The Best Recipe for Germ-Free Air: Viledon Filter Systems for Cleanroom Technology

viledon®

The Freudenberg Nonwovens Group

Freudenberg

Where every single germ counts...

The pharmaceutical industry bears an unusually high degree of responsibility to both mankind and the natural environment during the entire production cycle for solid or liquid medicines. Beginning with research and development, continuing through the production process all the way to final packaging, ultra-stringent safety regulations have to be complied with, designed to minimise the risk of contamination with micro-organisms, particles and pyrogens.

Equally stringent safety regulations apply in the related fields of biotechnics and medical technology, as well as the production of foodstuffs and cosmetics free of preservatives, all of which necessitate assured safety zones during particular stages of the process.

A crucial element in this context is the quality of the air, whose maximised purity is essential for monitored chemical/pharmaceutical processes and numerous others as well.

The high degree of air purity required for producing and packaging sterile medicines, the handling of hazardous substances, and the processing of products not amenable to final sterilisation, or of highly perishable foodstuffs, can be created only in faultlessly functioning clean areas (cleanrooms, safety workbenches, isolators, etc.).

The table below shows the classification of clean areas under the GMP (Good Manufacturing Practice) Guidelines drawn up by the American FDA (Food & Drug Administration) and also by the EC, combined with a recommendation for the filter classes to be installed in the final stage. Detailed definitions of the room classes concerned can be found in the specialised literature. Careful attention must be paid to the production line's operating modes (at rest, production).

To attain the clean air quality required, air filters of different filter classes and designs are combined to form multi-stage systems.

A prefiltration unit, usually comprising two stages, collects coarse to fine particles, so as to store the principal mass of air contaminants. This reduces the loading on the final HEPA/ULPA filters, which by collecting ultra-fine particles determine the actual quality of the clean air involved.

In order to achieve maximised clean air quality directly at the sterile product, the air is delivered in a low-turbulence displacement flow. In the adjoining areas, the number of air changes per hours should be chosen to suit the particular room, the equipment and the staff concerned. The supply of filtered air to any zone must be dimensioned so as to ensure

EC Recommendations (GMP Guidelines) Room Class	GMP Guidelines of the FDA		Air flow	Recommended filter classes for the final HEPA/ULPA filters
	Maximum number of particles ≥ 0.5 µm	Maximum number of germs (CFUs*)		
A	100 per ft^3 3,531 per m^3	0.1 per ft^3 3 per m^3	low-turbulent/ „laminar"	H 13 / H 14
B	—	—	turbulent	H 13 / H 14
C	100,000 per ft^3 3,531,467 per m^3	2.5 per ft^3 88 per m^3	turbulent	H 13
D	—	—	turbulent	H 11 / H 13

* CFUs = Colony-Forming Units

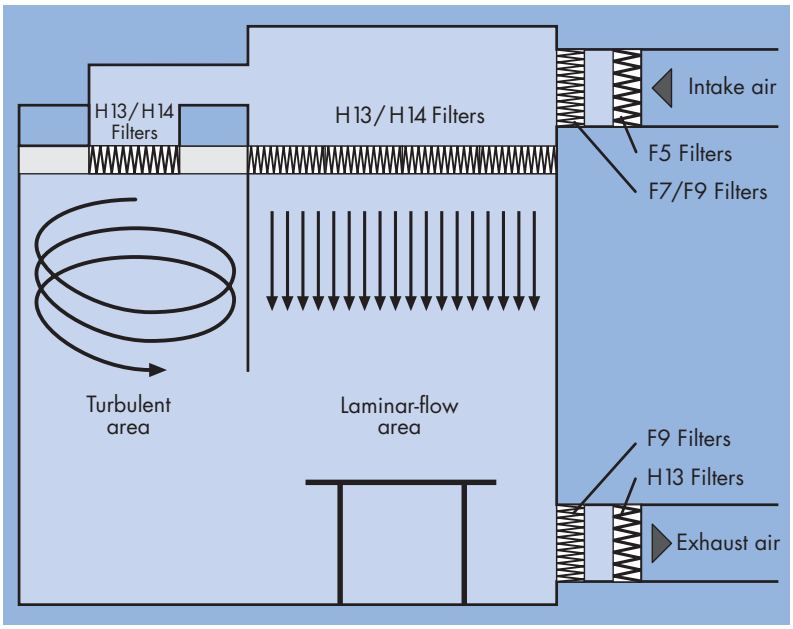
... it pays to be well on the safe side

that no matter what the operating conditions are, effective air flow is guaranteed and an overpressure is maintained against adjoining areas with a lesser risk.
The air flows are carefully routed so that particles generated by a person, a process or a machine are not carried into zones with a higher risk.
When handling hazardous substances, the exhaust air has to be cleaned by HEPA/ULPA filters too.

