

Zeta Plus™ C(P) & S(P) Series

Lenticular Depth Filter Cartridges

Zeta Plus C, CP, S & SP Series filters are a family of advanced depth filters designed to provide optimal clarification of pharmaceutical, biological, bioprocess, cosmetic and food & beverage fluids. Zeta Plus C, CP, S & SP Series filters are composed of inorganic filter aid, cellulose and a proprietary resin system that imparts a positive charge to the filter matrix, aiding its adsorption of negatively charged contaminants.

Grade Choice

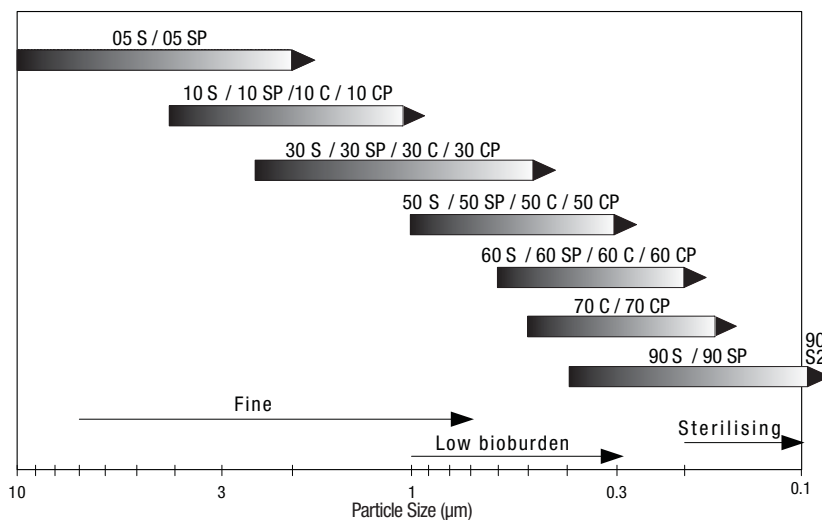
The Zeta Plus C, CP, S & SP Series filter are available in several grades, that meet the different filtration needs required by your applications. Filtration ratings are given in the following table for the various grades. The optimal filtration system for your particular application can be determined by on-site testing or by sample evaluation by a member of our Scientific Application Support Services group (SASS).

Pharmaceutical CP and SP Grade

Zeta Plus CP and SP media are manufactured following procedures described in 3M Purification's Drug Master Files submitted to the FDA (United States Food and Drug Administration). The characteristics and filtration mechanisms of the CP and SP Grades are the same as the standard C and S Series. The CP and SP Grade has complete product control and traceability.



Picture 1 : Zeta Plus Family



Graphic 1: Zeta Plus C, CP, S and SP Grade Selection

Applications

Zeta Plus C, CP, S & SP Series filters are optimised for clarification of pharmaceutical, biological, bioprocess, cosmetic and food & beverage fluids. Examples of applications include:

Bio Pharmaceuticals

- Blood Products
- Antibiotics
- Cough Syrups
- Intravenous Solutions
- Growth Media
- Bioprocess Fluid
- Cosmetics

Food & Beverages

- Spirits
- Water

Features and Benefits

Depth filtration media designed to retain contaminants by mechanical entrapment and electrokinetic adsorption

- High contaminant holding capacity for economical filtration and reliable particle removal

Full range of scaleable capsule and cartridge filter configurations

- Allows pilot testing and scale-up with the same materials that will be used in full-scale systems

FDA Drug Master File and USP Class VI Biological Safety

- Eases validation and regulatory submissions by providing vital documentation and traceability

