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Medium Stoppering R&D Freeze Dryer



STANDARDS

ASTM E2500

ISO 13408-3

ISO 14644-1

Medium Stoppering R&D Freeze Dryer - QualiRFD™ 8S

A Freeze Dryer with vial stoppering helps R&D teams develop cycles that stay stable after drying and during storage. The QualiRFD™ 8S Freeze Dryer is designed for medium-scale development batches where process repeatability and production-like handling matter. It runs an in-situ workflow, so freezing and drying occur inside the same chamber to reduce handling steps and improve consistency across trials.

QualiRFD™ 8S is an in-situ vacuum Freeze Dryer built around a dual-chamber layout that combines a drying chamber with a cold trap (condenser). The cold trap captures sublimated vapor efficiently while the chamber stays under controlled vacuum, supporting stable primary drying conditions. A stoppering function seals vial stoppers after the cycle, which helps reduce moisture uptake and contamination risk during storage and transfer.

The control platform supports recipe-based operation with multi-step segments, so teams can develop, save, and repeat temperature ramps and holds while optimizing cycles. Shelf-level sample temperature probing supports better visibility during cycle development and troubleshooting when product temperature limits are tight.

APPLICATIONS

Medium Stoppering R&D Freeze Dryer - QualiRFD™ 8S Applications

- Lyophilized pharmaceutical vials in development labs: Cycle development for injectables often needs controlled ramps, stable vacuum, and repeatable endpoints. Stoppering inside the Freeze Dryer helps preserve the dried cake and reduce rehydration after drying, which supports stability studies and packaging transfer.
- Biotech and life science reagents: Proteins, enzymes, and biological reagents benefit from low residual moisture and consistent sublimation behavior. Programmable segments and shelf temperature control help teams compare formulations and process windows using repeatable runs.
- In vitro diagnostic and research kits packaged in vials: Many IVD and research reagents are filled into vials before lyophilization. Stoppering after drying supports longer storage life by limiting moisture adsorption and reducing exposure during post-process handling.
- Specialty materials and chemical R&D: Freeze drying supports porous structures, powders, and other development samples where ice structure and drying conditions influence final morphology. Logged process trends help teams justify parameter changes and reproduce results between experiments.



Standards

- ISO 13408-3 (Aseptic processing — Lyophilization): guidance for control and validation of lyophilization when used in aseptic workflows, which fits vial-based and stoppering use cases.
- ASTM E2500: science- and risk-based approach for specifying, designing, and verifying pharma/biopharma manufacturing systems and equipment.
- ISO 14644-1: cleanroom air cleanliness classification, often referenced when Freeze Dryer installation and operation are tied to controlled areas.

FEATURES

Medium Stoppering R&D Freeze Dryer - QualiRFD™ 8S Key Features

- In-situ vacuum Freeze Dryer workflow that automates freezing and drying inside one chamber.
- Stoppering mechanism for sealing vial stoppers after drying to limit moisture pickup and support clean handling.
- Dual-chamber design with cold trap plus drying chamber for stable vapor capture during sublimation.
- Shelf-level independent sample temperature probing to support cycle development and confirmation runs.
- Stepwise or linear curve control for temperature ramps and holds across freezing, primary drying, and secondary drying.
- Shelf temperature control accuracy stated at $\pm 1^{\circ}\text{C}$, supported by PLC control and PID regulation.
- Cold trap pull-down performance stated from -20°C to -40°C in ≤ 20 minutes, supporting faster cycle readiness.
- Nitrogen backfill capability for inert gas use during drying or end-of-cycle handling.
- Program storage with up to 36 segments per program, plus the ability to modify parameters and skip segments during automatic runs.
- Maintenance reminders and safety protections, including alarm, emergency stop, and overpressure protection.

THEORY & METHOD

Theory and Method

Freeze drying removes solvent through freezing, sublimation, and desorption under reduced pressure. The product is first frozen on temperature-controlled shelves, which sets ice structure and affects vapor flow during drying. Primary drying follows under vacuum, where ice sublimates and vapor is captured on the cold trap at low temperature.

Secondary drying removes bound moisture by holding under vacuum while adjusting shelf temperature to reach target residual moisture. A stoppering Freeze Dryer adds a closure step at the end of the cycle, sealing vial stoppers to reduce moisture reabsorption and protect the product after the run.

TECHNICAL SPECIFICATIONS

Medium Stoppering R&D Freeze Dryer - QualiRFD™ 8S Technical Specification

Specification	Unit	QualiRFD™ 8S
Freeze drying area	m ²	0.3
Cold trap temperature (no-load)	°C	< -75
Vacuum level (no-load)	Pa	≤ 1
Shelf temperature range (no-load)	°C	-55 to +70
Maximum ice capacity	kg/24h	≥ 8

Specification	Unit	QualiRFD™ 8S
Number of shelf layers	pcs	3 + 1
Material tray size	mm	300 × 340
Shelf spacing	mm	70
Overall power	kW	5.5
Weight	kg	400
Dimensions	mm	853 × 1272 × 1679
Loadable materials	L/kg	3
Vial capacity (Φ12 mm)	pcs	2187
Vial capacity (Φ16 mm)	pcs	1200
Vial capacity (Φ22 mm)	pcs	654
Defrost mode	—	Electric defrost
Safety devices	—	Audible alarm, emergency stop, overpressure protection
Voltage	—	Three-phase 5-wire, 380 V



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Qualitest USA (Corporate Sales Office)

Toll-Free: 1.877.884.TEST (8378) | Fax: 954.697.8211
E-mail: info@qualitest-inc.com
Address: 8201 Peters Rd., #1000,
Plantation, FL 33324, USA.

Qualitest Canada & International

Tel: +1.905.944.9825 | Fax: +1.905.944.0304
E-mail: sales@qualitest-inc.com
Address: 70 East Beaver Creek Rd., #9, Richmond Hill,
Ontario L4B 3B2, Canada.

Qualitest Latin America (Mexico and LATAM Region)

E-mail: ventas@qualitest-inc.com

Qualitest KSA (Regional Office)

Tel: +966 11 500 6659
Address: Level 7, 3.09, District 3, King Abdullah
Financial District, Riyadh, Saudi Arabia

Qualitest Singapore (ASIA PACIFIC Regional Office)

Tel: +65 6393 5480 | E-mail: singapore@qualitest-inc.com
Address: 50 Raffles Place, Singapore Land Tower,
Level 46, Singapore, 048623.

Qualitest Indonesia (Representative Office)

Tel: +62 21 2985 9522 | Fax: +62 21 2985 9889
E-mail: indonesia@qualitest-inc.com
Address: One Pacific Place Level 11, Jl. Jend. Sudirman,
Kav. 52-53, SCBD Area, Jakarta 12190, Indonesia.

Qualitest FZE (Regional GCC/ME Office)

Tel: +971 4 8819252 | Fax: +971 4 8819262
Email: gcc@qualitest-inc.com
Address: Jafza One, BB 1610, Jebel Ali Free Zone,
PO Box 261440, Dubai, UAE.

Qualitest India

E-mail: india@qualitest-inc.com
Address: 15th Floor, Dev Corpora, Pokhran Road No.1,
Eastern Express Highway, Thane, Maharashtra,
Mumbai, 400601, India

