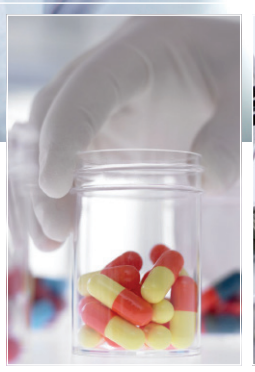
THE WORLD LEADER IN CLEAN AIR SOLUTIONS



Pharmaceutical Clean Air Solutions

PARTICULATE AND GASEOUS FILTRATION

AAF INTERNATIONAL
a member of DAIKIN group

AAF has an in-depth understanding of the challenges and opportunities for pharmaceutical and medical device manufacturing processes. This understanding and technical ability makes AAF the preferred partner in optimizing process performance for protecting human health.

Optimizing Process Performance for Protecting Human Health

Globalization, aging population, and economic shifts are transforming the pharmaceutical landscape. New medical needs and therapeutic areas are emerging that will put more pressure on innovation, productivity, and time-to-market. At the same time, sustainability has entered the playing field with a focus on energy efficiency, waste management, and emission reduction. All these developments shed a new perspective on the role for air filtration.

The Importance of Clean Air

Clean air is something nearly impossible to identify by our human senses. Most airborne particulates are so small that they cannot be perceived with the naked eye. In most cases, we do not know when something is wrong with the air quality until it is already too late and we see the damage that has occurred.

Within the pharmaceutical industry, strict requirements on air purity levels are needed because of the direct effect airborne contamination has on the quality of the pharmaceutical products. Human health and safety depend on it.

The Role for Air Filtration

No clean air is possible without a carefully selected and reliably functioning air filtration system. The performance of installed air filters, whether terminal filters or prefilters, directly determines how effectively harmful contaminants are prevented from entering the airstream in process environments. As such, air filtration represents a vital link in the overall pharmaceutical process chain.

This brochure provides insight into the most important aspects for realizing clean air conditions in pharmaceutical applications. The indispensable role for air filtration is explained through the lens of AAF's in-depth expertise, state-of-the-art air filtration solutions, and value-added support concepts.

Proven Expertise of AAF

AAF offers the most comprehensive air filtration portfolio in the industry, including particulate and gas-phase filters, that provides a customized clean air solution. Each product is carefully designed, manufactured, and tested in full compliance with all applicable standards to meet the most challenging demands at the lowest energy consumption.

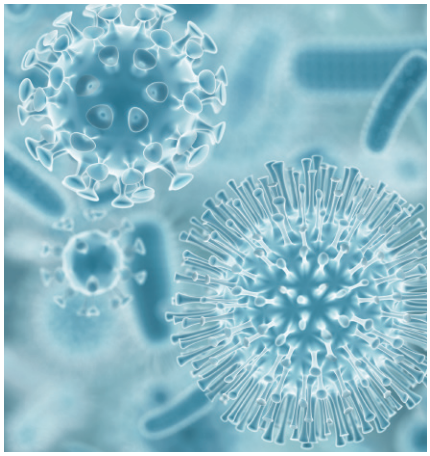
AAF manufacturing takes place in ISO 9001 and ISO 14001 certified facilities. AAF HEPA (High Efficiency Particulate Air) filters are produced, tested, and packaged in a state-of-the-art ISO 7 or cleaner cleanroom environment for optimized filter performance and quality assurance.

Many pharmaceutical applications today already benefit from AAF's recognized expertise in air filtration. The combination of an extensive product portfolio with high level technical support capabilities has provided significantly improved results for many satisfied customers.

Erik Geertsema
Test Engineer,
AAF

We manufacture and individually test all our HEPA filters in a modern cleanroom environment. We believe that only then is product performance assured, through which the most stringent customer requirements can be met.

Controlling Contaminants



The production of sterile products should be carried out under high levels of air cleanliness. Contamination of raw materials, finished goods, or personnel must be avoided at all times through the implementation of appropriate technical and organizational measures. The significance of such contamination risk may vary with the type of contaminant and the product that is being contaminated, but reliable airborne contamination control remains critical in all situations.

Quality of Medicinal Products

Everything that could come into direct contact with a pharmaceutical product is a potential risk toward contamination. Limiting exposure to airborne contaminants is critical, as it may result in health and safety issues. Preventive measures and quality management procedures are described in several industry guidelines: “CFR—Code of Federal Regulations Title 21”, “Guidance for Industry—Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice 2004”, and “European Union (EU) Guidelines to Good Manufacturing Practice (GMP) Medicinal Products for Human and Veterinary Use—Annex 1—Manufacture of Sterile Medicinal Products, 2008”. These guidelines are to ensure consistent production and control of pharmaceutical products for human use.

Air filtration plays a critical role in making sure that these objectives are met and that the risk of any adverse effects on product quality is reduced.

Balancing High Level Protection With Total Cost of Ownership

Mechanical Strength Reduces Contamination Risks

Following the recognized US guidance for Sterile Drug Products Processing, HEPA filters should be tested twice a year for leaks, to demonstrate filter integrity.

