

ZetaCarbon™

Filter Cartridge and Capsules

The Smarter Way For Carbon Use

Featuring:

- Carbon immobilised within a filter matrix
- Scale-up from disc to sheet and cartridge
- Wide range of different carbons available



ZetaCarbon: The efficient way to decolourise your process liquids

ZetaCarbon incorporates the latest technology to decolourise and remove contaminants from your process streams. ZetaCarbon eliminates the concerns of using powdered carbon. In today's manufacturing processes, efficiency, yield, quality and consistency are critical as well as operating in a safe environment for operators. Bulk carbon can also be a limiting step in many operations preventing enhanced yields and increased production batches. ZetaCarbon addresses all of these concerns.

Bulk Activated Carbon

Activated carbon is a highly porous carbonaceous material that is characterised 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 today to create the porosity and internal structure 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 $500 \text{ m}^2\text{g}^{-1}$) which allows the activated carbon to be efficient in adsorbing a wide range of molecules. Adsorption is caused by Van der Waals' type 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 ZetaCarbon medium.

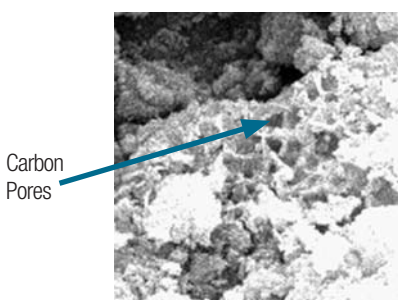


Figure 1:
Activated Carbon

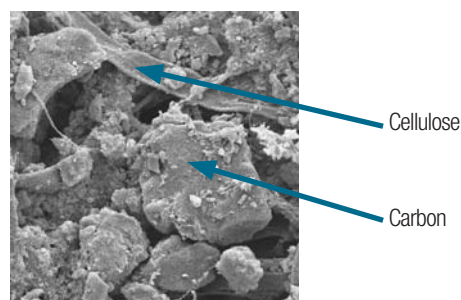


Figure 2:
ZetaCarbon Medium

ZetaCarbon Principle

The activated carbon is made into ZetaCarbon filter media by the addition of cellulose fibres and a binder resin. This eliminates the use of bulk carbon that causes dust-related issues, especially for operators.

3M Purification incorporate in its standard range five different types of activated carbon to cover a broad range of applications.

These have been specifically selected for their properties to meet industry requirements. ZetaCarbon filter media are available in different porosities so that solutions with different viscosities can be processed.

All the 3M Purification ZetaCarbon filter media available meet the market requirements whether 21 CFR or USP Class VI plastics compliance is required, with the necessary traceability and documentation.

The Drug Master File (DMF) and further technical details are available in the Regulatory Support File for ZetaCarbon filter media.



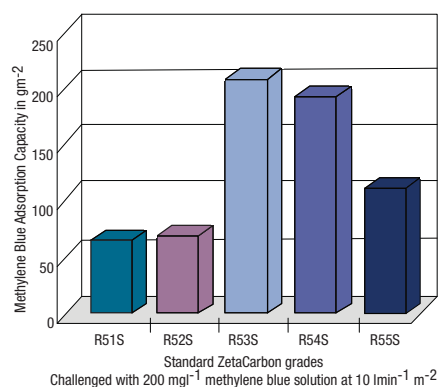
Advantages of using ZetaCarbon versus Bulk Activated Carbon

The concept of using activated carbon immobilised in a cellulose matrix brings a lot of advantages compared to bulk powder.

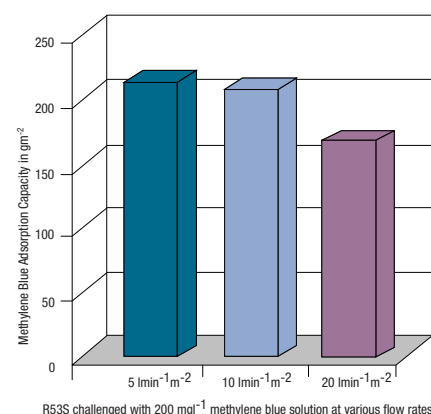
Some of the advantages of using ZetaCarbon are summarised in the Table 1 below:

