biotech products. Benchmark series freeze dryers have numerous options that allow the customer to configure the freeze dryer to fit any pharmaceutical application. With over 48 years of freeze dryer manufacturing experience, VirTis experienced product managers and engineers work directly with the customer to create a freeze dryer that delivers unmatched performance and features required in a short time frame. The end result is a freeze dryer that we guarantee for years of trouble free service with reproducible and consistent product cycles.

VirTis provides after-sale support too. Our technical staff and field service engineers can provide installation assistance, validation, IQ/OQ and documentation that stand up to all manufacturing regulations. Control System Qualification packages are available on our Allen Bradley PLC based control systems.

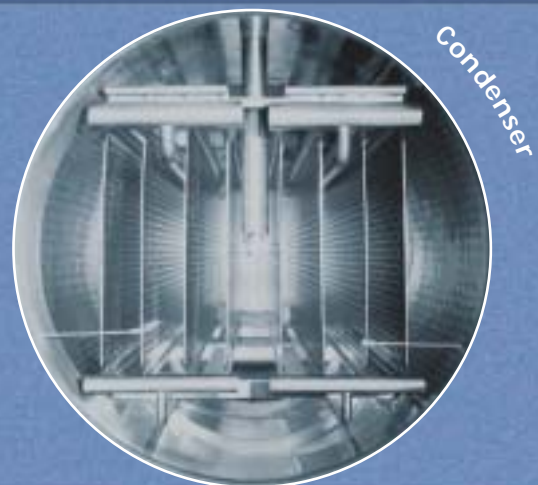
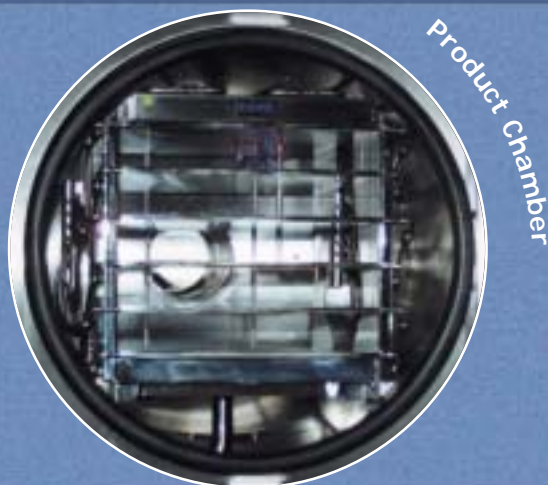
Features and Options:

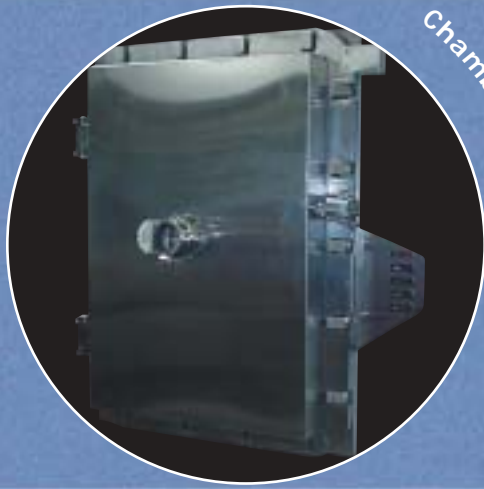
Product Chambers:

- Economical round or spacious square product chambers with rounded corners for effective cleaning and slope for drainage.
- Highly polished wetted surfaces to RA 25 finish or to customer requirements.

Condensers:

- Many external coil or plate condenser capacities to choose from. Internal condenser design when efficient use of space is required.
- Remote, horizontal or vertical placement of condenser based on space available.





Chamber Door



C.I.P. Clean In Place

Chamber Doors:

- Stainless steel insulated product and condenser doors with illuminated view ports standard.
- Optional Lucite doors for easy observation of product during freeze drying cycle.
- Auto-locking doors for safety during SIP and CIP cycles.
- Sub-door for loading in an isolator; automatic; and constant level loading.
- Sample thief to facilitate product analysis without drying cycle interruption.
- Two door pass-through design.

Shelves:

- Fixed shelves for bulk processing, hydraulic bottom-up or top-down stoppering for vial closure.
- Shelves polished to RA 25 finish or to customer requirements.
- Shelf temperature accuracy equal to or better than $\pm 1^{\circ}\text{C}$ shelf to shelf uniformity.
- Optional bellows system to isolate hydraulic system while stoppering.

Refrigeration:

- Refrigeration packages available with single, dual or backup compressors.
- Cascade refrigeration with -70°C shelf and -85°C condenser temperatures
- Liquid nitrogen refrigeration for processes requiring ultimate low temperature, simple maintenance, small footprint and low noise.
- Scroll compressor, single fluid systems and more.