Self-contained, single-use disposable capsule and cartridge modules

- Reduced labour time for change-outs and capsules eliminate cleaning validation



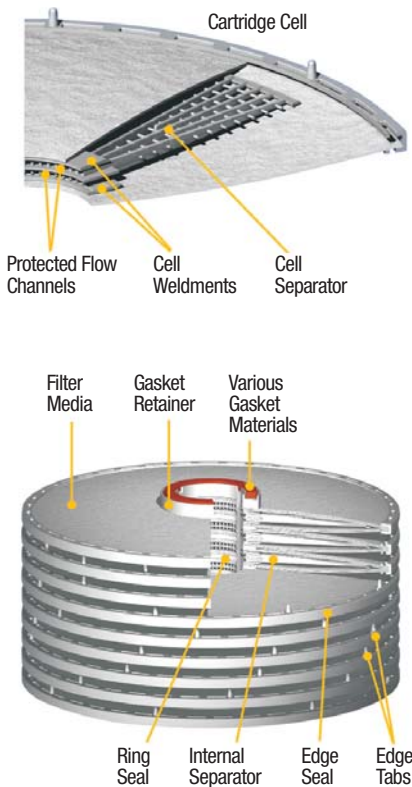


Figure 1: Zeta Plus Cartridge Construction

During the manufacturing process, molecules carrying a positive charge are chemically bonded to the filter matrix permanently forming an interconnected filtration structure with positively charged electrokinetic capture sites. The resulting porous depth filter is a tortuous network of charge-enhanced flow channels capable of removing bacteria, particulate, cellular debris and submicronic contaminants to a level which mechanical screening alone cannot achieve.

Cartridge Construction

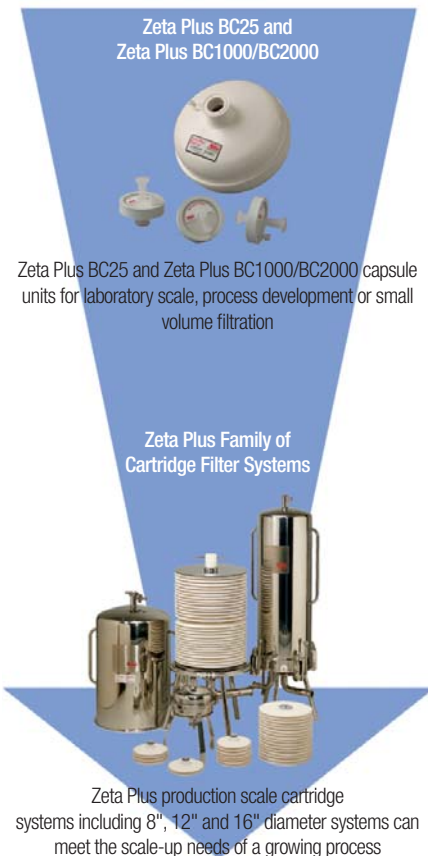
Zeta Plus C, CP, S and SP Series cartridges are designed for use with 3M Purification Zeta Plus sanitary style stainless steel filter housings. Cartridges are constructed from individual cells of Zeta Plus C, CP, S and SP Series filter medium assembled together with polypropylene ring seals under predetermined compression and unitised by three 316 stainless steel bands. Each cell is constructed using polypropylene molded edge seals and separators for high performance. Various gasket materials are available depending upon application. Filter cartridges are available in 8, 12 and 16-inch diameters.

Capsule Construction

Zeta Plus C, CP, S and SP Series filters are available in ready to use, fully disposable Zeta Plus BC capsules. The Zeta Plus BC Series capsules are completely encapsulated disposable filters for small volume biological, bioprocess and pharmaceutical filtration. Zeta Plus BC capsules are autoclavable and available in three sizes (25, 650 and 1300 cm² filtration area) to provide a high degree of application flexibility. They provide a perfect tool for scaling experiments.

Efficient Flow Rates

The graph shows initial Δp values for Zeta Plus CP and SP Series filter media versus specific flow rates (litre per min/m²), obtained with clean water.



Graphic 2: Zeta Plus Fow Rate Graphs

Quality Control

The Zeta Plus C, CP, S & SP Series cartridges and sheets are manufactured following an ISO quality certified assurance scheme. All the cartridges are labelled with a lot identification number to provide complete traceability.

Sanitary Housings

3M Purification provides a wide range of standard and specially designed sanitary filter housings to hold Zeta Plus C, CP, S and SP Series filter cartridges. All housings are designed with the pharmaceutical and bioprocessing industries in mind and feature 316L mirror-polished surfaces and easy-to-clean components.

Regulatory Support

Zeta Plus C, CP, S & SP Series filters are produced from materials which are 21CFR listed and filter components have successfully passed USP Class VI Biological Reactivity Tests.