Table 1: Advantages of ZetaCarbon Compared To Bulk Activated Carbon		
	Bulk Activated Carbon	ZetaCarbon Advantage
Carbon dust	Health issues: <ul style="list-style-type: none"> • Lung disease • Adsorbs oxygen Safety: <ul style="list-style-type: none"> • Fire risk 	<ul style="list-style-type: none"> • Less fire risk and almost no carbon dust.
Cleanliness	Production environment Production process: <ul style="list-style-type: none"> • Time consuming • Costly • Rarely 100% clean • Batch to batch contamination • Downstream carry over 	<ul style="list-style-type: none"> • Clean product • After initial flush of the cartridge, there is minimal release of carbon fines in the filtered solution
Process times	<ul style="list-style-type: none"> • Long due to contact time, preparation time and removal time 	<ul style="list-style-type: none"> • Decreased process time because of constant flow rate filtration and efficiency • No product rework because of consistent performance
Carbon powder	<ul style="list-style-type: none"> • Relies on diffusion of contaminants to reach active site • Additions of filter aid required to remove carbon 	<ul style="list-style-type: none"> • Activated carbon is fixed and the flow is forced through the matrix that increases efficiency
Process Steps	<ul style="list-style-type: none"> • A filtration step is required to remove the carbon • Carry over to solvent recovery plants 	<ul style="list-style-type: none"> • A single step is used as decolourisation is combined with the filtration step <p>Reduced costs in solvent recovery</p>

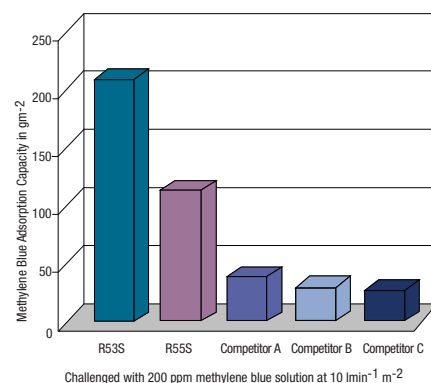
Graph 1: Adsorption Capacity of 3M Purification ZetaCarbon



Graph 2: Adsorption Capacity of 3M Purification ZetaCarbon R53S



Graph 3: Adsorption Capacity of Different Activated Carbon Media



Decolourisation efficiency of ZetaCarbon

The methylene blue value is widely used by activated carbon manufacturers as a reference for decolourisation 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 colour precursor called methyl-hydroxy-furfural) and in pharmaceutical and chemical synthesis (where many contaminants and by products are formed), activated carbon with high methylene blue value is beneficial. ZetaCarbon media can also be characterised by their methylene blue value.

Methylene blue test

Graph 1 shows the methylene blue adsorption capacity of several 3M Purification standard ZetaCarbon grades. Methylene blue tests cannot be used to universally describe and compare ZetaCarbon performance.

In every product, the nature of the molecules to adsorb varies, and it is always recommended to perform a bench scale test to identify the most efficient ZetaCarbon grade rather than selecting it only on methylene blue value.

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, contact time between the solution and the filter media is critical.

Graph 2 shows the influence of the flux on the adsorption capacity of the filter media.

It shows that when the flux increases the adsorption capacity of ZetaCarbon filter media decreases.

High decolourisation efficiency

Because of our advanced technology and our experience in manufacturing ZetaCarbon, 3M Purification incorporates into its filter media a high concentration of activated carbon.

This technology used in combination with a selection of the most efficient types of activated carbon on the market, enables ZetaCarbon to have high decolourisation capacity outperforming competitive media. Graph 3 shows the methylene blue adsorption capacity of some competitor media and ZetaCarbon R53S and R55S.

Evaluation and Scaling-up

3M Purification offers a range of ZetaCarbon products for laboratory-scale filtration, for process development scale-up work and for small lot production runs all the way to full scale. Biocap 25, 1000 and 2000 disposable devices have surface areas of 25 cm² through to 1300 cm² enabling development to scale-up. In addition, ZetaCarbon discs (47 mm and 90 mm diameter) are available. These are ideal for scale-up evaluation as working process volumes move from laboratory or bench-scale through pilot plant scale to full scale manufacturing operations. Numerous pharmaceutical and biotechnology companies world-wide have scaled-up reliably and predictably to high area 12 inch and 16 inch diameter cartridge systems using small surface area ZetaCarbon discs supplied in the 3M Purification filtration test kit, with the assistance of scientists from 3M Purification Scientific Application Support Services (SASS).