Sterilization:

- Steam-In-Place (S.I.P.) systems to completely sterilize the entire system at optimum temperatures and pressure.
- All steam chambers are ASME coded for 25 psig steam pressure and full vacuum (standard). Other pressure rating is available per request.
- All chambers constructed with 316L stainless steel with RA 25 finish to ensure long-term resistance to corrosion.
- Steam cycle completely automated and documented by our Allen-Bradley PLC based program.

Clean In Place:

- Clean-In-Place (CIP) option allows cleaning of all internal surfaces of lyophilizer with up to 4 different media during one cycle.
- Nozzles designed and strategically placed for effective removal of product and contaminants.
- Allen-Bradley PLC control system allows completely automated CIP cycle with optimized cleaning media flow.

Unit Layout:

- Numerous frame configurations to accommodate facility design and use space efficiently.
- Multi-floor split frame design.
- Open frame design for easy routine maintenance or full frame panel closure.
- Bio-seal flange for through wall clean-room installation.



Shelves



Steam in Place

S.I.P.

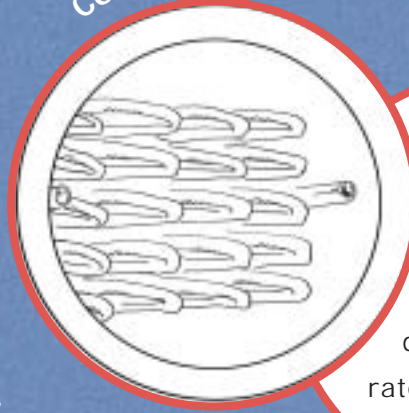
BENCHMARK COMPONENTS



Product Shelves:

Shelf temperature uniformity to $\pm 1^{\circ}\text{C}$.
Highly polished finish for maximum heat transfer to product. Optional redundant backup heat transfer system.

Condenser:

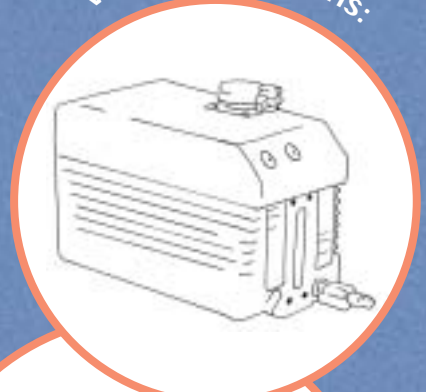


Heavy duty construction with coil or plate design. All condenser capacities rated in 24-hours.

Control Panel:

Space saving panel-mounted and/or personal computer workstation controls for easy operator interface.

Vacuum Systems:



High capacity vacuum pumps guarantee rapid evacuation time of the product and condenser chambers. Optional redundant and oil-less pumps available.

Frame:

Open frame construction for ease of maintenance or optional fully paneled unit for complete frame enclosure.

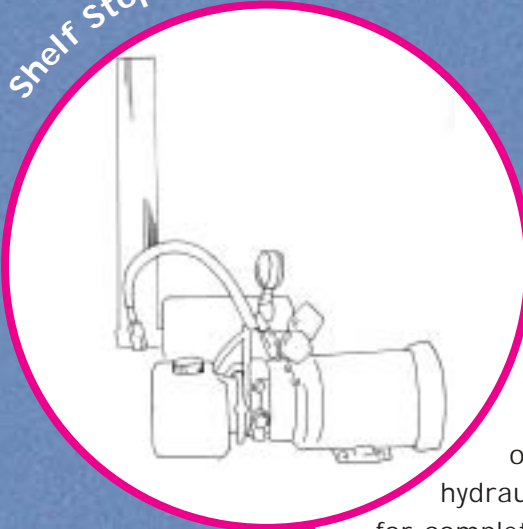
Refrigeration:

Reliable, efficient reciprocating compressors. Single, Dual, emergency backup and Cascade configurations available. Mechanical free liquid nitrogen refrigeration for simple maintenance, high cooling demand with minimal electrical requirements and no cooling water needed.

Product Chamber Door:

Insulated stainless steel door with view port to minimize product heat gain. Optional clear Lucite door for easy product viewing.