A typical cleanroom concept for pharmaceutical processes is illustrated diagrammatically on the right.

The absolute reliability of the filters used, in terms of collection efficiency, leakproof construction and secure mounting in the support system, is crucial for the safe manufacture of sterile products. Choosing a concomitantly high-quality filter system will always pay off, not least in terms of cleanroom validation and monitoring.

For cleanroom installations, Freudenberg offers a complete range of filters in the Classes G 3 to U 17, meeting even the toughest of requirements for efficient and dependable operation. The choice available also includes our newly developed combination filters for reducing pollutant gases and unwanted odours.



Typical cleanroom concept for pharmaceutical processes

Their unique media structure provides Class F 7 particle filtration plus effective gas adsorption with activated carbon in a single filter stage. So they can be used as replacements both for particle filters and for activated-carbon filters, offering high additional utility compactly designed in.

Pharmaceutical cleanroom with Viledon HEPA filters

Vertical-flow cleanroom module with Viledon HEPA filters

Economical top performance in the first place: Viledon Compact pocket filters

Viledon Compact pocket filters are depth-loading filters. The particles are arrested in the filter medium at the fiber surface.

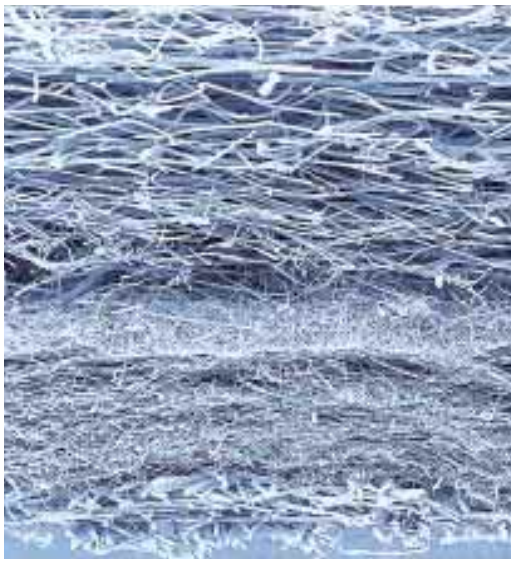
Viledon Compact pocket filters are predominantly used in prefiltration and have given cost-efficient, dependable service in a wide range of different applications. Their particular design features offer numerous advantages:

- The filter media of synthetic/organic fibers are progressive or triple-layered in structure and provide high dust holding capacity in conjunction with a slow rise in pressure drop and thus long lifetimes.

- Inherently rigid design of the filter pockets ensures uniform dust storage. The pockets will neither sag nor collapse, precluding any possibility of dust penetration at shutdowns or load changes. Even with high dust loads and damp conditions the inherent rigidity and the filtration efficiency are fully maintained.

- The filter pockets are welded to prevent leaks and securely foamed into the polyurethane front frame; dust penetration is thus reliably precluded even at high pressure drops.

- The welded-in spacers ensure optimum shaping of the filter pockets during operation, preventing any loss of active filtering area due to pocket surface contact.



500 µm

3-layer nonwoven filter medium, inner layer electrostatically spun microfibers

- The polyurethane front frame is corrosion-proof and reinforced by a foamed-in profile for maximum mechanical strength.

- The entire filter element is moisture-resistant up to 100% relative humidity, thermally stable up to 70°C, stands up well to most chemicals, and can be incinerated completely.

- Low maintenance and servicing costs.

- High-quality accessories, like a mounting frame made of stainless steel or galvanized sheeting, with a positive spring-lock system and a plug-in rubber seal.

Viledon Compact pocket filters – the design assets

Safety in the last instance: Viledon MaxiPleat and HEPA/ULPA filters

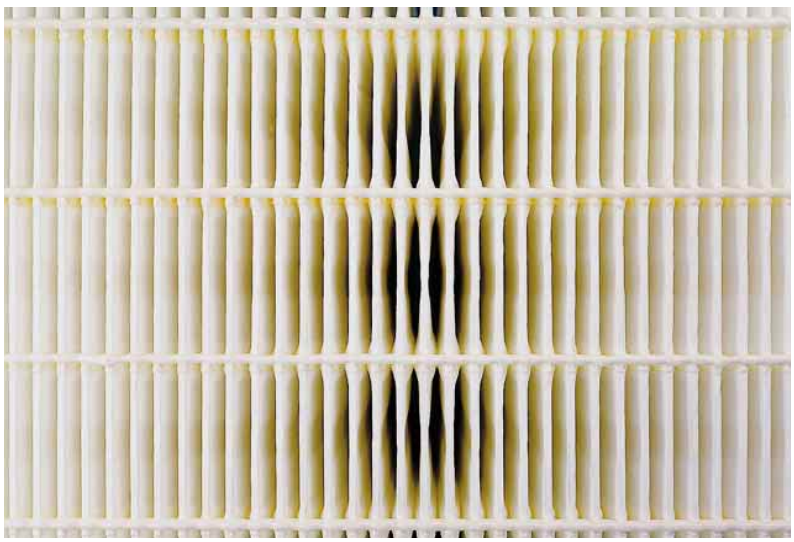
Viledon MaxiPleat and HEPA/ULPA filters constitute a technological quantum leap in the field of rigid/cassette filters. Their innovative design ensures a performance profile that pays off all along the line:

- A patented thermal embossing process guarantees optimum pleat geometry with equidistant spacing, as well as homogeneous air passage at a very low pressure drop.

