

Freeze Dryers Lyophilizers

Quanta Series

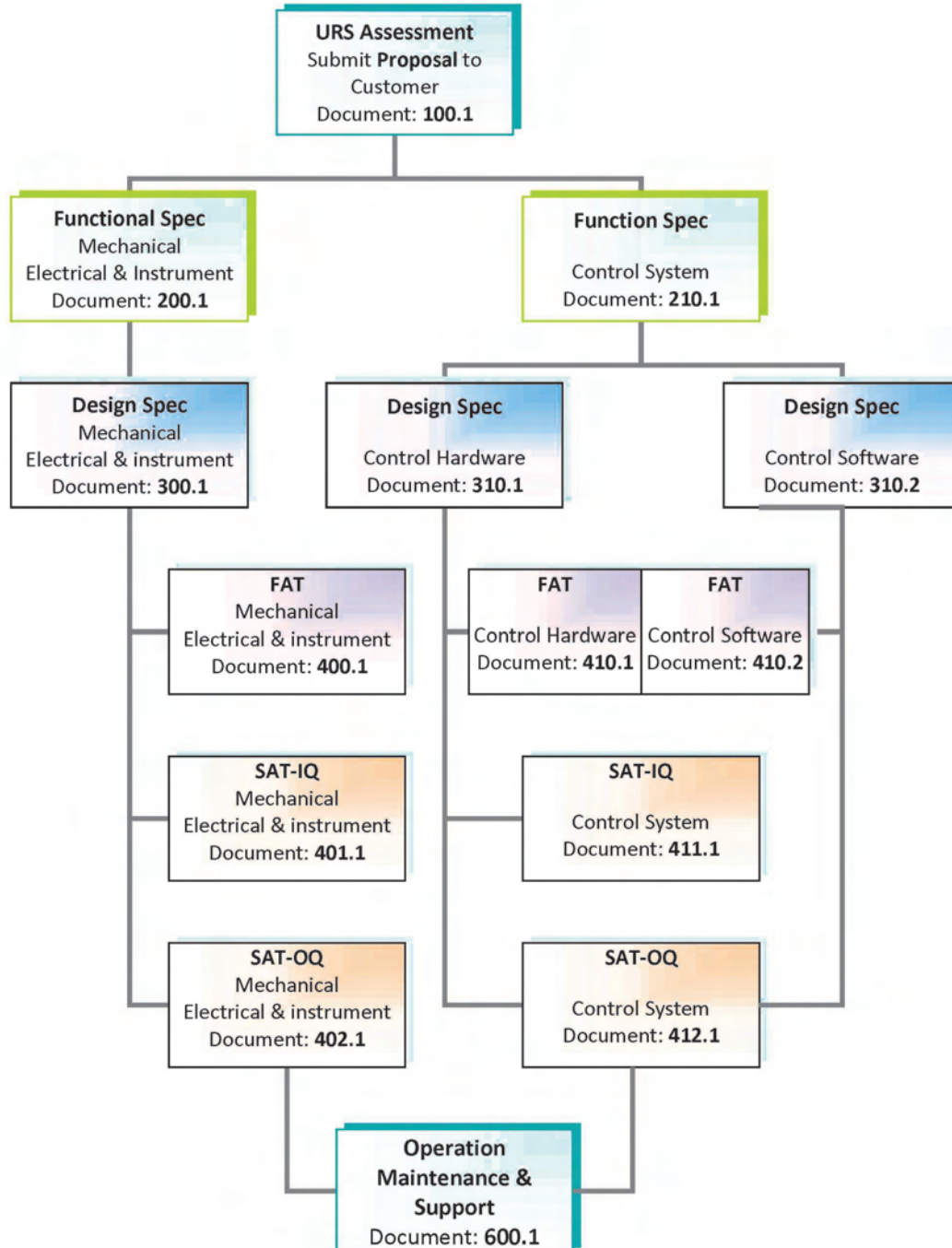


MILLROCK
TECHNOLOGY

Attention to Detail

It all starts by thoroughly identifying the application needs. We are diligent in defining a solution that meets the requirements. Once the project begins both a functional and design specification are generated to define the detail of the equipment. Then we follow-through.