ZetaCarbon filtration is scaled up using a fixed filter flux (fluid flow rate per effective filtration area). ZetaCarbon should be evaluated initially at a recommended flux of 3 l/min⁻¹m⁻². However, there are some successful applications where flux is much higher than this recommended value, whilst maintaining high adsorption efficiency.

Applications

ZetaCarbon can be used in any application where bulk activated carbon is involved. It is widely used in the following applications:

Pharmaceutical

- Decolourisation in production of vitamins, antibodies, dextrose, gelatine enzymes
- Parenterals
- Blood fractionation
- Pesticide removal from plant extracts

Chemicals

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

Cosmetics

- Alcohol deodorization
- Decolourisation of perfumes

Food and Beverage

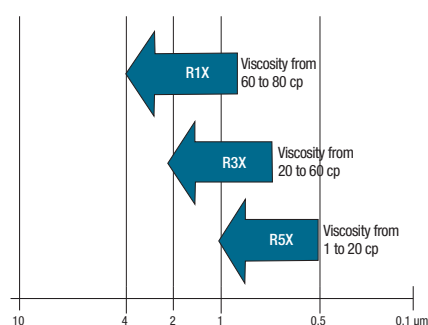
- Removal of trace organic contaminants from gelatine, pectin, juices, oils
- Decolourisation of wine and cider
- Decolourisation of sugar
- Spirit purification
- Fatty haze removal

Specific applications are summarised in the following table 2.

Table 2: Applications of ZetaCarbon	
Application	Recommended Grade
Antibiotic decolourisation	R33S, R53S, R35S, R55S
Endotoxin removal	R53S
Removal of detergent	R32S, R52S
Removal of precipitation agent	R33S, R53S
Vaccine purification	R33S, R53S
Decolourisation of antihistamine	R33S, R53S
Solvent decolourisation 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 decolourisation, pKa reduction, biliverdin removal	R33S, R53S
Trace contaminant removal from Vodka, Whisky and Gin	R31S, R51S
Silicon oil decolourisation	R11S, R14S



Graph 4: Types of Media for Different Fluid Viscosities



Grades of ZetaCarbon

ZetaCarbon is available in different filtration ratings in order to deal with products of different viscosity. Graph 4 can be used as a guide for optimum filter selection: Different types of carbon can be specified from our “A La Carte” range. This can minimise validation for ease of ZetaCarbon implementation into the process. Please see our ordering guide for more detail.

Cartridge construction

Cartridge construction and compression system ensures integrity in severe environments including *in-situ* steam sterilisation and hot water sanitation. The edge seal design for durable cell construction maintains integrity under the most demanding process conditions.

Filter housing

3M Purification offers a wide range of sanitary filter housings (standard and custom designs) for ZetaCarbon 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. We are also able to supply a range of housing accessories, such as CIP spray-ball, optimised maximum volume recovery system and the innovative Zeta Plus Cartridge Lifting Device.

Extractables

Inorganic and organic extractable testing was performed on ZetaCarbon media with a variety of fluids.

More information on extractables is included in the Regulatory Support File (RSF) or can be obtained from 3M Purification Scientific Application Support Services (SASS).

As an indication, the following table gives typical level of metal extractables (mgg⁻¹ of medium).

	Al	Ca	Fe	Mg	Fe	Si	Na
R51S	0.005	0.355	0.016	0.023	0.048	0.033	0.069
R52S	<0.005	0.470	0.005	0.070	0.083	0.160	0.510
R53S	<0.005	0.240	0.010	0.015	0.033	0.023	0.062
R54S	<0.005	0.190	0.009	0.035	0.053	0.029	1.218
R55S	0.026	0.190	0.022	0.022	0.056	0.034	0.415

Operating parameters

Max operating temp	80 °C
Max differential pressure	2 bar
Recommended rinse volume	54 l/m ²
Recommended test flow rate	3 l/min ⁻¹ m ⁻²
Steam sterilisation	1 cycle at 121°C for 30 min

* Hastelloy™ is a trade mark of Haynes Int.

Pyrogenicity

The SP and SLP versions of ZetaCarbon are tested for pyrogenicity by the LAL gel clot test.

Acceptance criteria are:

SP: ----- ≤ 0.50 EU/ml

SLP: ----- ≤ 0.125 EU/ml

Quality Control

A complete quality assurance programme following ISO 9001 procedures guarantees total quality.

