3M Purification

Product Brochure - Filter Cartridges and Capsules



Featuring:

- Activated carbon immobilized within a filter matrix
- Scale-up from discs and capsules to sheets and cartridges
- Wide range of different carbons available





Zeta PlusTM Activated Carbon Products: The efficient way to decolorize your process liquids

Zeta Plus™ Activated Carbon products incorporate our latest technology to decolorize and remove contaminants from process streams. In today's manufacturing processes, efficiency, yield, quality and consistency are critical, as well as operating in a safe environment for operators. Zeta Plus Activated Carbon products eliminate most of the handling concerns of using powdered carbon. Bulk carbon operations may also negatively impact yields, and thereby increase the required number of production batches. Zeta Plus Activated Carbon products may help address many of these operational and performance concerns.

Activated carbon

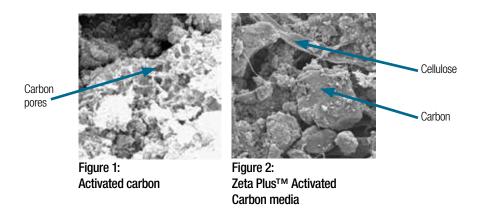
Activated carbon is a highly porous carbonaceous material that is characterized by a large internal surface area, providing exceptional adsorptive properties. Pores within the structure can be classified into different categories depending on their size: micropores (< 10 nm range), mesopores (10-25 nm range) and macropores (larger than > 25 nm).

Activated carbon can be produced from different sources such as peat, lignite, pine wood, coconut shell, etc. The raw material influences the pore structure of the activated carbon; as an example, activated carbon made from pinewood has a wide distribution of micro, meso and macro pores, whereas activated carbon obtained from coconut shell is typically microporous.

Two ways of activation used to create the porosity and internal structure of carbon are steam and chemical activation. In practice, steam activation leads to a greater degree of microporosity, while chemical activation makes a more macroporous/mesoporous structure.

The porous structure gives the activated carbon a very large internal surface area (larger than $500 \text{ m}^2\text{/g}$) which allows the activated carbon to be efficient in adsorbing a wide range of molecules. Adsorption is caused by Van der Waals' forces. These short-range interactions are influenced by the nature of the molecule being adsorbed, such as its molecular weight and the presence of functional groups (double bonds, halogen).

Figure 1 and figure 2 show activated carbon and Zeta Plus Activated Carbon media.





The Zeta Plus[™] Activated Carbon principle

Zeta PlusTM Activated Carbon filter media is made by formulating bulk activated carbon with cellulose fibers and a positively charged binder resin. This combination is wet formed into a robust porous filter matrix or media. The activated carbon particles are immobilized in the filter matrix ensuring minimal particle shedding during use.

3M Purification offers five standard product grades, each based on a different type of activated carbon. These carbon types have been specifically selected for their properties to cover a broad range of applications while meeting various industry requirements. Zeta Plus Activated Carbon filter media is available in three different porosities so that solutions with different viscosities can be processed.

3M Pharmaceutical Grade Zeta Plus Activated Carbon filter products meet the market requirements where USP <88> Class VI Biological Reactivity Tests compliance is required, with the necessary traceability and documentation.

Further technical information is available in the Regulatory Support File for Zeta Plus Activated Carbon filter products. In addition, a Drug Master File (DMF) is on record with the US FDA, which may be referenced as required.

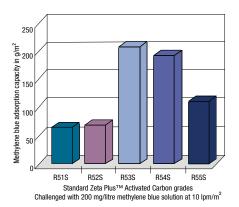
Advantages of using Zeta Plus Activated Carbon vs. bulk activated carbon

Immobilizing activated carbon in a filter matrix has many distinct advantages over bulk carbon. Some of the advantages of using Zeta Plus Activated Carbon are summarized in Table 1 below:

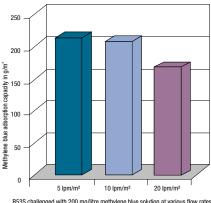
Table 1: Advantages of Zeta Plus [™] Activated Carbon compared to bulk activated carbon		
	Bulk activated carbon	Zeta Plus™ Activated Carbon advantage
Carbon dust	Potential health issuesSafety	Reduced fire risk and reduced carbon dust.
Cleanliness	 Production process: Time consuming Hard to clean Potential batch to batch cross-contamination Potential for downstream carry over 	Clean product After initial flush of the cartridge, there is minimal release of carbon fines in the filtered solution
Process times	Long due to contact time, preparation time and removal time	Decreased process time because of constant flow rate filtration and efficiency No product rework because of consistent performance
Carbon powder Relies on diffusion of contaminants to reach active site Additions of filter aid required to remove carbon		Activated carbon is fixed and the flow is forced through the matrix that increases mass transfer efficiency
Process steps	 A filtration step is required to remove the carbon fines Potential for carry over to solvent recovery plants 	A single step used as decolorization is combined with the filtration step Potential for reduced costs in solvent recovery



Graph 1: Adsorption capacity of Zeta Plus™ **Activated Carbon**



Graph 2: Adsorption capacity of Zeta Plus Activated Carbon R53S



R53S challenged with 200 mg/litre methylene blue solution at various flow rates

Decolorization efficiency of Zeta Plus™ Activated Carbon

One metric to characterize Zeta Plus™ Activated Carbon media is methylene blue (an organic dye) dynamic binding capacity. The methylene blue dynamic binding capacity is widely used by activated carbon manufacturers as a reference for decolorization efficiency. This molecule has a 8 nm diameter, which means that it has the ability to enter pores with a diameter larger than 8 nm. In the glucose syrup industry (where activated carbon is used to remove a color precursor called methyl-hydroxy-furfural), and in pharmaceutical and chemical synthesis (where many contaminants and byproducts are formed), activated carbon with high methylene blue capacity can be beneficial.

Methylene blue test

Graph 1 shows the methylene blue adsorption capacity of several 3M Purification standard Zeta Plus Activated Carbon grades.

Due to the chemical variations in contaminates targeted to be removed, methylene blue dynamic binding capacity can not be used to universally compare the performance Zeta Plus Activated Carbon in all applications. It is, therefore, recommended to perform a bench-scale test to identify the most efficient Zeta Plus Activated Carbon grade.

Flow rate influence

As discussed earlier, adsorption of molecules by activated carbon relies on Van der Waals' forces. As those interactions are of short range, residence time between the solution and the filter media is critical.

Graph 2 shows the influence of flux (flow rate per unit area) on the adsorption capacity of the filter media. It shows that when the flux increases the adsorption capacity of Zeta Plus Activated Carbon filter media decreases.

High decolorization efficiency

Zeta Plus Activated Carbon contains a very high loading level of the adsorbent. The five standard product grades offered are based on a range of targeted, high performing carbon types.

Evaluation and scaling-up

3M Purification offers a range of Zeta Plus Activated Carbon product configurations for laboratory-scale filtration, for process development studies and for small to large production scale operations. BC25 single-use capsules have effective filter areas of 25 cm² enabling process development and scale-up. In addition, Zeta Plus Activated Carbon discs (47 mm and 90 mm diameter) are available. These are ideal for carbon selection and scale-up evaluation. Numerous pharmaceutical and biotechnology companies worldwide have scaled-up reliably and predictably to 12" and 16" diameter cartridge systems using small surface area Zeta Plus Activated Carbon discs and BC25 capsules.

Zeta Plus[™] Activated Carbon filtration is scaled-up using a fixed filter flux (fluid flow rate per effective filtration area). Zeta Plus Activated Carbon should be evaluated initially at a recommended flux of 1-3 lpm/m². However, there are some successful applications where flux can be much higher than this recommended value, while maintaining high adsorption efficiency.

Applications

Zeta Plus[™] Activated Carbon can be used in any application where bulk activated carbon is involved. It is widely used in the following applications. The Pharmaceutical grade products are specifically designed and intended to be used in the pharmaceutical manufacturing applications.

