



# Large R&D Freeze Dryer



## STANDARDS

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ASTM E3250

FDA 21 CFR Part 11

IEC 61010-1

ISO 13408-3

## Large R&D Freeze Dryer - QualiRFD™ 10

A Freeze Dryer in the QualiRFD™ 10 is built for process development that needs production-like control in a research footprint. This freeze dryer machine supports parameter optimization, scale-up studies, and repeatable cycle development for sensitive materials.

The Large R&D Freeze Dryer - QualiRFD™ 10 model uses an in-situ vacuum freeze-drying workflow, with a dual-chamber design that integrates the cold trap and drying chamber in one system.

QualiRFD™ 10 is a pilot-scale R&D Freeze Dryer that mirrors key behaviors of production lyophilizers to help teams refine freeze-drying recipes before transferring to manufacturing. The system provides a controlled low-temperature condenser and a heated shelf environment to support primary and secondary drying studies.

A transparent chamber door supports visual observation during development work, while multi-level temperature probing helps track product temperature at different shelf positions.

## APPLICATIONS

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### Large R&D Freeze Dryer - QualiRFD™ 10 Applications

- Biotechnology and bioproducts: Develop stable drying cycles for proteins, enzymes, and other biologics where structure retention depends on tight control of product temperature and chamber pressure. The Large R&D Freeze Dryer – QualiRFD™ 10 format supports iterative cycle tuning and repeatability for R&D teams.
- Pharmaceutical R&D and formulation work: Build and refine lyophilization cycles for injectable and sterile-process candidates, including excipient screening and cycle optimization prior to scale-up. Instrumentation-focused guidance is commonly referenced for monitoring product temperature and equipment pressure during pharmaceutical freeze drying.
- Materials science and chemical engineering: Freeze-dry porous structures, powders, catalysts, and moisture-sensitive intermediates where solvent removal must avoid thermal damage or collapse. The wide shelf temperature span supports diverse formulations and process windows.
- Food and specialty ingredients (pilot development): Evaluate texture and rehydration behavior for high-value ingredients by controlling freezing profiles and sublimation conditions during product development trials.



## Standards

- ISO 13408-3: Aseptic processing guidance for lyophilization (freeze-drying) within healthcare product manufacturing contexts.
- ASTM E3250: Best-practice guidance for product temperature and equipment pressure instrumentation in pharmaceutical freeze drying.
- IEC 61010-1: General safety requirements for electrical laboratory equipment.
- FDA 21 CFR Part 11: Electronic records and electronic signatures expectations when applicable to regulated recordkeeping.

## FEATURES

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### **Large R&D Freeze Dryer - QualiRFD™ 10 Key Features**

- In-situ vacuum freeze-drying workflow supports pre-freeze and drying in place for streamlined operation.
- Dual-chamber structure combines cold trap and drying chamber in one integrated system layout.
- Casing design supports easier service access to support routine maintenance tasks.
- Independent sample temperature probing supports product monitoring across shelf positions during development cycles.
- Cold trap rapid cooling behavior supports faster turnaround between runs in pilot workflows.
- Sublimation-curve style control supports stepwise or ramp-like temperature transitions for cycle development.
- PLC + PID control architecture supports stable shelf temperature management for repeatable recipes.
- Inert gas backfill capability supports post-dry handling practices where oxidation or moisture pickup is a concern.
- Maintenance reminders and layered safety functions support safer operation around vacuum and refrigeration subsystems.

## THEORY & METHOD

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### Theory and Method

Freeze drying (lyophilization) removes solvent by sublimation under vacuum after the product is frozen. The process typically runs in stages: freezing, primary drying (ice sublimation under reduced pressure), then secondary drying (desorption of bound water at controlled shelf temperature). The Large R&D Freeze Dryer - QualiRFD™™ L is designed to support these stages with an integrated cold trap and shelf temperature control, enabling R&D teams to tune ramp/step profiles and evaluate cycle robustness.

## TECHNICAL SPECIFICATIONS

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### Large R&D Freeze Dryer - QualiRFD™ 10 Technical Specification

Specification	Large R&D Freeze Dryer - QualiRFD™ L
Freeze-drying area	0.7 m <sup>2</sup>
Recommended loading capacity	7 kg
Cold trap temperature	< -75 °C (no-load)
Vacuum level	≤ 1 Pa (no-load)
Shelf temperature range	-55 to +70 °C (no-load)
Maximum ice capacity	≥ 10 kg/24h
Number of shelf layers	4 + 1

Specification	Large R&D Freeze Dryer - QualiRFD™ L
Material tray size	480 × 360 mm
Shelf spacing	50 mm (optional 70 mm)
Overall power	5.5 kW
Weight	600 kg
Dimensions (W × D × H)	823 × 1008 × 1420 mm
Loadable materials	7 (L/kg listed)
Defrost mode	Natural defrost (optional electric defrost)
Safety devices	Audible alarm, emergency stop, overpressure protection
Voltage	Single-phase 3-wire, 220 V (110V is also available)
Optional features (site-listed)	Vacuum level control, eutectic point testing, chamber isolation valve, remote control, imported vacuum pumps, anti-oil backflow valve, oil mist filter



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