A critical leak is given when more than 0.01 percent of the upstream aerosol challenge penetrates a test spot. If a critical leak has been determined, it is customary to evaluate a possible impact on sterile processing. If a local defect is detected, this would require a filter repair or replacement, retesting, and finally the evaluation of possible effects on the production line in question.

To avoid leaks, the extremely sensitive surface of traditional HEPA filters used to be protected by a grid on the filter surface. New HEPA filters with the latest generation of membrane media represent a better solution, due to considerably improved mechanical strength and reduced pressure difference, thus increasing the economy and quality of sterile production units. The higher costs of such new filters are justified, since the risk of damages will be considerably reduced.

Dr. Lothar Gail
GMP and cleanroom consultant VDI.

No clean air is possible without a carefully selected and reliably functioning air filtration system. The performance of installed air filters, whether terminal filters or prefilters, directly determines how effectively harmful contaminants are prevented from entering the airstream in process environments. However, if the Facility Managers selecting air filters do not also consider the lifetime operating costs of a given product, facilities could be exposed to unnecessary risks and expenses.

Air in critical areas should always be supplied at the terminal stage by HEPA filtered unidirectional airflow, preceded by sequential prefiltration steps. Leak-free and high filtration efficiency performance of the HEPA filter is vital for ensuring that air purity is optimized, the pressure differentials between rooms are met, and healthy working conditions are achieved.

Typical Airborne Contaminants

Airborne contaminants differ in size and impact in a pharmaceutical manufacturing process. Figure 1 shows a typical size range of airborne particles and microorganisms. Each particle size range requires a specific air filtration technique to obtain the required air quality levels.

TCO Diagnostic®

A thorough air filter audit of your HVAC Systems is the first step in order to provide you with professional guidance and analysis for cost savings and risk reduction. By conducting this audit, AAF will be able to understand your current state and then utilize TCO Diagnostic,® an advanced analytical software tool, to identify how you can perform even better.

The purpose of TCO Diagnostic is to assist you in selecting the best filters for your air handling systems and to understand their sensitivity to your operating conditions, in order for your system to operate in the most optimal and effective manner.

TCO Diagnostic provides the insight to identify improvement opportunities, find the optimized options, and tailor to your specific needs for a comprehensive purchase perspective—improving air quality, energy savings, and operational flexibility while reducing Total Cost of Ownership.

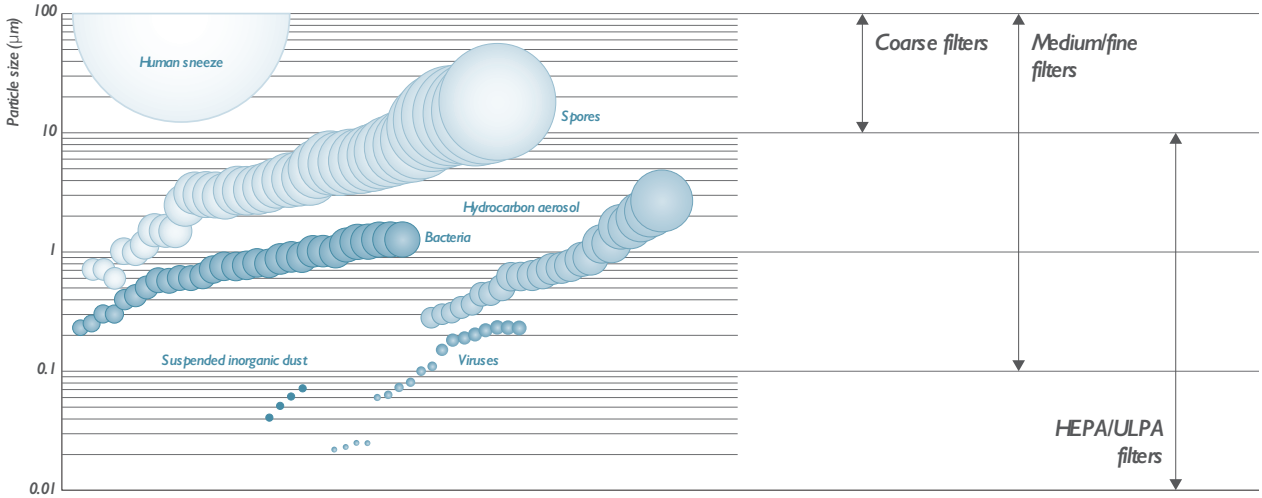


Figure 1

Classifying Air Filters

The type of activities within a particular pharmaceutical processing environment will determine the level of cleanliness that is required. To ensure that stringent air quality levels for safely manufacturing medicinal products are met, a carefully designed air filtration system is vital. Based on their performance efficiency, air filters are classified according to two widely accepted standards, ASHRAE 52.2 and the Institute of Environmental Sciences and Technology (IEST) Recommended Practice (RP) IEST-RP-CC001. Internationally EN1822 and the ISO standard 29463 (High Efficiency Filters and Filter Media for Removing Particles in Air) is the accepted classification method (Table 1).