GAMP Documentation



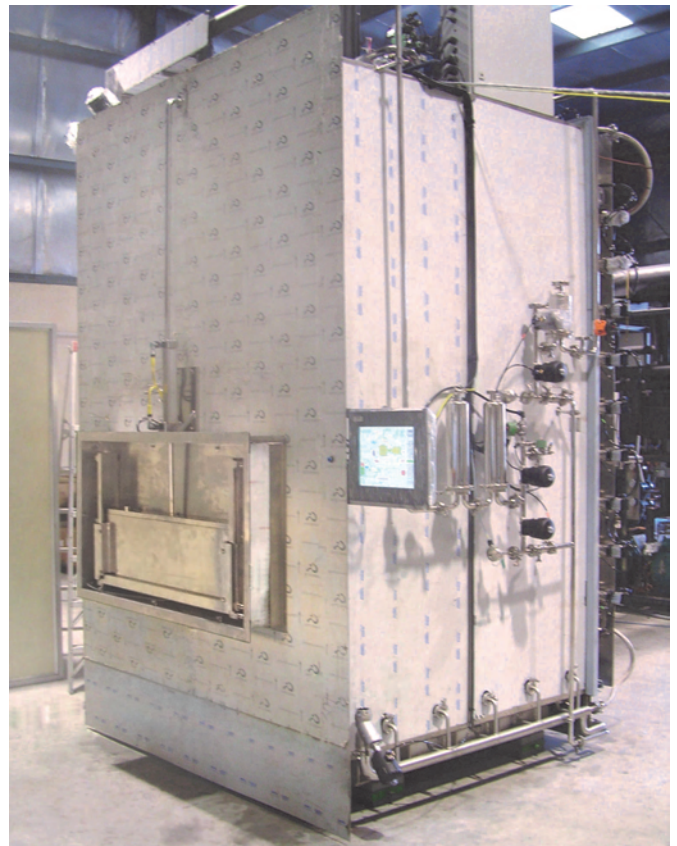
Pharmaceutical Grade - Steam Sterilizable

Freeze Dryers used for processing pharmaceutical and viral products require sterilization between freeze drying runs. The most common form of sterilization is steam sterilization. Not only do steam sterilizable freeze dryers have to be capable of maintaining a full vacuum they also need to be capable of maintaining high temperature and high pressures, which requires special design consideration and construction. Millrock Technology provides steam sterilizable systems with either a cylindrical or rectangular chamber, to best fit the price and performance requirements of the application.

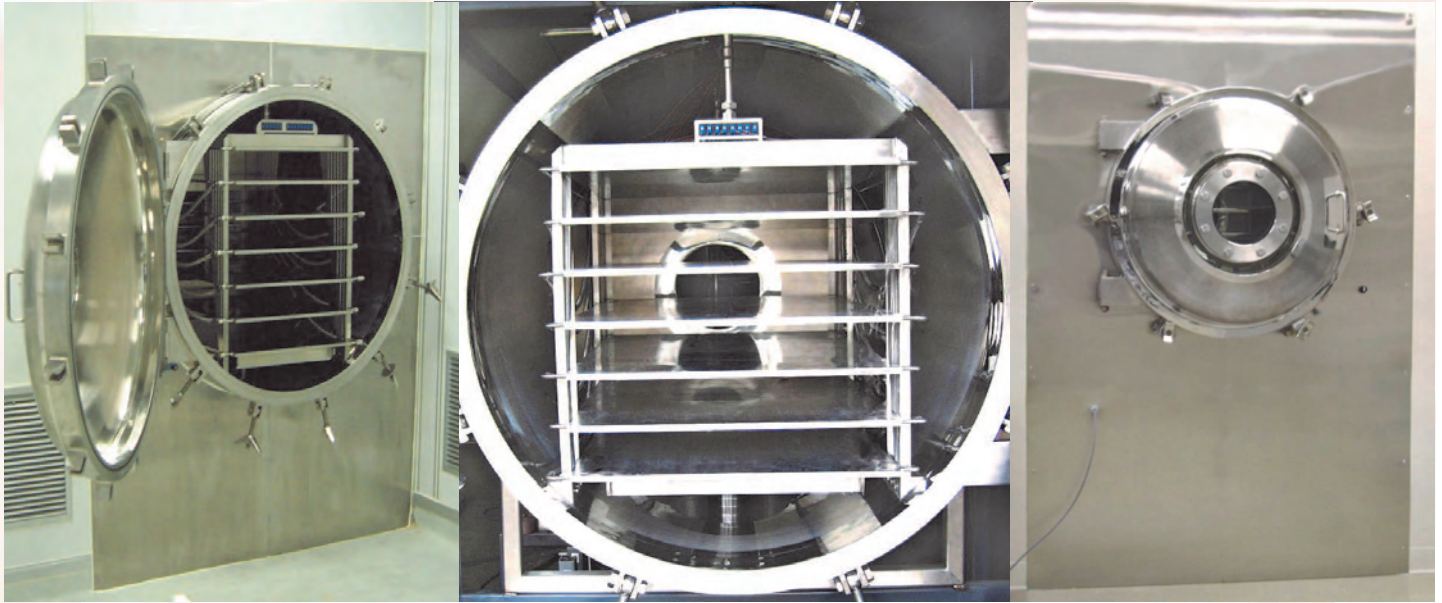
Typical Operating Specifications	
Condenser Cool Down	< 10 minutes to -50 C
Defrost Time	< 30 minutes
Ultimate Vacuum	5 mT
Vacuum Pull-Down	< 20 minutes to 100 mT
Vacuum Leak Rate	< 3 x 10 ⁻² mbar-liter/sec
Shelf Cooling (20 C to -40C)	<40 minutes
Shelf Heating	> 1 C/min