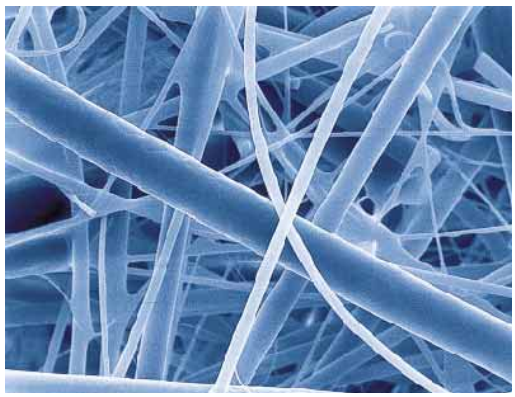
- The V-shaped pleat configuration ensures full utilisation of the filter area with uniform dust deposition. This in turn means long useful lifetimes and exceptionally cost-efficient, reliable operation.

- The filter's entire face area is evenly utilised without being impeded by vertical supports, i.e. superfluous air turbulence with resultant high pressure drops is precluded.

- Maximised operational reliability, thanks to interaction of the various material characteristics and process steps: high-strength filter medium, optimum dimensional stability of the pleat pack, leakproof integration in a distortion-resistant frame.



Optimum pleat geometry and equidistance due to patented embossing process



High-strength glassfiber filter medium with a special bonder system

- Low-turbulence downstream air flow thanks to equidistant, geometrically precise pleats.

- The frames of the MaxiPleat filters are made of halogen-free plastic. HEPA/ULPA filters are available in a wide range of frame variants, like MDF, anodised aluminium, galvanised steel sheeting, stainless steel or aluminium sheeting, plus complete filter/hood modules for single-flow configuration. All filters can be fitted with protection grids on request.

- Leakproof mounting of the HEPA/ULPA filters is assured by a continuous, foamed-on PU seal or a gel-channel/knife-edge configuration for fluid sealing systems.

- The filter elements are light in weight and disposal-friendly, as the innovative conversion technology minimizes the use of sealing and pleat-fixing agents. All filters with non-metal frame versions are completely incinerable.

- All MaxiPleat and HEPA/ULPA filters are moisture-resistant up to 100% relative humidity and thermally stable up to 70°C, with peaks up to 80°C.

- Low maintenance and servicing costs.

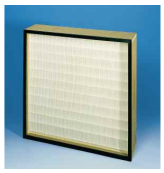
Technical data overview

	G 35 S F 45 S	G 35 SL F 40	F 50	T 60	MF 70 MF 90	MX 75 MX 85	MX 95 MX 98
Filter class to EN 779	G 3 G 4	G 3 G 4	F 5	F 6	F 6 F 7	F 6 F 7	F 8 F 9
Front dimensions standard element	595x595 mm	595x595 mm	595x595 mm	595x595 mm	595x595 mm	592x592 mm	592x592 mm
Overall depth	330 mm	650 mm	650 mm	650 mm	650 mm	292 mm	292 mm
Nominal volume flow rate	3,400 m^3/h	4,250 m^3/h	4,250 m^3/h	4,250 m^3/h	4,250 m^3/h	4,250 m^3/h	4,250 m^3/h
Initial pressure drop at nominal volume flow rate	20 Pa 40 Pa	20 Pa 30 Pa	45 Pa	65 Pa	65 Pa 120 Pa	100 Pa 110 Pa	120 Pa 150 Pa
Recommended final pressure drop*	200 Pa	200 Pa	250 Pa	400 Pa	400 Pa	400 Pa	400 Pa
Average arrestance/ ASHRAE dust	86 % 95 %	87 % 95 %	97 %	99 %	> 99 %	99 % > 99 %	> 99 %
Average efficiency	–	–	51 %	63 %	75 % 85 %	75 % 86 %	92 % 96 %
Dust holding capacity/ ASHRAE dust	1,180 g 590 g	2,300 g 1,425 g	1,380 g	1,585 g	700 g 550 g	690 g 570 g	510 g 450 g
Moisture resistance/ rel. humidity	100 %	100 %	100 %	100 %	100 %	100 %	100 %
Thermal stability/ temporary peaks	70°C 80°C	70°C 80°C	70°C 80°C	70°C 80°C	70°C 80°C	70°C 80°C	70°C 80°C

* This figure is recommended out of cost-efficiency considerations. It can be exceeded in certain applications without problems.