ASHRAE 52.2

ASHRAE Standard 52.2 describes a method of laboratory testing to measure the performance of air filters as a function of particle size. The method of testing measures the performance of air filters in removing particles of specific sizes as the filters become loaded by standard loading dust. The dust is fed at intervals to simulate accumulation of particles during service life. The standard defines procedures for generating the aerosols required for conducting the test. The standard also provides a method for counting airborne particles of 0.3 micrometers to 10 micrometers upstream and downstream of the air filter in order to calculate removal efficiency by particle size. The overall reporting value of the air filter is expressed as Minimum Efficiency Reporting Value (MERV) **(Table 2).**

AAF offers a broad range of ASHRAE 52.2 compliant and energy efficient air filters as prefiltration to final HEPA filters. The choice of prefiltration will determine the cleanliness of the air entering the final filter, and therefore its lifetime.

Table 1: Design Guide for Cleanrooms

Cleanroom Design[1]

Cleanliness Classification[2]	Airflow Pattern[3]	Average Air Velocity	Air Changes per Hour
ISO CLASS 8 (100,000)	Non-unidirectional / Mixed	1 – 8 fpm	5 – 30
ISO CLASS 7 (10,000)	Non-unidirectional / Mixed	10 – 15 fpm	30 – 60
ISO CLASS 6 (1,000)	Non-unidirectional / Mixed	25 – 40 fpm	125 – 240
ISO CLASS 5 (100)	Unidirectional	40 – 80 fpm	240 - 480
ISO CLASS 4 (10)	Unidirectional	50 – 90 fpm	300 – 540
ISO CLASS 3 (1)	Unidirectional	60 – 90 fpm	360 – 540
ISO CLASS 2	Unidirectional	60 – 100 fpm	360 - 600

NOTES:

[1] This table relates cleanliness class to both the average air velocity in the cleanroom andrate of air changes per hour. The range of values listed is a consensus of existing practiceand is not intended to indicate design. It is up to the designer and end user to arrive at avalue either inside or outside the range that is consistent with project needs. Generally theapproach is to the higher values in cleanrooms housing a relatively dirty process or wherethe cleanroom garment program or discipline is relaxed. The lower end of the range is moreappropriate for cleaner processes and a more disciplined cleanroom gowning procedure.

[2] Cleanliness classifications in parenthesis refer to the former FED STD 209E Classifications.

[3] Airflow pattern listed represents the more common airflow characteristics for cleanrooms ofthat class.

Table 2: Air Filter Classification per ASHRAE 52.2.

Standard 52.2 Minimum Efficiency Reporting Value (MERV)	Complete Average Particle Size Efficiency, % in Size Range, µm			Average Arrestance, %, Addendum B
	Range 1 0.30 - 1.0	Range 2 1.0 - 3.0	Range 3 3.0 - 10.0	
1	n/a	n/a	$E_3 < 20$	$A_{avg.} < 65$
2	n/a	n/a	$E_3 < 20$	$65 \le A_{avg.} < 70$
3	n/a	n/a	$E_3 < 20$	$70 \le A_{avg.} < 75$
4	n/a	n/a	$E_3 < 20$	$75 \le A_{avg.}$
5	n/a	n/a	$20 \le E_3 < 35$	n/a
6	n/a	n/a	$35 \le E_3 < 50$	n/a
7	n/a	n/a	$50 \le E_3 < 70$	n/a
8	n/a	n/a	$70 \le E_3$	n/a
9	n/a	$E_2 < 50$	$85 \le E_3$	n/a
10	n/a	$50 \le E_2 < 65$	$85 \le E_3$	n/a
11	n/a	$65 \le E_2 < 80$	$85 \le E_3$	n/a
12	n/a	$80 \le E_2$	$90 \le E_3$	n/a
13	$E_1 < 75$	$90 \le E_2$	$90 \le E_3$	n/a
14	$75 \le E_1 < 85$	$90 \le E_2$	$90 \le E_3$	n/a
15	$85 \le E_1 < 95$	$90 \le E_2$	$90 \le E_3$	n/a
16	$95 \le E_1$	$95 \le E_2$	$95 \le E_3$	n/a

IEST-RP-CC001

To ensure the highest levels of air purity, pharmaceutical processes need to rely on high efficiency particulate air filters as terminal filters. These air filters are subject to classification according to IEST-RP-CC001 (HEPA and ULPA filters). This recommended practice (RP) covers basic provisions for HEPA and ULPA filter units as a basis for agreement between customers and suppliers.

Air Filter Classification According to IEST-RP-CC001

Table 3: Recommended Test and Minimum Rating for Filters Types A Through K.

