

Gruenberg

S Series Sterilizers



Gruenberg offers a range of standard and optional controls.



- 21 CFR Ready Controls
- Pressure Locks
- Web-Based
- Service Connectivity
- Factory Acceptance Test

Gruenberg

S-Series Class 100 Pharmaceutical Sterilizer

Our new pharmaceutical sterilizer is cGMP compliant, flush front, and offers more standard features than competing models.

- HEPA filtration minimum 99.97% efficient at 0.3 microns
- Intake HEPA filter prevents contaminants from entering the sterilizer during operation
- Exhaust HEPA filter ensures that contamination will not be drawn into the sterilizer as the cycle ends
- Side wall filters provide distinct advantages
- Filtration takes place just before the air enters the sterilization chamber so that class 100 conditions are ensured
- Easy access to filters for validation and maintenance

STANDARD FEATURES

Designed and manufactured to comply with all pertinent cGMP requirements. Interior is manufactured with a fully welded 304L-2B stainless steel liner. All interior corners are rounded with a 3/4" radius to provide ease of wipe downs.

- Standard Sterilizers are rated for 260°C depyrogenation.
- ISO14644-1, ISO Class 5 (209e Full Class 100) sterilizing conditions throughout the process cycle (1.5°C/Minute ramp rate, with option of rapid capacity filters up to 10°C/minute ramp rate.) HEPA filters are installed in the air intake, exhaust and recirculation wall. The intake HEPA filter prevents contaminants from entering the sterilizer during operation and is protected with an upstream prefilter. The exhaust HEPA filter ensures contamination will not be drawn into the sterilizer at the cycles end. Side wall filters provide filtration immediately prior to the process air entering the sterilization chamber.
- A Bio-seal flange is provided to seal the sterilizer into the facility wall at the "clean" side of the system and ensures a positive barrier preventing particulate from entering the room from the maintenance area.
- Pass Through with interlocked pneumatically locked doors. The doors are provided with a pneumatic latching and locking system. The door will latch automatically and will remain locked to provide proper pass-through operation.
- UL 508A Listed Control Panel.
- Lockable Disconnect Switch on Control Panel Door. Lockout Tagout capable.
- Both Control Systems are 21 CFR Part 11 Ready.

Optional Equipment:

- Accelerated Cycle Time (10°C / minute) The standard HEPA filters will be replaced by advanced filters that can operate under greater differential thermal expansion. In addition to the upgrade in filtration, the system will require additional heat input to maintain the accelerated heat up rate.
- 316L Stainless Steel Interior
- Cooling Coil in Intake Stream
- Pressure Differential Control System
- GAMP 4 Documentation
- IQ/OQ Protocols (unexecuted or executed) Full validation documentation in accordance with the GAMP regulations.
- Chart Recorder
- Stainless steel trucks and trays in standard and custom sizes.

Physical Specifications

Model	Interior Dimensions W" x D" x H"	Exterior Dimensions W" x D" x H"	Heating Input (Std. Ramp Rate)	Chamber Capacity (cubic feet)
SC55H8.3PTSS	20 x 30 x 24	45.75 x 50.44 x 85.38	9 kW	8.3
SC55H13.2PTSS	24 x 34 x 28	49.75 x 54.44 x 93.38	18 kW	13.2
ST55H31.4PTSS	32 x 34 x 50	70.75 x 54.44 x 97.38	24 kW	31.4
ST55H59.9PTSS	37 x 56 x 50	75.75 x 76.44 x 103.38	45 kW	59.9
ST55H95.8PTSS	48 x 69 x 50	86.75 x 89.44 x 103.38	54 kW	95.8

Gruenberg has available a variety of additional pharmaceutical sterilizers and depyrogenation ovens to meet your specific requirements. Note: exterior dimensions are overall cabinet dimensions.

Performance Specifications

	Maximum Heating Rate	Maximum Cooling Rate (to 40°C)	Maximum Tem- perature	Estimated Cycle Time
Accelerated Ramp	10°C / Min.	4°C / Min. Air	260°C	2.3 Hours
	10°C / Min.	8°C / Min. Water	260°C	1.9 Hours
Standard Ramp	1.5°C / Min.	1.5°C / Min.	260°C	6.0 Hours

Custom Configurations Available.

All sterilizers are designed for your specific temperature and cycle time requirements.

