

Zeta Plus™ VR Series

Depth Filter Cartridges & Capsules

Application

The removal and/or inactivation of contaminating viruses from biotherapeutics is a requisite for ensuring final product safety. Zeta Plus™ VR Series depth filters may help remove viruses from biological fluids. They provide high flow rates, scalability, economy, disposability and ease-of-use in the biological manufacturing environment.

Applications for Zeta Plus VR Media include processing:

- Human Plasma-derived proteins
- Recombinant proteins from cell culture and fermentation
- Monoclonal antibodies
- Serum and other raw materials derived from animal sources



Features & Benefits

Quality Control tested for media ion exchange capacity.

- Assurance of filter media consistency & performance.

Self-contained, single-use disposable capsules & cartridge modules

- Single-use, disposable design eliminates validation concerns associated with reusable clearance options (chromatography column sanitization & regeneration).

Range of cartridge sizes, sanitary design cartridge housings & disposable capsules.

- Facilitates scaleup from small volume feasibility trials to production scale operations.



Zeta Plus VR Series filter media is available in a wide range of cartridge sizes including 8-, 12- and 16-inch diameter filter cartridges for varying flow rates and batch volumes. 3M Purification Inc.'s sanitary design ZPB Zeta Plus filter housings are designed for pharmaceutical and biological manufacturing environments.

Zeta Plus™ VR Series filter media is a family of cellulosic depth filtration media designed to retain contaminants by both physical entrapment and ion exchange adsorption. It is composed of high-area process filter aids embedded in a cellulose fiber depth matrix. During the manufacturing process, a cationic charge modifier is chemically bound to the matrix components, forming a permanent, interconnected, rigid depth filter with positively-charged electrokinetic capture sites. The resulting porous depth filter structure is a tortuous network of adsorptive flow channels capable of retaining contaminating viruses through a combination of anion exchange adsorption and mechanical entrapment.

Zeta Plus depth filtration is a key component in biopharmaceutical production schemes for clarifying cell culture fluids (cell separation) and is utilized world wide in the fractionation of human and animal plasma proteins.

Zeta Plus VR Series Filter Selection

A range of cartridge sizes is available for varying batch size, so scale-up is easy and predictable from lab-scale, to pilot plant, to full production scale. Three different cartridge sizes (8, 12 and 16-inch diameter) make scale-up straight forward and predictable. Zeta Plus cartridges are used in a flow-through mode, enabling the process stream to be passed through the filter cartridge while various contaminants are retained within the depth filter matrix. Small, low area disposable BC capsules are available for laboratory scale and process development work.

Zeta Plus VR Series Disposable Capsules, Filter Cartridges, and Filter Sheets—Configured to Suit Your Every Need

Zeta Plus VR Series filter products are scaleable and can be used for applications ranging from milliliter lab volumes to production scale cGMP operations. Filter media is available in the following configurations:

Zeta Plus VR Series Filter Sheets: VR filter media is available in a range of filter sheet sizes to fit plate-and-frame filter presses (contact 3M Purification Inc. for specific sheet sizes and part numbers).

Zeta Plus VR Series BC Disposable Filter Capsules: VR filter media is available in disposable capsules for bench scale filtration.

Zeta Plus VR Series Filter Cartridges and Sanitary Housings: VR filter media is available in 8-inch, 12-inch and 16-inch diameter, easy-to-use, disposable cartridges. A range of sanitary design Zeta Plus filter housings is available for VR Series cartridges.

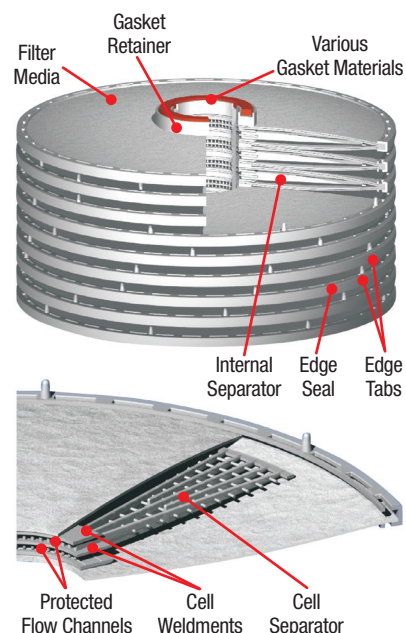
Table 1: Selection of Zeta Plus VR Series Filter Media

Filter Media Choice	Recommended For:		Nominal Retention Rating (µm)	20°C Water Flow @ 5 psid (gpm/ft²)	Autoclavable or In-situ Steam Sterilizable	[Al3+] in 20°C water @ 5L/ft² (ppb)
	Plasma Proteins	Cell Culture Proteins				
VR 02	•	•	0.8	1.9	Yes	20
VR 03		•	0.8	1.2	Yes	40
VR 05		•	0.2	0.4	Yes	40
VR 06	•	•	0.2	0.6	Yes	20
VR 08	•	•	0.2	0.4	Yes	60

