Áreas Limpias: Sistemas de HVAC Farmacéutico

Capítulo Nº 4: Filtrado del Aire

Temario:

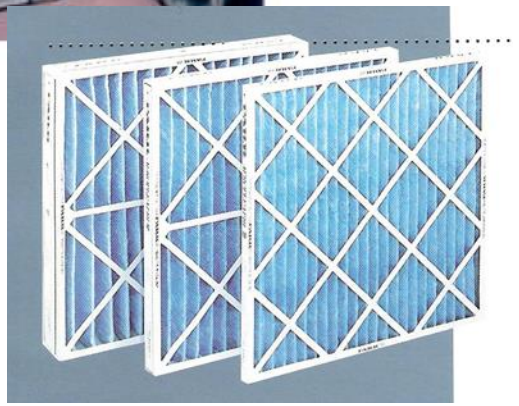
1. Exigencia Regulatoria
2. Introducción a las áreas limpias
3. Diseño y Requerimientos de Usuario (URS)
4. **Filtrado del Aire**
5. Tipos de Flujo de Aire
6. Sistemas de HVAC
7. Validación de un Sistema de HVAC
8. Pruebas de Sala Limpia

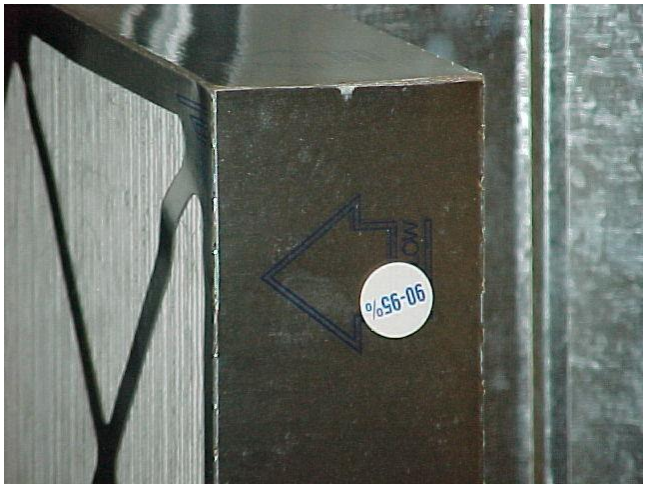
Parte 2: Filtrado del Aire

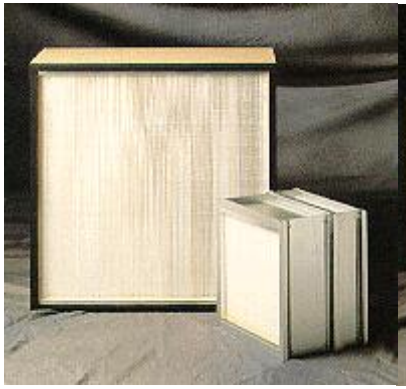
Estándares de Filtración

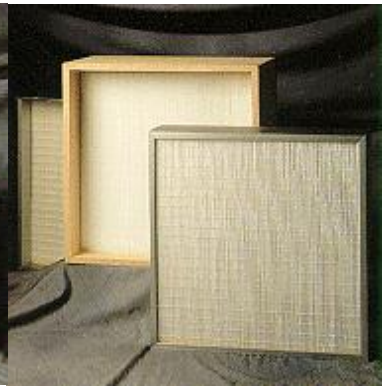
- **ASHRAE 52. (1,2) 1992/96. METODOS DE PRUEBA PARA ELEMENTOS UTILIZADOS EN FILTRACION DE AIRE**
- **EUROVENT 4/9:1992, 4/10:1996. METODOS DE PRUEBA PARA FILTROS DE AIRE**
- **EN 779:1993 Y EN 1822 . ESPECIFICACIONES PARA FILTROS DE PARTICULAS EN SISTEMAS DE VENTILACION (EN 779 (G y F) & EN1822 (H y U))**
- **IEST : Institute of Environmental Sciences and Technology. Conjunto de Normas sobre pruebas en fábricas, y en terreno de Filtros Absolutos y otros**

Estándares de Filtración









Filtros en una UMA

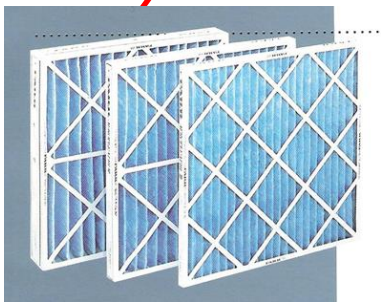
Motor - Ventilador

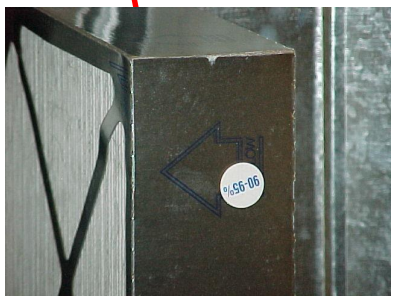
Suministro

Filtro absoluto

Filtro intermedio

Pre-Filtro





Estándares de Filtración

Prefiltración Filtración Alta Filtración

EU Class	% (Average)	% (Average)	% Integral Value	EN 779 & EN 1822
			99,99995	U16
			99,9995	U15
14			99,995	U14
13			99,95	H13
12				
11			99,5	H12
10			95	H11
9		95	85	F9/H10
8		90	75	F8
7		85		F7
		80		
6		75		F6
		70		
		65		
		60		
5		55		F5
		50		
		45		
		40		
4		35		G4
	95	30		
	90	25		
3	85	20		G3
	80			
2	75			G2
	70			
	65			
				G1