Features	
Control System PLC	Opto 22 or Allen-Bradley
Shelf Temperature Range	-60C to +65C (+80C option)
Shelf Heat Transfer	Hollow Fluid Filled
Shelf Material and Finish	316L, 20 Ra or better
Shelf Area	8 sq ft to 10 sq ft
Shelf Assembly	Bulk or Hydraulic Stoppering
Condenser Temperature	-75 C
Chamber Configuration	Cylindrical or Rectangular
Chamber Rating	AMSE, IE: 25 PSI at 128 C
Condenser Style	Coil or Plate
Compressors	Two Stage Carlyle, Bitzer, Mycom (screw)
Defrost	Steam
Vacuum Pump	Leybold Rotary Vane or Dry Pumps
Vacuum Control	Capacitance Manometer with Solenoid/Needle Valve
Gas Backfill	Included
Product Sensors	One per shelf standard
Water Ring Pump	Nash-Elmo
Frame	Welded and Painted

- All wetted components 316L stainless steel
- Validation port included
- Sterilization temperature: Controllable 121-125 degrees C
- Evacuation and drying: Water ring pump
- Insulation: High temperature CFC-Free foam with a stainless steel shroud around both chambers
- Filter: 0.2 micron Sartorius with integrity testing ports
- System cooling to ambient and drying in less than 2 hours using the refrigeration system and a liquid ring pump
- Slope to drain
- Cylindrical Chamber up to 70 sq ft (6.5 sq m)



Cylindrical Chamber



Rectangular Chamber



Options

- Hydraulic Stoppering with Bellows Seal
- Isolation Valve
- Screw Compressors
- MKS Proportional Control
- Clean In Place Piping and Control
- Electropolished Shelves and Chamber
- Auto-Locking Door
- Pizza Door - Single height loading
- Pass-Through Design
- Cooling Jacket on Chamber and Door
- LN2 Cooling
- 21 CFR Part 11 Compliant Software
- Validation Docs
- IQOQ Workbook
- Factory Acceptance Testing
- Site Acceptance Testing



Biotech and Industrial

Biotech and Industrial applications vary greatly. To accommodate the large range of requirements Millrock Technology offers systems in either 304 stainless steel for non-pharmaceutical applications and 316L stainless steel for pharmaceutical applications.

Condenser assemblies can be internal or external with either bulk or stoppering style shelf assemblies. Cylindrical chambers offer cost savings and can be supplied up to 80 square feet in shelf area. Features such as isolation valves and clean-in-place (CIP) piping can be provided.