Pharmaceutical

- Decolorization in production of vitamins, antibodies, dextrose, gelatine, enzymes
- Parenterals
- Blood fractionation

Chemicals

- Bulk pharmaceutical actives and intermediates
- Decolorization of solvents
- Decolorization of fine chemicals
- Removal of organic contaminants

Cosmetics

- Alcohol deodorization
- Decolorization of perfumes

Food and beverage

- Removal of trace organic contaminants from gelatin, pectin, juices, oils
- · Decolorization of wine and cider
- Decolorization of sugar
- Spirit purification
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- Haze removal

Specific applications are summarized in the following Table 2.

Table 2: Applications of Zeta Plus [™] Activated Carbon		
Application	Recommended grade	
Antibiotic decolorization	R33S, R53S, R35S, R55S	
Endotoxin removal	R53S	
Removal of detergent	R32S, R52S	
Removal of precipitation agent	R33S, R53S	
Vaccine purification	R33S, R53S	
Decolorization of antihistamine	R33S, R53S	
Solvent decolorization, e.g. acetone	R31S, R51S	
Removal of trace organic contaminants from active compounds	R31S, R51S, R34S, R54S	
Removal of trace organic contaminants from X-ray contrast media	R33S, R53S	
Blood fractionation: albumin decolorization, pKa reduction, biliverdin removal	R33S, R53S	
Trace contaminant removal from vodka, whisky and gin	R31S, R51S	
Silicone oil decolorization	R11S, R14S	

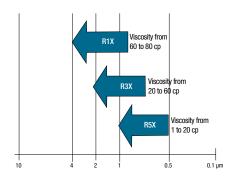








Graph 3: Types of media for different fluid viscosities



Grades of Zeta Plus[™] Activated Carbon

Zeta Plus[™] Activated Carbon is available in different porosities or filtration ratings to optimize performance with fluids having different viscosities. Graph 3 can be used as a guide for optimum filter selection.

Cartridge construction

Cartridge construction provides integrity in severe environments including *in situ* steam sterilization and hot water sanitation. The edge seal design for durable cell construction maintains integrity under many demanding process conditions.

Filter housings

3M Purification offers a wide range of sanitary filter housings (standard and custom designs) for Zeta Plus Activated Carbon cartridges. To comply with the regulations in the pharmaceutical and bioprocessing industry, these filter housings are in 316L stainless steel or Hastelloy® with mirror-polished or electropolished surface finish.

Extractables

Inorganic and organic extractable testing was performed on Zeta Plus Activated Carbon media with a variety of fluids.

More information on extractables is included in the Regulatory Support File (RSF).

Operating parameters

Table 3: Zeta Plus™ Activated Carbon recommeded operating parameters		
Max. operating temperature Cartridges: 176 °F (80 °C)		
	BC25 capsules: 104 °F (40 °C)	
Max. differential pressure	2.4 bar (35 psid)	
Minimum Required Pre-conditioning Flush	54 l/m² (1.25 gal./ft²) with water, or other suitable fluid, at a volumetric flow rate up to 1200 L/m²/hr	
Recommended test flow rate	3 liters/min/m² of media	
Steam sterilization	Cartridges: 1 cycle at 250 °F (121 °C) for 30 min.	
	BC capsules: autoclave only	
* Contact 3M Purification for additional information.		

Zeta Plus[™] Activated Carbon Filters

Pyrogenicity

The SP and SLP versions of Zeta Plus[™] Activated Carbon are tested for extractable endotoxin concentration by the *Limulus* Amebocyte Lysate bacterial endotoxin test (LAL). Acceptance criteria are:

 $SP: \le 0.50 \text{ EU/ml}$ $SLP: \le 0.125 \text{ EU/ml}$

Quality control

3M Purification's Quality Assurance program follows ISO procedures.

Each media batch is sample audited for flow, density and extractable endotoxin amount for SP and SLP grades. For SP and SLP media, a certificate of quality is packed with the product. In addition, Zeta Plus Activated Carbon cartridge packaging is labelled with a batch identification number to provide complete traceability from the raw materials to the finished product.