Filter Type	Penetration Test		Last (Scan) Test[1]			Minimum Efficiency Rating	Designated Leak Penetration
	Method	Aerosol	Method	Aerosol	Comments		
HEPA (type A)	MIL-STD-282	Thermal DOP	None	None		99.97%	n/a
HEPA (type B)	MIL-STD-282	Thermal DOP	None	None	Two-flow leak test	99.97%	n/a
HEPA (type C)[1]	MIL-STD-282	Thermal DOP	Photometer	Polydisperse DOP/PAO		99.99%	0.010%
HEPA (type D)[1]	MIL-STD-282	Thermal DOP	Photometer	Polydisperse DOP/PAO		99.999%	0.0050%
HEPA (type E)[1]	MIL-STD-282	Thermal DOP	None	None	Two-flow	99.97%	n/a
HEPA (type F)[1]	IEST-RP-CC007	Open	Particle Counter	Open		99.9995% at 0.1-0.2 or 0.2-0.3 µm	0.00250%
HEPA (type G)[1]	IEST-RP-CC007[2]	Open	Particle Counter	Open		99.9999% at 0.1-0.2 or 0.2-0.3 µm	0.0010%
HEPA (type H)[1]	IEST-RP-CC007	Open	None	None		99.97% at 0.1-0.2 or 0.2-0.3 µm	n/a
HEPA (type I)[1]	IEST-RP-CC007	Open	None	Open	Two-flow leak test	99.97% at 0.1-0.2 or 0.2-0.3 µm	n/a
HEPA (type J)[1]	IEST-RP-CC007	Open	Particle Counter or Photometer	Polydisperse DOP/PAO		99.99% at 0.1-0.2 or 0.2-0.3 µm	0.010%
HEPA (type K)[1]	IEST-RP-CC007	Open	Particle Counter Photometer	Polydisperse DOP/PAO		99.995% at 0.1-0.2 or 0.2-0.3 µm	0.0080%

[1]Either of the two scan test methods or an alternative method may be used for filter types C, D, F, and agreed. Designated leak details for these filter types are given in IEST-RP-CC034.

[2]Filter medium tested at most-penetrating particle size (MPPS) prior to filter assembly. All filters are leak-tested but in some instances may not be tested for overall penetration. The MPPS for testing this filter type is determined from the media according to IEST-RP-CC021.

Filters that meet the requirements of IEST-RP-CC001 are suitable for use in clean air devices and cleanrooms that fall within the scope of ISO 14644, and for use in supply air and contaminated exhaust systems that require extremely high filter efficiency (99.97% or higher) for submicrometer (µm) particles.

IEST-RP-CC001 describes 11 levels of filter performance and six grades of filter construction. The level of performance and grade of construction required should be specified. The filter efficiency required should also be specified if it is not covered by the performance level specified in this RP (Table 3).

Testing Capabilities of AAF

All HEPA and ULPA filters produced by AAF are built in an ISO 7 cleanroom environment and tested in an ISO 4 cleanroom with full compliance to IEST standards. In a modern test rig, each air filter is individually tested by well-trained AAF personnel before shipment to the customer.

HEPA and ULPA filters are leak tested using a challenge aerosol. The test results are documented in a test report for each individual HEPA or ULPA filter. This report gives full information about the tested air filter, test parameters (airflow, test method and aerosol), and the test results according to IEST-RP-CC001, and are available for every filter when requested. Air filter labels include the identification of the air filter type, a serial number for full traceability, the test standard used, the filter class, and the nominal airflow rate at which the air filter has been classified.

Strict quality procedures ensure that all HEPA and ULPA filters leaving the AAF factory are leak-free, perform according to applicable standards, and are consistent with the individual customer requirements.

Classifying Cleanrooms

The production of sterile pharmaceuticals is subject to special requirements in order to minimize risks of particulate and microbial contamination. Manufacturing is carried out in clean areas within which the concentration of airborne particles needs to be controlled. The classification and monitoring of such clean areas follow the ISO 14644 standard and the EU GMP Directive 2003/94/EC.

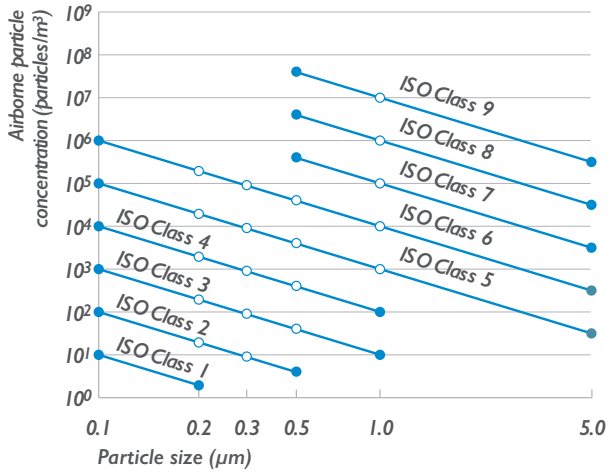
Classification Standards

Pharmaceutical cleanrooms and clean air devices are classified according to ISO 14644-1. The level of airborne particulate cleanliness, applicable to a clean area, is expressed as an ISO class. The lower the classification number, the higher the level of cleanliness. The ISO class represents maximum allowable concentrations for considered particle sizes, ranging from 0.1 µm up to 5.0 µm. Figure 2 shows a graphic illustration of the nine ISO cleanroom classes with the concentration limits for the given particle sizes. Different room classes are typically necessary for the various pharmaceutical clean areas and production steps taking place.

For the operational environmental monitoring of the production of sterile preparations, EU GMP distinguishes four alpha grades. Each grade is assigned maximum permitted airborne particle concentrations for sizes ≥ 0.5 µm and ≥ 5.0 µm 'at-rest' and 'in operation' state. Particles of 0.5 µm and larger can be considered as the most critical particle sizes that need to be effectively filtered out by HEPA filtration for obtaining the required aseptic process conditions. GMP grade A is the most stringent classification and equals ISO 5 according to ISO 14644-1. This type of area is expected to be almost completely free from particle sizes ≥ 5.0 µm, both 'at-rest' and 'in operation' condition.