Typical Operating Specifications	
Condenser Cool Down	< 10 minutes to -50 C
Defrost Time	< 30 minutes
Ultimate Vacuum	5 mT
Vacuum Pull-Down	< 20 minutes to 100 mT
Vacuum Leak Rate	< 3 x 10 ⁻² mbar-liter/sec
Shelf Cooling (20 C to -40C)	<40 minutes
Shelf Heating	> 1 C/min



Features	
Control System PLC	Opto 22 or Allen-Bradley
Shelf Temperature Range	-60C to +65C (+80C option)
Shelf Heat Transfer	Hollow Fluid Filled
Shelf Material and Finish	316L, 20 Ra or better Optional Electropolish
Shelf Area	8 sq ft to 400 sq ft
Shelf Assembly	Bulk or Hydraulic Stoppering
Condenser Temperature	-75 C
Chamber Configuration	Cylindrical or Rectangular
Chamber Rating	Full Vacuum
Condenser Style	Coil or Plate
Compressors	Two Stage Carlyle, Bitzer, Mycom (screw)
Defrost	Hot Gas or Hot Water
Vacuum Pump	Leybold Rotary Vane or Dry Pumps
Vacuum Control	Pirani with Solenoid & Needle Valve
Gas Backfill	Included
Product Sensors	One per shelf standard
Frame	Welded and Painted



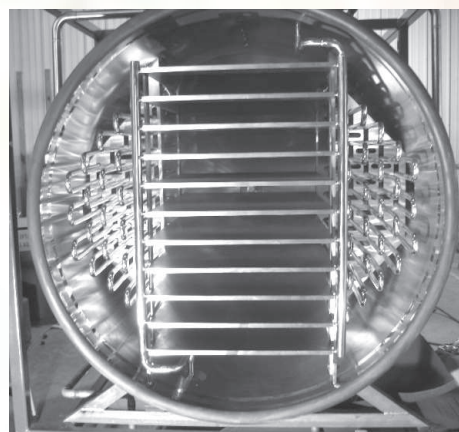
Examples

Example Applications

- Veterinary Vaccines
- API - Active Pharmaceutical Ingredients
- Diagnostic Kits
- Nutraceuticals
- Biological Material
- And any other application where freeze drying is needed



Internal Condenser

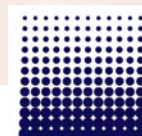


External Condenser



Options

- 304 or 316L Stainless Steel
- Internal or External Condenser
- Isolation Valve
- Bulk or Hydraulic Stoppering
- Bellows Seal on Hydraulic Stoppering
- Acrylic or Stainless Steel Door
- MKS Proportional Vacuum Control
- Clean In Place Piping and Control
- Pizza Door - Single height loading
- Pass-Through Design
- LN2 Cooling
- 21 CFR Part 11 Compliant Software
- Validation Docs
- IQOQ Workbook
- Factory Acceptance Testing
- Site Acceptance Testing



Design Flexibility



Millrock Technology works with each customer to fit their specific application needs. Selecting the right components and the right controls is critical to a successful freeze dryer project. We will guide you through the process to define the proper system, based on our knowledge and experience.

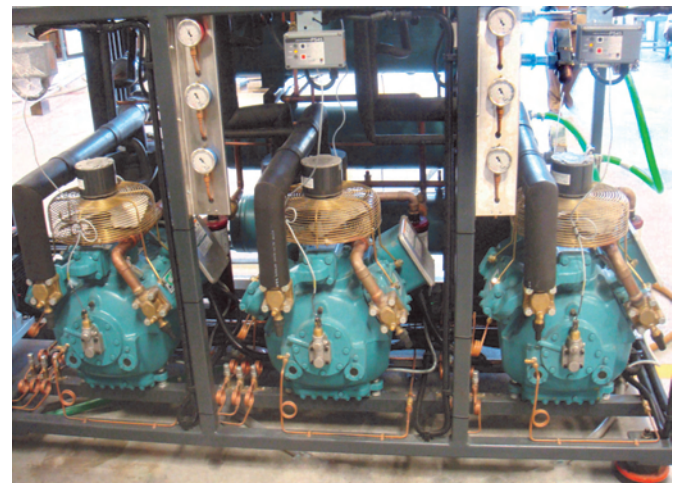
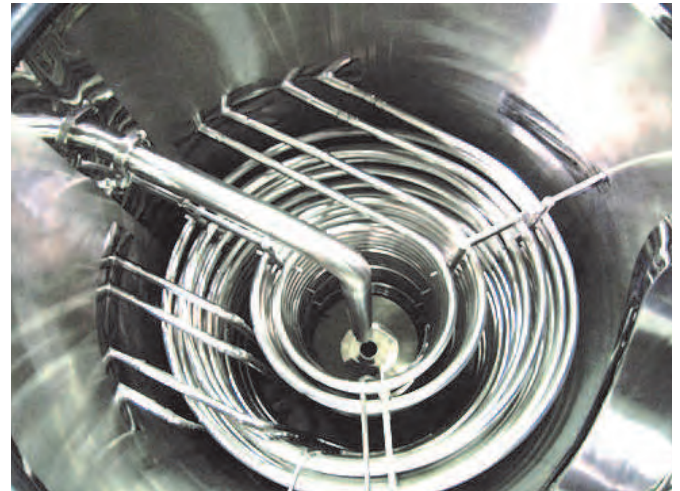
Leveraging our experience and familiarity with a broad range of applications, we tailor the equipment to provide the most cost effective solution.