Each media batch is sample audited for flow, density and pyrogenicity for SP and SLP grades. For SP and SLP media, a quality control certificate is packed with the product. In addition, ZetaCarbon cartridge packaging is labelled with a batch identification to provide complete traceability from the raw materials to the finished product.

All 12" and 16" ZetaCarbon 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.

Scientific Applications Support Services (SASS)

3M Purification's 95+ 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 Purification's Scientific Application Support Services group works closely with customers to solve difficult separations problems and to recommend the most economical and efficient filter system. SASS 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 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.



ZetaCarbon Ordering Information

1. Zeta Plus BC Capsules

Catalogue Number	Basic Cartridge Design - Effective Filter Area	Gasket Material**	Grade	Quality Grade
BC	0025 (Capsule, 25 cm ²)	L = Luer Lock S = Sanitary Flange	R11, R12, R13, R14, R15, R31, R32, R33, R34, R35, R51, R52, R53, R54, R55 "A la Carte" R10 + AC name R30 + AC name R50 + AC name	S SP SLP
BC	1000 (Capsule, 650 cm ²)	A = Single Filter B = 3 Filter Pack		
BC	2000 (Capsule, 1300 cm ²)			

Examples of entire product description: BC0025LR11SP, BC2000AR55S

8" Diameter Cartridges

Catalogue Number	Basic Cartridge Design - Effective Filter Area	Gasket Material**	Grade	Quality Grade
C08	D = 8", 7 cells, 0.23 m ² , DOE (Double open end)	E = PTFE	R11, R12, R13, R14, R15, R31, R32, R33, R34, R35, R51, R52, R53, R54, R55 "A la Carte" R10 + AC name R30 + AC name R50 + AC name	S SP SLP
C08	P = 8", 6 cells, 0.20 m ² , O-Ring Plug-in	Standard: A = Silicone (MVQ)		
C08	P4 = 8", 4 cells, 0.13 m ² , O-Ring Plug-in	Other: B = Fluorocarbon (FPM) C = Ethylene Propylene (EPDM) D = Nitrile (NBR)		
C08	P2 = 8", 2 cells, 0.065 m ² , O-Ring Plug-in			

12" Diameter Cartridges and 16" Diameter Cartridges*

Catalogue Number	Basic Cartridge Design - Effective Filter Area	Gasket Material**	Grade	Quality Grade
C12	D = 12", 13 cells, 1.30 m ² , DOE	Standard: A = Silicone (MVQ)	R11, R12, R13, R14, R15, R31, R32, R33, R34, R35, R51, R52, R53, R54, R55 "A la Carte" R10 + AC name R30 + AC name R50 + AC name	S SP SLP
C16	Y = 16", 14 cells, 3.20 m ² , High Flow, DOE	Other: B = Fluorocarbon (FPM) C = Ethylene Propylene (EPDM) D = Nitrile (NBR) E = PTFE		
C16	M = 16", 13 cells, 3.00 m ² , Standard, DOE			

* 8", 12" and 16" diameter cartridges, in Double Open End configuration, can be obtained with Hastelloy™ bands.

** Letter H should be added at the end of the part number (Other gasket materials are available).

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

Important Notice

3M Purification MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Since a variety of factors can affect the use and performance of a 3M Purification product in a particular application, some of which are uniquely within the user's knowledge and control, user is responsible for determining whether or not the 3M Purification product is fit for a particular purpose and suitable for user's method of application.

Limited Warranty

3M Purification warrants it this product to be free from defects in material and workmanship during normal use for a period of one (1) year from the date of shipment from the factory. If the Product(s) is (are) defective within this warranty period, your exclusive remedy and 3M Purification's sole obligations shall be, at 3M Purification's option, to replace or repair the Product(s) or refund the original purchase price of the Product(s). This warranty does not apply to failures that result from abuse, misuse, alteration or damage not caused by 3M Purification or failure to properly follow installation and use instructions.

Limitation of Liability: 3M Purification will not be liable for any loss or damage arising from the use of the Product(s), whether direct, indirect, special, incidental, or consequential, regardless of the legal theory asserted, including warranty, contract, negligence or strict liability. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you.

This warranty gives you specific legal rights and you may have other rights which vary from state to state, or country to country.

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