Figure 2:

ISO 14644-1 Cleanroom Class Particulate Concentration Limits



The graph shows the minimum and maximum particle size limits acceptable for each of the ISO classes shown. The classification lines do not represent actual particle size distributions found in cleanrooms and clean zones.

Sterile Manufacturing Activities

The pharmaceutical industry is expected to take proactive steps in ensuring that products are safe and effective. EU GMP regulations require building a quality approach into the manufacturing process, to minimize or eliminate risk of cross-contamination and errors (Table 4).

Table 4: Typical Cleanroom Activities for Terminal Sterilization and Aseptic Preparation

GMP Grade	Examples of Typical Activities	
	Terminal Sterilization	Aseptic Preparation
A	Filling of products for sterilization (unusual risk profile)	Handling of sterile starting materials and components Preparation of materials and products (non-sterile filtering) Handling and filling of aseptically prepared products
B	–	Background area for grade A zones
C	Filling of products for sterilization (usual risk profile) Preparation of materials and products (sterile filtering)	Preparation of components (unusual risk profile)
D	Preparation of components (usual risk profile)	Handling of components after washing

Monitoring Microbial Contamination EU GMP Annex 1

Clean areas for the production of sterile products are classified according to the required characteristics of the environment. Each manufacturing operation requires an appropriate environmental cleanliness level for minimizing the risks of particulate and microbial contamination of the concerning starting material or product. EU GMP Annex 1 sets limits for microbial contamination for each of the four identified cleanroom grades (Table 5).

The air in risk zone areas, particularly vulnerable to biocontamination, needs to be protected from viable particles, consisting of one or more live organisms. Methods for evaluation and control are provided by ISO 14698 (Biocontamination Control).

The Role for Air Filtration

Especially for aseptically prepared parenteral medicine (such as injectables and infusions), no contamination can be accepted, otherwise severe harm or life-threatening health risks to the patient can result. It is exactly in this area where air filtration comes in as the critical link in the overall chain.

Air in critical areas should always be supplied at the terminal stage by HEPA filtered unidirectional airflow, preceded by sequential prefiltration steps. A leak-free and high filtration efficiency performance of the HEPA filter is vital for ensuring that air purity is optimized, the pressure differentials between rooms are met, and healthy working conditions are achieved.

Table 5: Cleanroom Classification According to EU GMP Annex 1

Maximum Permitted Number of Particles /m³ Equal to or Greater than the Tabulated Size					International Cleanroom Standard Comparison for "At-rest"		
	At-rest		In Operation				
Grade	0.5 µm	5.0 µm	0.5 µm	5.0 µm	FED 209E	FED 209D	ISO 14644
A	3,520	20	3,520	20	M 3.5	Class 100	ISO 5
B	3,520	29	352,000	2,900	M 3.5	Class 100	ISO 5
C	352,000	2,900	3,520,000	29,000	M 5.5	Class 10,000	ISO 7
D	3,520,000	29,000	Not Defined	Not Defined	M 6.5	Class 100,000	ISO 8

Qualifying HEPA Filters

Pharmaceutical cleanrooms require an extensive validation procedure before initiating pharmaceutical production. The process then has to be revalidated in predefined intervals. For HEPA terminal filtration, this means that there is initial qualification and periodic requalification of its performance characteristics.

Qualification Procedure

FDA cGMP Guidelines, including Section IV-Buildings and Facilities; Section IX-Validation of Aseptic Processes; and Section X-Laboratory Controls describe the principles of validation and qualification that are applicable to the production of medicinal products. This procedure typically follows a V-shaped model, consisting of three sequential steps (Figure 3). Each of these steps poses its own stringent demands on HVAC installations in general and HEPA filtration specifically. Selecting high quality manufactured HEPA filters will enhance the probability of success in this validation sequence.

Installation Qualification (IQ): does the HEPA filter specification match what I had ordered and expected?

Examples of HEPA filter requirements:

- Individual test report according to IEST-RP-CC001
- Complete and accurate labeling, including serial number for traceability
- Correct packaging and testing information

Operational Qualification (OQ): does the HEPA filter perform according to functional specifications during 'at-rest' operation?

Examples of HEPA filter requirements:

- Absence of any visual damage to filter media, gasket, and frame
- Successful in-situ test result with confirmed filter integrity
- Actual initial resistance performance consistent with specification

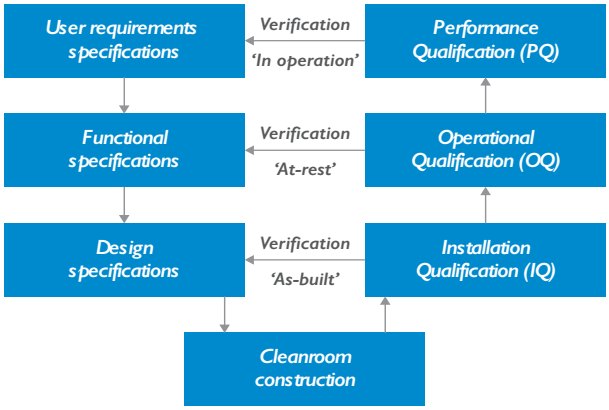
Performance Qualification (PQ): does the HEPA filter demonstrate reliable performance during full-scale operation?