Pharmaceutical freeze dryers require 316L stainless steel on all wetted parts and are mounted in clean room environments, while many industrial applications only need 304 stainless steel and may not require the same level of sophistication.

Matching the shelf area with condenser capacity can optimize system performance. The compressors, vacuum pumps, and fluid pumps are sized for the best system operating performance.

Mission critical applications may require that all major components are redundant. This would include the compressors, vacuum pumps, and fluid pumps. Redundancy can be provided in either a 'save the product mode' or a full fail-safe mode to provide full functional performance at all times.

Let us help you make your freeze drying project a successful one.

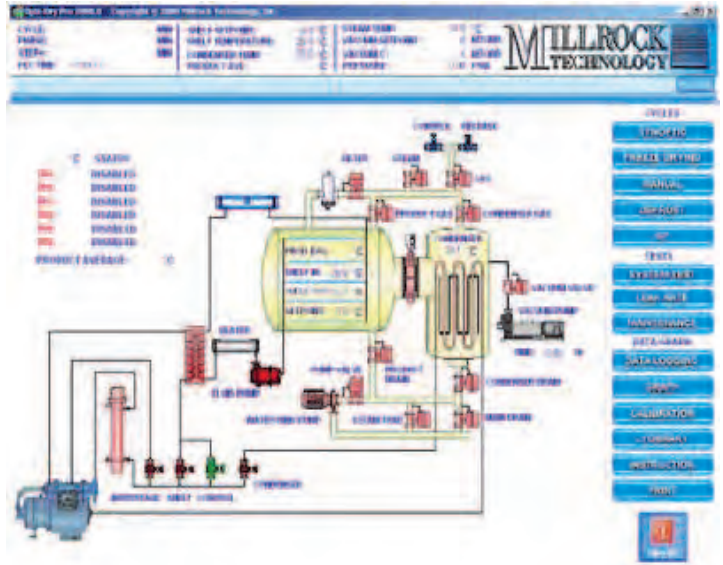
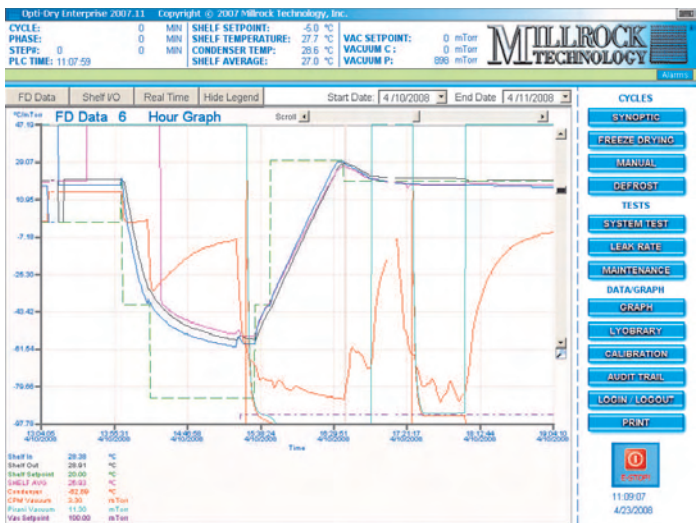