Shelf Stoppering:

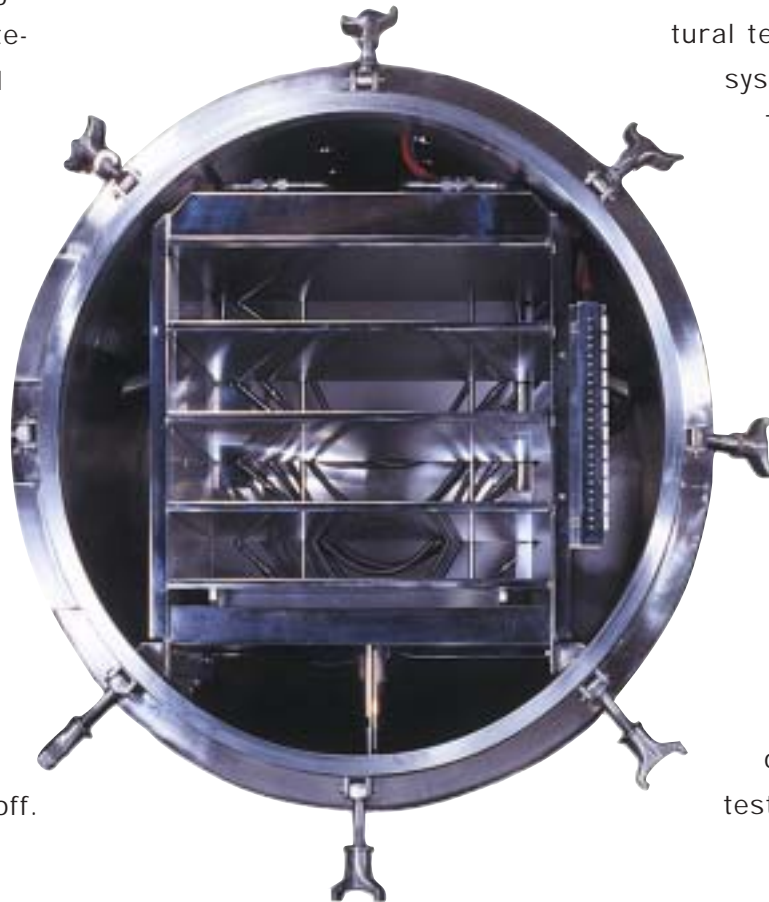


Powerful bottom-up or top-down hydraulic stoppering for complete vial closure with adjustable stoppering pressure and optional stainless steel bellows.

Installation/Start-Up and Validation Support:

VirTis engineers, product managers and technicians will be available to you through the entire purchasing and installation process. Once your equipment is delivered to your facility, installation and start-up will be scheduled at a convenient time for your personnel. Your equipment will be operational within the requirements of your production schedule. Once your freeze dryer is properly installed, our engineers will train operators and maintenance staff on the critical performance parameters, all subsystems, routine and long term maintenance.

VirTis validation support includes a wide-range of testing procedures designed to verify and record all your freeze dryer parameters. Our engineers will perform all system tests and prepare documents for sign-off.



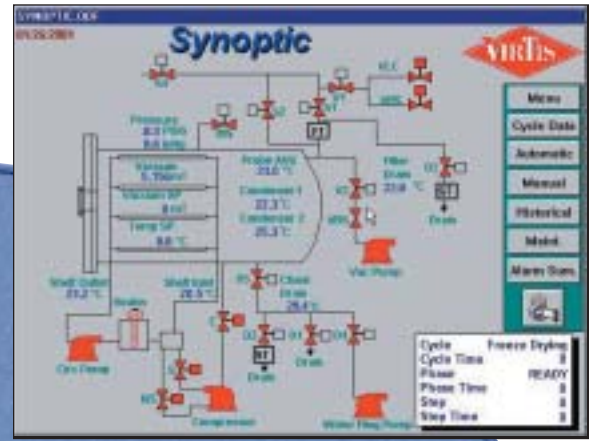
Our IQ/OQ procedures will ensure compliance with FDA and cGMP requirements.

VirTis has extensive Control Systems Qualification Packages (CSQP) for your PLC controls performed here at VirTis or at your facility. This testing is tailored for each customer and provides industry standard required documentation for the functional and structural testing of the control system and workstation.

These documentation and testing procedures verify that the system is installed and operating properly. The control system (including its functionality) is then completely validated. Please consult the factory for a complete list of documentation and testing procedures.

Allen Bradley PLC Based Controls with Intellution Fix™ Operating System:

VirTis PLC based controls allow easy and reliable operation of your freeze dryer through a personal computer workstation, when valuable production batches and research projects are at stake. Operators utilize the workstation to monitor events, control processes, supervise alarms and generate historical reports for FDA requirements. All screens are easily accessed through labeled icons on each screen. Alarms generated, security controlled screens, batch reports and system function testing allow your system to comply with all validation requirements.



Cycle Control: Multiple Steps of temperature, vacuum pressure and time to completely automate your freeze drying recipe.

