QUALITEST™

Extra Large R&D Freeze Dryer

STANDARDS

ASTM E2500
ISO 13408-3
ISO 14644-1
ISO 14644-2

Extra Large R&D Freeze Dryer – QualiRFD™ 15

Freeze Dryer performance often makes or breaks scale-up from lab recipes to pilot batches. The QualiRFD™ 15 Freeze Dryer is built for R&D groups that need repeatable cycle development, clear process visibility, and parameter control that stays consistent when you move closer to production settings. It uses an in-situ workflow where pre-freezing and drying happen inside the same chamber, which reduces handling steps and supports cleaner, more consistent runs.

QualiRFD™ 15 is an in-situ vacuum Freeze Dryer designed for process exploration, formulation screening, and small-batch pilot studies in regulated and industrial labs. The unit combines a drying chamber with a low-temperature condenser (cold trap) to capture sublimated vapor efficiently while maintaining stable vacuum conditions. A transparent chamber door supports live observation during freezing, primary drying, and secondary drying, which helps you confirm product behavior without interrupting the cycle.

A recipe-driven control platform supports stepwise ramps and holds so your team can build, save, and repeat cycles during optimization work. The system also records key trends such as shelf temperature, product temperature, cold trap temperature, and vacuum, making it easier to compare trials and justify parameter changes.

APPLICATIONS

Extra Large R&D Freeze Dryer – QualiRFD™ 15 Applications

- Pharmaceutical R&D and lyophilized dosage development: Teams use the Freeze Dryer to develop and refine lyophilization cycles for injectables and other formulations. Work typically includes determining safe freezing rates, defining primary drying limits, and confirming secondary drying targets to support stability and shelf-life goals.
- Biotechnology and life science sample preservation: Proteins, antibodies, enzymes, and other biomolecules can be lyophilized for longer-term storage, shipping, or downstream testing. Controlled shelf temperature and vacuum trending help researchers reduce collapse risk and maintain activity after reconstitution.
- In vitro diagnostic and research reagents: The QualiRFD™ 15 format supports development batches for IVD reagents and similar products that benefit from low residual moisture and stable storage conditions. Cycle repeatability supports method transfer from development to controlled pilot batches.
- Materials and chemical research: Freeze-drying can be used to prepare porous structures, powders, polymers, coatings, and film-related samples for R&D work. Controlled drying curves help reduce deformation and support repeatable morphology in comparative studies.
- Environmental sample preparation: Labs can process environmental samples such as water/soil-related extracts and other monitoring samples when freeze-drying is used as a preparation step before analysis. Logged cycle data supports consistency across studies and time periods.


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Standards

- ISO 13408-3 (Aseptic processing of health care products — Lyophilization): guidance for control and validation of lyophilization as an aseptic process.
- ASTM E2500: risk-based approach for specification, design, and verification of pharmaceutical/biopharmaceutical manufacturing systems and equipment.
- ISO 14644-1 / ISO 14644-2: cleanroom air cleanliness classification and monitoring, commonly referenced when Freeze Dryer installation and operation are tied to controlled environments.

FEATURES

Extra Large R&D Freeze Dryer – QualiRFD™ 15 Key Features

- In-situ Freeze Dryer workflow with freezing and drying completed in the same chamber for cleaner handling and consistent results.
- Dual-chamber architecture (drying chamber + cold trap) designed to capture vapor efficiently during sublimation.
- Transparent chamber door for real-time observation of the Freeze Dryer process without stopping the run.
- PID shelf temperature control to minimize deviations and support uniform drying across shelf positions.
- Freeze-drying curve control for stepwise ramps and holds through freezing, sublimation, and desorption, with support for process optimization trials.
- Inert gas backfill capability through a controlled valve connection, supporting post-drying backfill to protect sensitive samples.
- Recipe management with stored programs containing multiple temperature-control segments for repeatable experimentation and pilot batches.
- Comprehensive data trending and export for cold trap temperature, sample temperature, and vacuum curves to support documentation and cycle development.

- Manual and automatic operating modes for hands-on experimentation or consistent batch execution once parameters are set.
- Alarm history and user access control to support troubleshooting, maintenance workflows, and controlled operation.

THEORY & METHOD

Theory and Method

A Freeze Dryer removes solvent in two main stages under vacuum:

Freezing and ice formation

The product is cooled on temperature-controlled shelves until the solvent crystallizes. Freezing rate impacts ice crystal size, which influences mass transfer resistance during drying.

Primary drying (sublimation)

Chamber pressure is reduced, and shelf temperature is raised in a controlled manner. Ice sublimates directly to vapor, which flows to the cold trap and re-freezes there. Tight control of shelf temperature ramp/hold steps helps prevent collapse or melt-back.

Secondary drying (desorption)

After most ice is removed, the shelf temperature is adjusted to drive off bound water (or residual solvent). Cycle segmentation supports repeatable studies that target residual moisture limits and reconstitution behavior.

TECHNICAL SPECIFICATIONS

Extra Large R&D Freeze Dryer – QualiRFD™ 15 Technical Specification

Item	Unit	QualiRFD™ XL
Freeze-drying area	m²	1.03
Recommended loading capacity	kg	10
Cold trap temperature (no-load)	°C	< -75
Ultimate vacuum level (no-load)	Pa	≤ 1
Shelf temperature range (no-load)	°C	-55 to +70
Maximum ice capacity	kg/24h	≥ 15
Number of shelf layers	pcs	6 + 1
Tray size	mm	480 × 360
Shelf spacing	mm	70
Overall power	kW	6.5
Weight	kg	700
Dimensions	mm	876 × 1190 × 1727

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