Component	Options
Chamber	Cylindrical or Rectangular 304 or 316L Stainless Steel Full Vacuum Rating or ASME Pressure Rated for Steam Pass Through Design Water Jacket for Post SIP Cooling
Door	Acrylic or Stainless Steel Insulation View port Lighted Pizza Door Auto-Locking
Shelves	304 or 316L Stainless Steel 20Ra or Electro-polished Finish
Shelf Assembly	Bulk or Hydraulic Stoppering Bottom-Up or Top-Down Bellows Seal
Refrigeration	Reciprocating or Screw or LN2
Condenser	Internal or External Vertical or Horizontal Coil or Plate Isolation Valve
Vacuum Pump	Rotary Vane or Oil-Free Dry Pump
Vacuum Measurement	Pirani Capacitance Manometer
Vacuum Control	Solenoid and Needle Valve Foreline Vacuum Control
Other Options	Clean in Place Piping Redundant Systems LN2 Trap And much more



Control Simplicity

- PC/PLC Platform with Ethernet Communication
- Windows Based Control Software
- 10 Freezing and 16 Primary Drying Steps
- Unlimited Recipe Storage
- System Status on Every Screen
- Synoptic Overview Screen
- Maintenance/Troubleshooting Screen
- Manual Operation
- Automatic System Test with History Data Storage
- Automatic Defrost
- Automatic Leak Rate Test
- Graphical Display of Runs
- Numeric Data Collection by Run - Excel Importable
- 'Out of Range' Product Thermocouple Correction
- Remote Monitoring and Control Capability
- 21CFRPart11 Compliance Module

Freeze Drying	10 Freezing Steps 16 Drying Steps with Pressure Control 1 Step Secondary Drying 1 Step Final Drying Alarms, Recipe Management, Data Logging
Manual	Individual switches for shelf, condenser, vacuum, isolation valve and release. Single set-points for shelf and
Defrost	Automatic
System Test	Performance evaluation of shelf, condenser, vacuum, heating, and control.
Leak Rate	Automatic testing of leak rate.
Mainte-	Independent operation of components, with troubleshooting and calibration.

Ack	Time In	Time Last	Description	Status	Value
	09:30:52.765	09:30:52.765	Condenser overload!	COMM	Fixed
	09:30:52.765	09:30:52.765	Short power out!	COMM	Fixed
	09:30:52.765	09:30:52.765	Shelf in probe out of range!	COMM	Fixed
	09:30:52.765	09:30:52.765	Shelf set point not satisfied!	COMM	Fixed
	09:30:52.765	09:30:52.765	Vacuum overload!	COMM	Fixed
	09:30:52.765	09:30:52.765	Vacuum time out!	COMM	Fixed

Total Alarms: 6 | Filter: Off | Sort: Time In, Descending | Run

21 CFR Part 11 Software Option

Millrock Technology offers a 21 CFR Part 11 software system that provides the necessary platform to meet the needs of cGMP freeze drying. All data is stored in a secure SQL database to prevent manipulation. Program access is controlled through a multi-level password system to limit access to critical areas. New and modified data entry requires an electronic signature that is level controlled to prevent unauthorized changes. All changes are logged in a change log database to provide a full audit trail that meets FDA requirements.

At the end of each batch a formal report is generated that provides the operating parameters of the freeze drying run as well as a full audit trail of changes and all alarm conditions during the run.

- Electronic Signatures
- Encrypted Database
- Password Protection
- Change Log Audit Trail
- Batch Reporting

Security

Group Profile

Group Name: OPERATORS

Security Areas: ALARM, DATA, DEFROST

Application Features: Recipe Download from Recipe, Recipe Load, Recipe Text Output from Reci

Buttons: Modify..., Modify..., OK, Cancel, Help

Group Accounts

Current Groups:

- ADMIN
- GUEST
- MAINTENANCE
- OPERATORS
- SUPERVISORS

Buttons: Add..., Modify..., Delete, OK, Cancel, Help

Electronic Signature

Load existing FD Recipe

Perform Comment

Predefined Comments:

Comment: Loading Recipe for Batch 2008-858

Performed By:

Perform Username: Engineer

Perform Password:

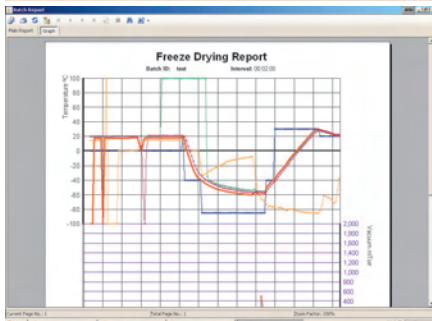
Buttons: OK, Cancel, Help

Batch Reporting

PDQ60XB Freeze Dryer

FREEZE DRYING BATCH SUMMARY

BATCH NAME	START DATE	END DATE	RECIPE	Report	ALARM	SIGNATURE	EVENT
afp	4/25/08 17:39	4/25/08 17:39	MILKROCK	Graph Data	Alarm	Signature	Event
afp	4/25/08 17:37	4/25/08 17:37	MILKROCK	Graph Data	Alarm	Signature	Event
afp	4/25/08 17:37	4/25/08 17:39	MILKROCK	Graph Data	Alarm	Signature	Event
afp	4/25/08 17:32	4/25/08 17:32	MILKROCK	Graph Data	Alarm	Signature	Event
afp	4/25/08 17:15	4/25/08 17:19	MILKROCK	Graph Data	Alarm	Signature	Event
afp	4/25/08 17:04	4/25/08 17:15	MILKROCK	Graph Data	Alarm	Signature	Event
afp	4/25/08 17:01	4/25/08 17:01	MILKROCK	Graph Data	Alarm	Signature	Event
afp	4/25/08 16:46	4/25/08 16:46	MILKROCK	Graph Data	Alarm	Signature	Event
afp	4/25/08 16:40	4/25/08 16:40	IL WAFER	Graph Data	Alarm	Signature	Event
afp	4/25/08 16:37	4/25/08 16:38	IL WAFER	Graph Data	Alarm	Signature	Event
afp	4/25/08 16:33	4/25/08 16:33	FAT	Graph Data	Alarm	Signature	Event
afp	4/25/08 16:20	4/25/08 16:20	FAT	Graph Data	Alarm	Signature	Event
afp	4/25/08 14:57	4/25/08 14:58	TEST1	Graph Data	Alarm	Signature	Event
afp	4/25/08 14:14	4/25/08 14:14	TEST1	Graph Data	Alarm	Signature	Event
afp	4/25/08 13:36	4/25/08 13:46	FAT	Graph Data	Alarm	Signature	Event
afp	4/25/08 12:06	4/25/08 12:02	FAT	Graph Data	Alarm	Signature	Event



Batch Report

Print Date: 02/03/09

Batch ID: ABA

Cycle Start Time: 09/15/08 00:00:00

Cycle End Time: 09/16/08 00:00:00

Shift	Setpoint	Condenser Temp	Probe Average	Shall to Temp	Vacuum Setpoint	Vacuum	Vacuum Capa	Vacuum Picon
09/15/08 13:47	20.00	18.77	17.59	18.67	100.00	100.00	0.00	711.900.00
09/15/08 13:58	20.00	18.77	17.59	18.67	100.00	100.00	0.00	711.900.00
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09/15/08 15:00	20.00	21.48	18.28	19.28	100.00	100.00	0.00	711.900.00