All 12" and 16" Zeta Plus Activated Carbon filter cartridges are supplied with the part and lot number engraved into the side of the gasket retainer. This individual engraving helps cartridge traceability once the filter is removed from the protective packaging and assists in regulatory compliance.

Application Engineering

3M Purification's 100 years of experience are synonymous with quality, performance and high level technical support. The cornerstone of 3M Purification's philosophy is service to customers, not only in product quality and prompt delivery, but also in validation assistance, applications support and in the sharing of scientific information.

3M's Application Engineering team works closely with customers to solve difficult separations problems and to recommend the most economical and efficient filter system. Our application specialists are skilled in performing on-site testing and relating test results to full-scale manufacturing operations.

A world leader in fluid purification

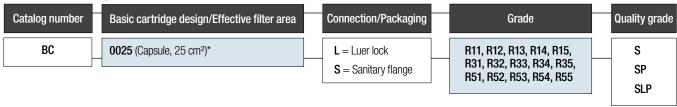
3M Purification's manufacturing sites producing Zeta Plus Activated Carbon have ISO registered quality systems. Global manufacturing together with trained stocking distributors and state-of-the-art laboratory support bring quality solutions to existing and challenging new filtration applications.





Zeta Plus™ Activated Carbon Series filters - Ordering guide

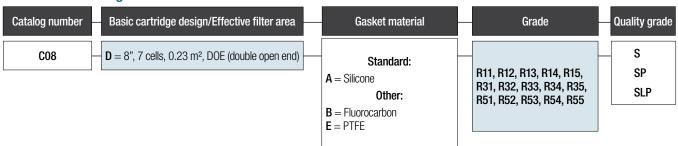
Zeta Plus™ BC Capsules



 $\mathsf{P} = \mathsf{Pharmaceutical}$

Examples of entire product description: BC0025LR11SP, BC2000AR55S

8" Diameter Cartridges



Note: Please order using 3M ID#

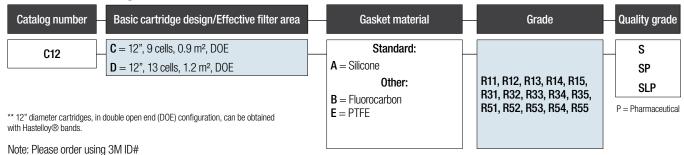
3M ID #	Ordering Guide #	3M ID #	Ordering Guide #
70020299338	C08DER32SP	70020299429	C08DER52SLP
70020299346	C08DER33SP	70020299437	C08DER53SLP
70020299353	C08DER35SP	70020299445	C08DER55SLP
70020299361	C08DER52SP	70020299452	C08DDR51SP
70020299379	C08DER53SP	70020299460	C08DBR32SP
70020299387	C08DER55SP	70020299478	C08DAR32SP
70020299395	C08DER32SLP	70020299486	C08DAR53SLP
70020299403	C08DER33SLP	70020299494	C08DAR55SLP
70020299411	C08DER35SLP	70020331875	C08DAR13SP

^{*} Minimum order quantity 4 pieces



Zeta Plus™ Activated Carbon Series filters - Ordering guide continued

12" Diameter Cartridges**



3M ID #	Ordering Guide #
70-0202-9834-8	C12CAR32SP
70-0202-9835-5	C12CAR33SP
70-0202-9836-3	C12CAR35SP
70-0202-9837-1	C12CAR52SP
70-0202-9838-9	C12CAR53SP
70-0202-9839-7	C12CAR55SP
70-0202-9840-5	C12DAR32SP
70-0202-9841-3	C12DAR33SP
70-0202-9842-1	C12DAR35SP
70-0202-9843-9	C12DAR52SP
70-0202-9844-7	C12DAR53SP
70-0202-9845-4	C12DAR55SP
70-0202-9846-2	C12CER32SP
70-0202-9847-0	C12CER33SP
70-0202-9848-8	C12CER35SP
70-0202-9849-6	C12CER52SP
70-0202-9850-4	C12CER53SP
70-0202-9851-2	C12CER55SP
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70-0202-9854-6	C12DER35SP
70-0202-9855-3	C12DER52SP
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70-0202-9857-9	C12DER55SP
70-0202-9858-7	C12CAR32SLP
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70-0202-9863-7	C12CAR55SLP
70-0202-9864-5	C12DAR32SLP