Examples of HEPA filter requirements:

- Absence of leakage (e.g., media) and bypass (e.g., gasket seal) according to IEST-RP-CC034
- Consistent particulate collection efficiency over time
- Absence of fiber shedding that could cause contamination

Figure 3:

Cleanroom Validation Procedure, Derived from ISO 14644-4



Installed HEPA Filter Integrity Testing

The purpose of installed HEPA filter integrity testing, also called in-situ testing, is to confirm a flawless performance during normal operation. Filter integrity measurements encompass tests for installed filter leakage, such as in the media or sealant to frame, and bypass, such as in the frame, gasket, or grid system. As such, this testing differs from factory leak testing that focuses on measuring filter integrity under laboratory conditions.

Both filter leakage and bypass can result in a penetration of contaminants that exceeds the expected value of downstream concentration. As these situations may seriously harm the sterility of critical parameters, and therefore the quality of medicinal products, periodic requalification of terminal HEPA filters is required. Subject to risk assessment of the cleanroom activity, this interval is typically set at six months for GMP grade A aseptic processes.

The most commonly used methods for testing the integrity of installed HEPA filters are described in the ISO 14644-3 standard: Aerosol Photometer (AP) and Discrete Particle Counter (DPC). The AP method typically uses a high concentration 10-40 ug/liter of oil-based aerosol for scanning air filters for leakage.

A low concentration aerosol challenge exposure is always recommended, as this testing leads to a less contaminated filtration system and therefore an optimized energy efficiency and improved HEPA filter lifetime expectancy.

Dedicated Support From AAF

With AAF's patent-pending Membrane Media Filtration Technology, filters can now be scan tested with the industry standard photometer at the standard aerosol concentrations set forward, as well as the low aerosol concentration DPC method. AAF engineers work with state-of-the-art test equipment and can provide a project team or supervisor on site for practical assistance. As AAF firmly believes that independency in testing is critical, its core policy is to educate staff and test agencies locally for transferring knowledge and sharing best practices.

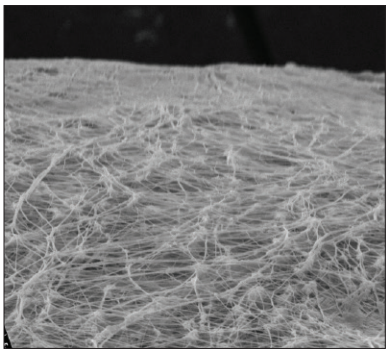
Please contact your local AAF affiliate office for more details on the in-situ testing support that AAF can provide to ensure that terminal filter performance is optimized for its purpose.

HEPA Membrane Filtration Technology

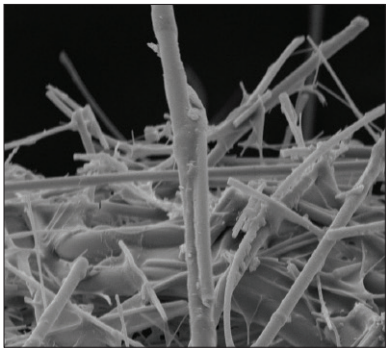
AAF HEPA Membrane Filtration Technology is designed specifically for the unique requirements and challenges of the pharmaceutical industry. Patent pending membrane media has the proven durability, polyalphaolefin (PAO) compatibility, high particulate filtration efficiency, and the lowest pressure drop to meet the demands of pharmaceutical manufacturing.

Industry-Leading Durability

Independent tests have shown that filters with membrane media Filtration Technology have superior mechanical strength over filters with traditional ultra fine microglass media. This superior durability and tensile strength is 84 times the pleated strength of microglass.



Resilient Membrane Media Technology media at fold tip @ 10,000x magnification.



Fractured ultrafine microglass media fibers at fold tip @ 10,000x magnification.

Reduce Operational Risk

The pharmaceutical industry estimates that 77% of production downtime can be attributed to failures of equipment and environmental problems.* Traditional HEPA filters typically fail due to some form of contact combined with the poor mechanical strength of the filter. Effectively managing the risks and costs associated with successful operation requires utilizing HEPA filters with dramatically higher tensile strength.

Increase Uptime

While FDA Testing Guidance requires critical room leak-testing certification twice a year, non-critical rooms require testing only once a year. With the extremely high tensile strength and durability of membrane media pleated filter media, ISO 7 and 8 areas can be tested annually. Increasing time between certifications results in less PAO exposure to the gel seal (gel degradation), lower labor costs, and increased production time.

Manufactured in ISO 7 Clean Facilities

HEPA Membrane media is manufactured by AAF. By doing so, we control the quality and consistency of the media. This media is produced in an ISO 7 cleanroom to ensure the purity and cleanliness of the product. The filter is then assembled, tested, and packaged in an ISO 7 clean manufacturing facility, resulting in unparalleled product performance and operational efficiency.