Batch Reports: Collects data specific for research and batch production. Process parameters are collected and reports generated to customer and FDA requirements.

Trending: Complete graphic historical trending of all recipe parameters easily viewed by operator.

PLC Lyophilizer Controls:



Alarms: System archives and lists all events, alarms and acknowledgements during an operation.

Security: Multi-level security allows complete control of screen access from operator to administrative level.

Data Export: Able to export cycle data into a spreadsheet program for data manipulation.

Synoptic Screen: Allows user real time view of operational sub-systems of the freeze dryer from the computer screen.

Validation Testing: Complete testing library allows functional testing of all cycle control parameters.

Validation Freeze Temperature		Current Cycle Data	
Validation Freeze Temperature	48.8 °C	Cycle Time	8 Min
Additional Freeze Time	603 Min	Phase	READY
Condenser Test Temperature	-28.0 °C	Phase Time	8 Min
Vacuum Test Pressure	100 mT	Vacuum	5.156 mT
Cold Test Temperature	-45.0 °C	Shelf Temperature	20.7 °C
Cold Test Time	300 Min	Condenser Temperature	22.1 °C
Warm Test Temperature	48.0 °C		
Warm Test Time	300 Min		

Stage	Temp (°C)	Pressure (mT)	Time (Min)
1. Heat	25.0	500.0	15.0
2. Heat	48.0	150.0	15.0
3. Heat	48.0	150.0	15.0
4. Heat	48.0	150.0	15.0
5. Heat	48.0	150.0	15.0
6. Heat	48.0	150.0	15.0

VIRTIS BENCHMARK FREEZE DRYER 1000, 2000 & 3000 SERIES

BENCHMARK SERIES	1000		2000		3000	
Shelf Options	Area Ft ² /M ²	Clearance (MM)	Area Ft ² /M ²	Clearance (MM)	Area Ft ² /M ²	Clearance (MM)
2 Shelf	5.33/.49	(169)	8.33/.77	(215)		
3 Shelf	8.0/.74	(108)	12.0/1.16	(139)	18.00/1.67	(167)
4 Shelf	10.47/.99	(78)	16.67/1.55	(101)	24.00/2.23	(122)
5 Shelf	13.33/1.24	(60)	20.80/1.93	(78)	30.00/2.79	(95)
6 Shelf	16.00/1.50	(48)	25.00/2.32	(63)	36.00/3.34	(77)
7 Shelf			29.17/2.70	(52)	42.00/3.90	(64)
8 Shelf					48.00/4.46	(54)
Shelf Dimensions (IN/MM)	16 x 24/410 x 610		20 x 30/510 x 760		24 x 36/610 x 915	

*Shelf Latching kits available for larger spacing.

Options

Shelf Temperature °C	-60 to +65 Standard -70 to +65 Cascade	-60 to +65 Standard -70 to +65 Cascade	-60 to +65 Standard -70 to +65 Cascade
Condenser Temperature °C	-75 Standard -85 Cascade	-75 Standard -85 Cascade	-75 Standard -85 Cascade
Condenser Capacities (Liters)	12 External (Option) 20 Standard	20 Internal (Option) 34 Standard	34 Internal (Option) 42 Standard 64 External (Option)
Isolation Valve	Butterfly	Butterfly	Butterfly
Stoppering	Bottom Up/Hydraulic	Bottom Up/Hydraulic	Bottom Up/Hydraulic
Standard Electrical Service	220/3/50 230/3/60 380/3/50 440/3/60	220/3/50 230/3/60 380/3/50 440/3/60	220/3/50 230/3/60 380/3/50 440/3/60
Redundancy Options	All Pumps and Compressors	All Pumps and Compressors	All Pumps and Compressors
Door Closure	Latching Auto-locking (Option)	Latching Auto-locking (Option)	Latching Auto-locking (Option)

VIAL CAPACITY PER SQUARE FOOT OF SHELF AREA

18MM Diameter	288	25MM Diameter	138
23MM Diameter	178	52MM Diameter	32

Dimensions and weight are specific to configuration.

All freeze dryers are built in our ISO 9001 registered facilities to meet the most exacting current Good Manufacturing Practices (cGMP) standards. VirTis offers the best warranties in the business and a 24-hour emergency support line.

Our experienced product managers are waiting to work with you to meet your requirements, budget and time line. For more information, call VirTis at 800.431.8232 or contact your local representative today.

an SP Industries Company
ISO 9001 Registered
Web Site: <http://www.virtis.com>
E-Mail: sales@virtis.com



Just ask anyone in the world.

815 Route 208
Gardiner, NY 12525-9989 USA
Fax 845.255.5338
1-800-431-8232