Batch Report

Print Date: 02/03/09

Batch ID: FAT

Signature Time: 12/16/08 18:29

Action Message: [OPTDRY] Batch FAT Start by OPTDRY:ADMIN

Operator: ADMIN

Performed By: ADMIN

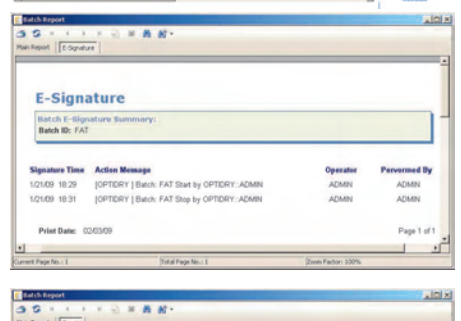
Signature Time: 12/16/08 18:31

Action Message: [OPTDRY] Batch FAT Stop by OPTDRY:ADMIN

Operator: ADMIN

Performed By: ADMIN

Print Date: 02/03/09



Batch Report

Print Date: 02/03/09

Batch ID: ABA

Cycle Start Time: 09/15/08 00:00:00

Cycle End Time: 09/16/08 00:00:00

Shift	Setpoint	Condenser Temp	Probe Average	Shall to Temp	Vacuum Setpoint	Vacuum	Vacuum Capa	Vacuum Picon
09/15/08 13:47	20.00	18.77	17.59	18.67	100.00	100.00	0.00	711.900.00
09/15/08 13:58	20.00	18.77	17.59	18.67	100.00	100.00	0.00	711.900.00
09/15/08 13:59	20.00	19.38	17.59	18.67	100.00	100.00	0.00	711.900.00
09/15/08 14:00	20.00	19.38	17.59	18.67	100.00	100.00	0.00	711.900.00
09/15/08 14:01	20.00	19.38	17.59	18.67	100.00	100.00	0.00	711.900.00
09/15/08 14:02	20.00	19.38	17.59	18.67	100.00	100.00	0.00	711.900.00
09/15/08 14:03	20.00	19.38	17.59	18.67	100.00	100.00	0.00	711.900.00
09/15/08 14:04	20.00	19.38	17.59	18.67	100.00	100.00	0.00	711.900.00
09/15/08 14:05	20.00	19.38	17.59	18.67	100.00	100.00	0.00	711.900.00
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09/15/08 14:09	20.00	20.15	18.28	19.28	100.00	100.00	0.00	711.900.00
09/15/08 14:10	20.00	20.15	18.28	19.28	100.00	100.00	0.00	711.900.00
09/15/08 14:11	20.00	20.15	18.28	19.28	100.00	100.00	0.00	711.900.00
09/15/08 14:12	20.00	20.15	18.28	19.28	100.00	100.00	0.00	711.900.00
09/15/08 14:13	20.00	21.48	18.28	19.28	100.00	100.00	0.00	711.900.00
09/15/08 14:14								

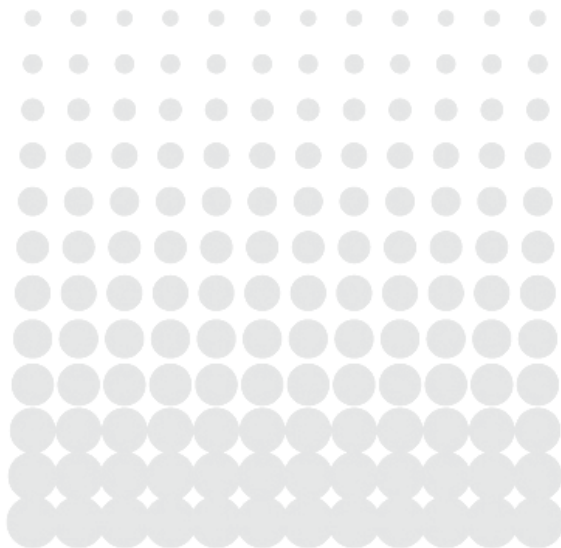


Experience Since 1957

Freeze Drying is Our Focus

Millrock Technology provides Pharmaceutical quality (cGMP) and industrial grade freeze dryers that meet the most demanding application requirements. As the science and equipment of freeze drying continues to evolve....Millrock freeze dryers are continuously updated with the latest features and technology to provide optimum performance.

Quanta Examples	12	24	30	50	60	96	144	320	
Shelf Area	Sq Ft	12	24	30	48	60	96	144	300
	Sq M	1.11	2.22	2.78	4.44	5.57	9.29	13.3	29.7
Number Shelves	6	8	10	5	6	8	12	16	
Shelf Size	in x in	12 x 24	18 x 24	18 x 24	30 x 48	30 x 48	36 x 48	36 x 48	48 x 60
	mm x mm	300 x 600	450 X 600	450 x 600	600x 915	600 x 915	915 x 1215	915 x 1215	1500 x 1500
Condenser Capacity Liters	30	60	75	100	150	200	300	600	
Condenser Temp				-75C					
Shelf Temp				-60C					
Cooling				Water Cooled					
Vial Capacity									
2 ml (15mm)	5080	10470	13090	21424	26780	43888			
5 ml (22mm)	2380	4880	6100	10050	12560	20120			
10 ml (24mm)	1835	3952	4940	8170	10220	17032			
20 ml (29mm)	1290	2650	3320	5610	7020	11344			



MILLROCK TECHNOLOGY, Inc

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Note: Specifications subject to change without notice.

All specifications based on 20C ambient on 60Hz

Rev 1108

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