99,999%@0,1-0,2mu

99,99%@0,3mu

99,97%@0,3mu

CEN/TC/195
WG1-G1-F9
WG2-H10-16

MPPS,
DEHS
Aerosol
EN1822

Dust Spot Efficiency
ASHRAE 52/76
BS6540 Part 1 (1985)

Arrestance %

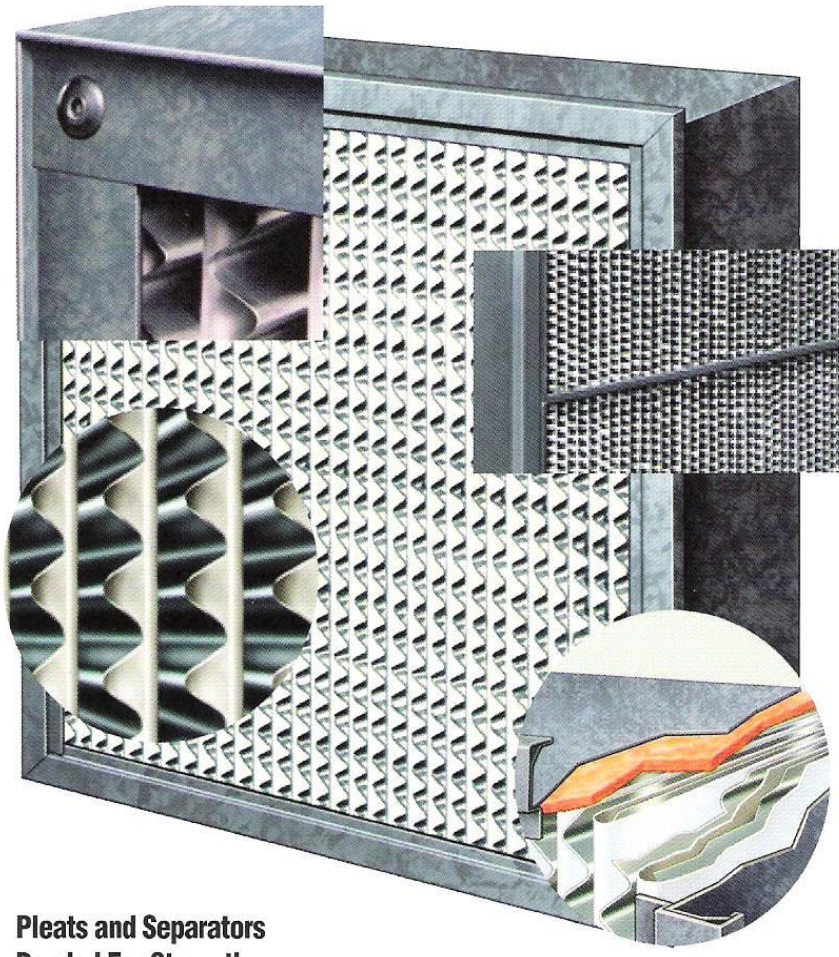
Eurovent Class –
Eurovent 4/5 (2-9)
Eurovent 4/9 (2-9)
Eurovent 4/4 (10-14)

Estándares de Filtración

Crimped Rear Flanges *(SH) are rolled over and riveted to add strength, eliminate sharp edges, and prevent bypass leakage.*

Corrugated Aluminum Separators with Rolled Edges *maintain uniform pleat spacing for optimum airflow. The separators are rolled to eliminate sharp edges, preventing media damage during shipping and personal injury during installation.*

VariCel's rigid construction with supported pleat media pack maintains a compact, unitized structure even under tough operating conditions. Variable air velocity and re-



Pleats and Separators Bonded For Strength

Media Pack Restraint *Steel brace on air leaving side adds support to the media pack.*

Media Pack Sealant — *A layer of high efficiency media seals the media pack into the cell sides. The media sealant prevents bypass leakage and damage to the media and separators during shipping and handling. By allowing slight movement of the media pack when the filter is jarred, the cushioning sealant helps prevent tears and punctures to the media.*

Estándares de Filtración

Levels of protection and recommended filtration

Level of protection	Recommended filtration
Level 1	Primary filters only (e.g. EN 779 G4 filters)
Level 2	Protected areas operating on 100% outside air: primary plus secondary filters (e.g. EN 779 G4 plus F8 or F9 filters)
Level 3	Production facility operating on recirculated plus ambient air, where potential for cross-contamination exists: Primary plus secondary plus tertiary filters (e.g. EN 779 G4 plus F8 plus EN 1822 H13 filters) (for full fresh air system, without recirculation, G4 and F8 or F9 filters are acceptable)

Note: The filter classifications referred to above relate to the EN 1822 and EN 779 test standards (EN 779 relates to filter classes G1 to F9 and EN 1822 relates to filter classes E10 to U17). Refer to Figure 8 for comparative classifications of other filter standards.

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2019

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