

We'll make short work of your sterilisation process!

## VAPOVAC Steriliser

VAPOVAC Steriliser - VHP Sterilisation for Freeze Dryers

Do you want to:

... shorten process cycle times?

... make sterilization more effective?

...save energy and natural resources?

GEA Lyophil leads the way in sterilising freeze drying equipment using Vaporized Hydrogen Peroxide (VHP) the innovative method that delivers all three advantages at the same time. GEA Lyophil is the most experienced manufacturer offering this technology for both new-build plants and for retro-fit to existing installations.



The VAPOVAC steriliser from GEA Lyophil uses VHP technology to sterilise equipment under vacuum at room temperature. It uses a very small quantity of hydrogen peroxide to penetrate the freeze dryer vessels and all associated piping of the equipment and effectively eliminates all residual contamination. The freeze dryer is then fully vented leaving no harmful residues.



Steam sterilisation, by comparison, uses a lot of energy, requires complex pressurised vessel and piping systems, and requires time-consuming cooling before re-use.

*Lyophil Technologies*

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## Technical information

### Required equipment for the freeze dryer:

- **Water ring Pump**  
Size and capacity of the water ring pump should be chosen according to the freeze dryer volume to ensure a short evacuation step before and after sterilisation.
- **Vacuum pump set**  
A final pressure below 0.02 mbar is recommended. In case of multiple injection phases, the pumps should be compatible with vaporized hydrogen peroxide.
- **Leakage tightness**  
The pressure rise rate must be below 0.1mbar/min.
- **Pressure sensors**  
Pressure sensors with a complete measuring range of 0.001...2.000 mbar are required.

### Requirements for traditional retrofits:

- Chamber pressure sensor (range 0.1...100mbar)
- H<sub>2</sub>O<sub>2</sub>-inlet pipe between VAPOVAC-Steriliser and sterile filter
- Hydrogen peroxide check port in the freeze dryer wall
- Two drain temperature sensors

### Options:

Depending on the setup of the Freeze Dryer the following options are available:

- Temperature controlled pipe heating for the complete venting system
- Hydrogen peroxide destroyer at the exhaust line of the vacuum pump set
- Aggregates with higher performance

### Utility Requirements

#### Power Supply (Steriliser only):

- 3/PE, 1kW, in compliance to federal or state regulations
- Further power requirements depend on aggregate power consumption

#### Media:

- Air supply 6 bar regulated
- 35 mass.-% H<sub>2</sub>O<sub>2</sub>

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### Low cost and kind to the environment

The VAPOVAC steriliser uses little energy so it is cheaper and kinder to the environment. The chamber, condenser and the connecting pipes are at atmospheric pressure making them less expensive and easier to install; the elimination of high-pressure hoses also makes the process safer and reduces the wear caused by pressure changing stresses.

### Faster turnaround for greater efficiency

The entire operation takes place at room temperature so sterilisation can be performed in approximately 3 hours for an average production freeze dryer, compared with approximately 8 hours for steam sterilisation. This gets the plant running again much more quickly for greater productivity and efficiency.

- Low investment and operational costs
- Short process time
- Long service intervals
- No toxic residues
- Effective sterilisation
- Meets GAMP, cGMP, FDA, DIN, ISO and all other European and US codes.
- Available for new installations and retro-fit in existing plants.
- International and European patents are pending.

### Process Sequence

#### Drying

The drying chamber and condenser are dried to prevent absorption of hydrogen peroxide by condensate.

#### Evacuation

The freeze dryer is evacuated to a very low pressure to ensure a homogeneous distribution of the hydrogen peroxide.

#### Injection

When the injection set pressure is reached, the H<sub>2</sub>O<sub>2</sub> solution is sprayed into the vaporizer. The liquid evaporates within seconds and the vapor is directed into the freeze dryer.

#### Residence Time

After injection the residence time of the hydrogen peroxide is monitored and can be adjusted to ensure effective sterilisation.

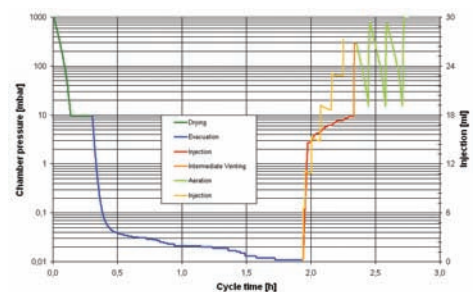
#### Aeration Phase

After sterilisation the hydrogen peroxide is completely and safely removed from the chamber to comply with federal regulations. The control system requires the operator to confirm that successful H<sub>2</sub>O<sub>2</sub> evacuation has been achieved to complete the sterilisation process.

#### Retrofit

Would you like to make your old freeze dryer sterilisable but are put off by the high costs involved? Then consider using H<sub>2</sub>O<sub>2</sub> sterilisation. Retrofitting your existing freeze dryer only requires a few minor changes to hardware, and some software modifications - a minimal effort in time and cost compared to equipping a non-sterilisable unit with steam sterilisation. After the retrofit, the freeze dryer will meet current FDA standards and can provide many years more service. The requalification can be part of the regular maintenance and revalidation cycle, so there is no additional cost or time involved.

Retrofits can be carried out for GEA Lyophil plants and for freeze dryers from other manufacturers.



[www.geapharmasystems.com](http://www.geapharmasystems.com)

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