Recommended Operating Parameters

Nominal Retention Ratings	0.2 to 0.8 micron
Maximum Operating Pressure	VR Cartridges: 35 psi maximum cartridge pressure drop. BC25 Capsules: 40 psig max. inlet pressure, 35 psi max. media pressure drop.
Maximum Operating Temperature	Zeta Plus VR Cartridges: 82° C. BC25 Capsules: 40° C.
Minimum Required Pre-conditioning Flush	50 L/m² at 20 L/m²/min with water, or other suitable fluid, at a volumetric flow rate up to 1200 L/m²/hr
Sterilization Parameters	Zeta Plus VR Series Cartridges: In-situ steam sterilized or autoclaved, for 30 minutes at 121°C (1 cycle). BC25: Autoclave for 30 minutes at 121°C (1 cycle).
Recommended Flow Rates	BC25: 3 - 30 ml/min.

Cartridge Construction



Viral Reduction Validation

Many factors influence the choice of process steps to be studied when performing viral clearance evaluation and validation.

Viral clearance validation studies are performed with a select panel of model viruses. Different model viruses are chosen to validate blood and plasma products, and separately, cell-culture derived products.

Virus removal efficiency is highly dependent on fluid and processing conditions. Extensive qualification and validation studies using suitable virus model systems in a controlled laboratory study are required.

Quality Control of Zeta Plus VR Series Filters

3M Purification Inc. applies rigorous Quality Control testing and standards both during in-process manufacturing and during final lot release. A Certificate of Quality is provided with each Zeta Plus VR Series filter cartridge and disposable BC capsule.

Each grade of Zeta Plus VR Series filter media is Quality Control tested on a lot release basis for the presence and magnitude of positive charge.

Effective Filtration Area	
BC25 Capsule	3.9 in² (25 cm²)
45109 (8-inch diameter cartridge, 8-cell)	2.8 ft² (0.26 m²)
45167 (8-inch diameter cartridge, 7-cell, o-ring plug-in)	2.5 ft² (0.23 m²)
Z8FA2NPX2 (8-inch diameter cartridge, 2-cell plug-in)	0.7 ft² (650 cm²)
Z8FA4NPX2 (8-inch diameter cartridge, 4-cell plug-in)	1.4 ft² (1300 cm²)
45264 (12-inch diameter cartridge, 7-cell bodyfeed)	7.2 ft² (0.67 m²)
45245 (12-inch diameter cartridge, 16-cell)	16.4 ft² (1.5 m²)
Z16P (16-inch, 14-cell, netted)	34.7 ft² (3.2 m²)

Zeta Plus™ VR Series Ordering Guide

8" Diameter Cartridges

Catalog Number	Configuration	VR Series
45109 (8" 8-cell)	13 - Fluorocarbon 22 - Silicone 23 - Expanded PTFE	VR02 VR06 VR03 VR08 VR05
45167 (8" 7-cell, O-ring plug-in)	03 - Fluorocarbon 04 - Silicone	VR02 VR06 VR03 VR08 VR05
Z8FA2NP (8" 2-cell, plug-in) Z8FA4NP (8" 4-cell, plug-in)	03 - Fluorocarbon 04 - Silicone	Pkg Code 2 VR02 VR06 VR03 VR08 VR05

16" Diameter Cartridges

Catalog Number	Gasket Material	VR Series
Z16P (16" 14-cell)	A - Silicone B - Fluorocarbon	VR02 VR06 VR03 VR08 VR05

BC Capsules

Catalog Number	VR Series
BC0025L (Luer) BC0025S (Sanitary)	VR02 VR06 VR03 VR08 VR05

12" Diameter Cartridges

Catalog Number	Geometric Variation	Gasket Material	VR Series
45264 (12" 7-cell, Bodyfeed) 45245 (12" 16-cell)	01 - Standard Polypropylene	A - Silicone B - Fluorocarbon	VR02 VR06 VR03 VR08 VR05

Product Use

Identified uses: Manufacturing of pharmaceutical (drug) products, including active pharmaceutical ingredients and vaccines.

Prohibited uses: As a component in a medical device that is regulated by any agency, and/or globally exemplary agencies, including but not limited to: a) FDA, b) European Medical Device Directive (MDD), c) Japan Pharmaceuticals and Medical Devices Agency (PMDA); Applications involving permanent implantation into the body; Life-sustaining medical applications; Applications requiring FDA Food Contact compliance without use restrictions

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