Further technical data and available sizes of Viledon filters can be found in the corresponding data sheets.






	SF 11	SF 13	SF 13	SF 13	SF 14	Filter/Hood module
Filter class to EN 1822	H 11	H 13	H 13	H 13	H 14	H 14
Front dimensions standard element	610x610 mm	610x610 mm	610x610 mm	610x610 mm	610x610 mm	610x1220 mm
Overall depth	292 mm	78 mm	150 mm	292 mm	71 mm 92 mm	140 mm
Pleat depth	200 mm 280 mm	50 mm	100 mm	200 mm 280 mm	50 mm 70 mm	50 mm 70 mm
Nominal volume flow rate for standard element	3,000 m^3/h 3,400 m^3/h	1,000 m^3/h	1,500 m^3/h	2,500 m^3/h 3,400 m^3/h	600 m^3/h	1,200 m^3/h
Initial pressure drop at nominal volume flow rate	160 Pa	250 Pa	250 Pa	250 Pa	125 Pa 100 Pa	145 Pa 120 Pa
Recommended final pressure drop*	600 Pa	600 Pa	600 Pa	600 Pa	600 Pa	600 Pa
Initial efficiency for MPPS**	≥95 %	≥99.95 %	≥99.95 %	≥99.95 %	≥99.995 %	≥99.995 %
Initial efficiency to DIN 24184	≥98 %	≥99.97 %	≥99.97 %	≥99.97 %	–	–
Utilization category to ZH/1/487 (BIA test)	–	K 1, K 2	K 1, K 2	K 1, K 2	–	–
Moisture resistance/ rel. humidity	100 %	100 %	100 %	100 %	100 %	100 %
Thermal stability	80°C	80°C	80°C	80°C	80°C	80°C

** MPPS = Most Penetrating Particle Size
(≙ Efficiency minimum)

The figures given are mean values subject to tolerances due to the normal production variations.

Quality probed to perfection

Reg. Nr. 1420

Freudenberg Vliesstoffe KG
Filter Division
Weinheim/Germany

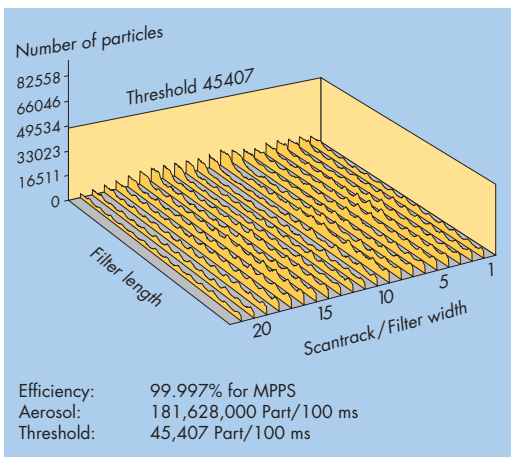
At Freudenberg, quality is an across-the-board commitment, which starts off with full comprehension of the customer's requirements, before translating these into products, processes and services. A modern quality management system to ISO 9001 monitors all operations, from the very beginning of development work and application-engineering consultancy all the way through to delivery of the finished product.

Multi-scanner for HEPA and ULPA filters

Consistently high quality of the filter media used is essential if the completed filter elements are to perform properly.
For quality assurance of HEPA and ULPA filters, the corresponding filter media are tested by means of a newly developed 18-channel CNC (Condensation Nuclei Counter) test stand to measure pressure drop and collection efficiency. This enables the specific minimum curve with the MPPS (Most Penetrating Particle Size / efficiency minimum) to be determined for the medium under test.

The MPPS concerned will later be used as the test particle size in the multi-scan test for final inspection of the completed filter elements. In accordance with the relevant standard, every single HEPA filter of the H13 class is subjected to the approved oil-mist-test to ensure there are no leaks.
The multi-scan test stand has been developed specifically for certification testing of high-quality cleanroom filters. The multi-scanner determines the pressure drop at nominal volume flow, the clean-air-side velocity profile, the efficiency for MPPS, and any leak points at the horizontally inserted filter element.
During the scan operation to determine the individual filter efficiency, up to 30 infeed-nozzle/probe pairs in a comb configuration (connected to a corresponding number of CNCs) move across the filter's surface.
The test reports generated by the multi-scanner are an important constituent of the qualification and validation documents required for submission to supervising authorities.

You will find more detailed information on our range of filters in our product-specific literature.
Give us a call, we're here to help you!



Multi-scan test report for a H14 filter

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