**Source: Pharmaceutical Manufacturing Magazine (2004).*

Particulate Filtration Solutions

HEPA and ULPA Filters

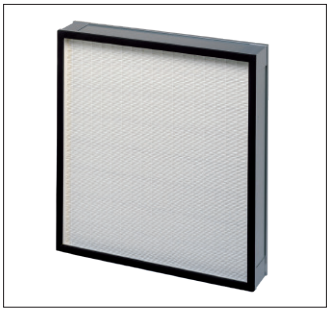
HEPA filters are the most efficient air filters commercially available. They are used in pharmaceutical manufacturing and other applications requiring ultra-clean air—semiconductor, electronics, cleanroom, food processing, hospitals, and labs. AAF HEPA filters are individually tested before shipment to ensure they meet rated efficiency and resistance. AAF HEPA and ULPA filters are available in a variety of efficiencies—from 99.97% tested on .3 µm particles to 99.9995% and higher tested on .1 to .2 µm particles. All filters are available scan-tested.

High Temperature HEPA Solutions

To prevent endotoxin contamination in sterile conditions, containers and closure surfaces need to be depyrogenated. Endotoxins are removed by applying dry heat sterilization, where the air is cleaned by a reliable HEPA filtration system. AAF high temperature HEPA filters are designed to provide excellent protection of this critical depryogenation process.

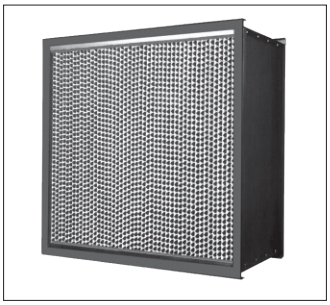
The HEPA/ULPA Filter line delivers:

- Built according to IEST-RP-CC001.6
- Designed to meet the demanding requirements of the most critical applications
- Membrane Media Filtration Technology provides superior durability
- Chemical-resistant capabilities for highly corrosive environments
- High capacity, space saving designs
- Filters designed specifically for high airflow applications requiring HEPA efficiency at an ultra low pressure drop



High Temperature HEPA Filters feature:

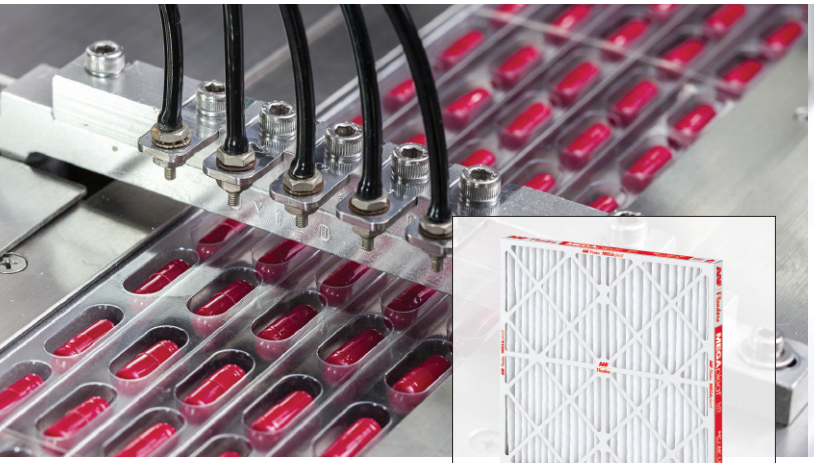
- High temperature resistance with a steel frame construction
- Thorough heat-cycle tests confirm damage-free construction and consistent performance
- Unique combination of high temperature operation and superior durability, optimizing process results and limiting unscheduled downtimes
- The right solution for ensuring that strict air cleanliness conditions are met

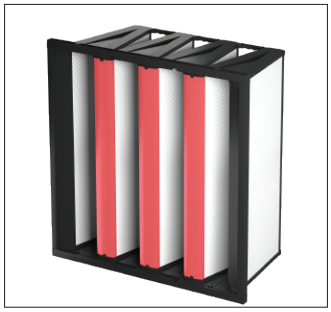


Particulate Filtration Solutions

High Efficiency Extended Surface Filters

These rigid, high efficiency extended surface filters are ideal for use in all high efficiency applications. The supported pleat filters provide strength and integrity in high flow, turbulent, and variable airflow conditions.



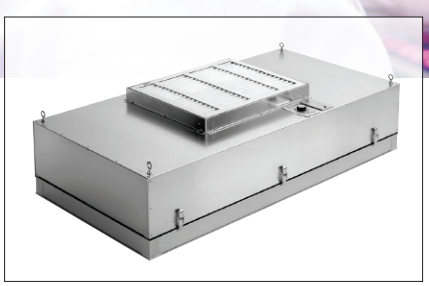


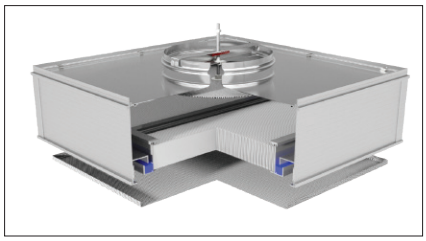
The High Efficiency Extended Surface Filter line provides:

- MERV ratings from 11 to 16
- Strongest and longest-lasting MERV 9 pleated filter on the market
- Lowest life cycle pressure drop and highest Dust Holding Capacity (DHC) reduces energy consumption and total operating costs
- Most energy efficient 4" filter available with longer life and the lowest initial resistance
- Patented Impress® Technology delivers a higher DHC and a lower pressure drop for greater energy efficiency
- Heavy duty construction and high performance in tough operating conditions

Disposable Ceiling Modules

HEPA and ULPA filters are available are available in a variety of configurations to fit the highest efficiency filter requirements for new, existing, and retrofitted cleanroom applications.