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70-0202-9892-6 C12DDR53SP 70-0202-9893-4 C12DDR55SP	70-0202-9890-0	C12DDR35SP
70-0202-9893-4 C12DDR55SP	70-0202-9891-8	C12DDR52SP
	70-0202-9892-6	C12DDR53SP
70-0202-9894-2 C12CDR32SLP	70-0202-9893-4	C12DDR55SP
	70-0202-9894-2	C12CDR32SLP

Zeta Plus™ Activated Carbon Series filters - Ordering guide continued

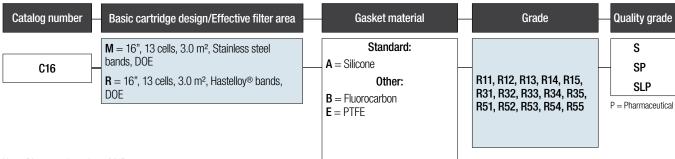
12" Diameter Cartridges Continued

3M ID #	Ordering Guide #
70-0202-9895-9	C12CDR33SLP
70-0202-9896-7	C12CDR35SLP
70-0202-9897-5	C12CDR52SLP
70-0202-9898-3	C12CDR53SLP
70-0202-9899-1	C12CDR55SLP
70-0202-9900-7	C12DDR32SLP
70-0202-9901-5	C12DDR33SLP
70-0202-9902-3	C12DDR35SLP
70-0202-9903-1	C12DDR52SLP

3M ID#	Ordering Guide #
70-0202-9904-9	C12DDR53SLP
70-0202-9905-6	C12DDR55SLP
70-0202-9906-4	C12CDR12SP
70-0202-9908-0	C12DDR12SP
70-0202-9909-8	C12DDR13SP
70-0202-9912-2	C12CDR35S
70-0202-9914-8	C12DDR51SP
70-0202-9918-9	C12DBR13SP

Flat sheets and discs are also available upon request. Please contact your local 3M Purification representative or distributor for further support and information.

16" Diameter Cartridges



Note: Please order using 3M ID#

3M ID #	Ordering Guide #
70-0202-9811-6	C16MAR32SLP
70-0202-9787-8	C16MAR32SP
70-0202-9812-4	C16MAR33SLP
70-0202-9788-6	C16MAR33SP
70-0202-9813-2	C16MAR35SLP
70-0202-9789-4	C16MAR35SP
70-0202-9814-0	C16MAR52SLP
70-0202-9790-2	C16MAR52SP
70-0202-9815-7	C16MAR53SLP
70-0202-9791-0	C16MAR53SP
70-0202-9816-5	C16MAR55SLP
70-0202-9792-8	C16MAR55SP
70-0202-9817-3	C16MER32SLP
70-0202-9793-6	C16MER32SP
70-0202-9818-1	C16MER33SLP
70-0202-9794-4	C16MER33SP
70-0202-9819-9	C16MER35SLP
70-0202-9795-1	C16MER35SP

3M ID #	Ordering Guide #
70-0202-9820-7	C16MER52SLP
70-0202-9796-9	C16MER52SP
70-0202-9821-5	C16MER53SLP
70-0202-9797-7	C16MER53SP
70-0202-9822-3	C16MER55SLP
70-0202-9798-5	C16MER55SP
70-0202-9823-1	C16RER32SLP
70-0202-9805-8	C16RER32SP
70-0202-9824-9	C16RER33SLP
70-0202-9806-6	C16RER33SP
70-0202-9825-6	C16RER35SLP
70-0202-9807-4	C16RER35SP
70-0202-9826-4	C16RER52SLP
70-0202-9808-2	C16RER52SP
70-0202-9827-2	C16RER53SLP
70-0202-9809-0	C16RER53SP
70-0202-9828-0	C16RER55SLP
70-0202-9810-8	C16RER55SP





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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