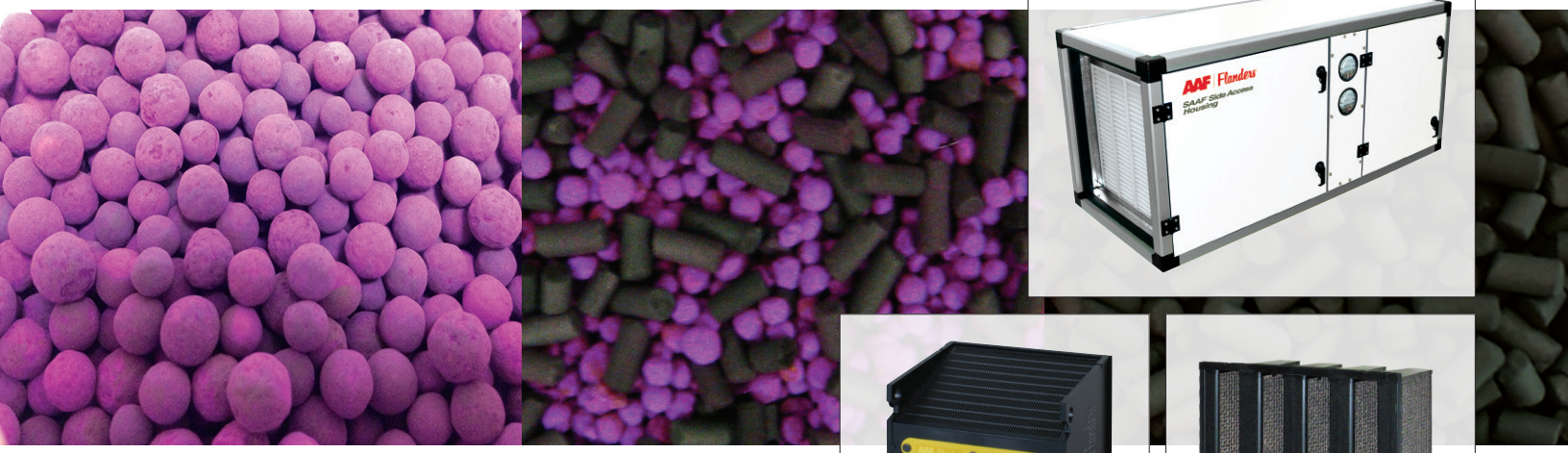


Disposable Ceiling Modules feature:

- Designed for pharmaceutical and biotech applications requiring an easily replaceable HEPA filter cartridge without risk of bypass leakage
- Self-contained fan/HEPA filter modules for critical applications
- Roomside replaceable HEPA/ULPA filter modules that are lightweight, low-profile ducted units

Gaseous Filtration Solutions

AAF has assumed an industry leading position with the development of its innovative SAAF™ (pronounced as “SAFE”) product line designed to reduce or eliminate harmful gaseous contaminants. In combination with our expertise in airborne particulate filtration, SAAF products and solutions allow us to develop unique and effective total filtration solutions to protect people, processes, and equipment.



No other company offers this combination of experience, expertise, innovation, and capability to combat airborne contaminants, particulate and/or gaseous, and deliver the best clean air solutions.

The SAAF product line features:

- Patented chemical media cassettes with superior sealing and energy savings. These cassettes also fit in most legacy units. The housings are designed for quiet operation and durability.
- Complete chemical media line – adsorbents, oxidants, and blends configured by and produced under the supervision of our world-class global research and development teams.
- Environmental Measurements related to the ISA Standard S71.04: “Environmental Conditions for Process Measurement and Control Systems. Airborne Contaminants to determine types of contaminants and their relative concentrations.”
- RoHS compliant Corrosion Control (ASHRAE TC 9.9 Guideline).
- Comprehensive, industry leading software – SAAF Tech Tools analyzes applications, develops solutions, configures equipment and media, and delivers a complete technical proposal.

Cleanroom Components

For guaranteeing an efficient installation and effective operation of terminal air filtration systems, AAF offers a broad range of matching cleanroom components. These components vary from ceiling grids to light fixtures.

Please contact your local AAF affiliate office for tailored advice and a custom-made solution, designed by AAF cleanroom specialists.

Proven Expertise of American Air Filter

AAF offers the most comprehensive air filtration portfolio in the industry, including particulate and gas-phase filters, to provide a customized clean air solution. Each product is carefully designed, manufactured, and tested in full compliance with all applicable standards to meet the most challenging demands with the lowest Total Cost of Ownership.

Contact your local AAF representative for a complete list of AAF air filtration product solutions.

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ISO Certified Firm

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