Compatibility

Temperature, contact time, chemical concentration, flow rate, aeration and differential system pressure are all variables that can affect chemical compatibility of filter materials. Therefore it is always advisable to perform tests replicating process conditions to determine ultimate compatibility. Table 1 is provided as a guide only. Please contact your local 3M Purification SASS Team for further support on validation and compatibility.

| CHEMICALS | S(P) Max. (82°C) | C(P) Max. (60°C) | GASKETS | | | |
|-------------------------------|---------------------|---------------------|---------|---------------|--------------------|----------|
| | | | Nitrile | Fluorocarbone | Ethylene Propylene | Silicone |
| Ethyl Acetate | G | G | P | P | P | F |
| Acetone 100% | G | G | P | G | G | G |
| Acetic Acid 5%-20% | G | G | G | G | G | G |
| Benzene | G | G | P | F | P | F |
| Chloroform | G | G | P | G | P | F |
| Chlorothene | G | G | P | G | P | F |
| Methylene chloride | G | G | P | F | P | P |
| 1,4 - Dioxane | G | G | P | P | P | P |
| DMF | G | G | F | P | P | No Data |
| Water (25°C - 82°C) | G | G | G | G | G | G |
| Ethanol 10% | G | G | G | F | G | G |
| Ethanol 50% | G | G | G | F | G | G |
| Hexane | G | G | G | G | P | F |
| Sodium Hydroxide 2% | F-P | F-P | F | G | G | G |
| Methanol | G | G | G | P | G | G |
| Methyl Ethyl Ketone (MEK) | G | G | P | P | G | G |
| Methyl Isobutyl Ketone (MIBK) | G | G | P | P | G | G |
| n-Heptane | G | G | G | G | P | F |
| Carbon Tetrachloride pure | G | G | F | G | P | F |
| 1,1,1 - Trichloroethane | G | G | P | G | P | F |
| Xylene | G | G | P | G | P | F |

Explanation of ratings:
 G = Satisfactory - to maximum temperature given for material, unless restriction is noted.
 F = Fair - to maximum temperature given for material, unless restriction is noted.
 P = Not recommended.

Extractables

A static soak test of Zeta Plus C, CP, S & SP materials was performed to determine the maximum amount of organic and inorganic compounds extracted by various solvents. Extraction tests were performed using 100 ml of fluid per 20 cm² of media.

Operating Parameters

| | Maximum Operating Pressure | Maximum Operating Temperature | Recommended Flush | Sterilization Parameters | Maximum Flow Rate (FLUX) (in l/min per m ²) |
|---|--|-------------------------------|--|---|---|
| Standard and Special precoat Zeta Plus Cartridges | 2.4 bar | 82 °C | 54 l/m ² at 20 litre per min/m ² | autoclave or in-situ steam sterilisation for 1 hour at 121 °C | 1.2 to 12 |
| Zeta Plus BC25 Capsules | Inlet pressure: 2.75 bar Media pressure: 2.4 bar | 40 °C | 54 l/m ² at 20 litre per min/m ² | Autoclave for 30 minutes at 121 °C (1 cycle) | 1.2 to 12 |
| Zeta Plus BC1000 and BC2000 Series Capsules | Inlet pressure: 5.5 bar at 25 °C 2.75 bar at 60 °C Media pressure: 2.4 bar | 60 °C | 54 l/m ² at 20 litre per min/m ² | Autoclave for 30 minutes at 121 °C (up to 3 cycles) | 1.2 to 12 |

| Zeta Plus S(P) Series extractables (mg/g of media) | | | | |
|--|---------|--------------|----------|--------|
| Solvents | Na | K | Ca | Mg |
| Water | 0.075 | 0.039 | 0.160 | 0.070 |
| Water (82°C) | 0.077 | 0.133 | 0.066 | 0.014 |
| Ethanol 10% | 0.013 | 0.004 | 0.017 | 0.002 |
| Ethanol 50% | 0.014 | 0.002 | 0.012 | 0.002 |
| Acetic Acid | 0.062 | 0.157 | 0.490 | 0.936 |
| n-Heptane | <0.001 | <0.001 | <0.001 | <0.001 |
| Solvents | Fe | Heavy metals | Organics | |
| Water | 0.0009 | <0.0001 | <0.005 | |
| Water (82°C) | 0.0011 | <0.0001 | <0.005 | |
| Ethanol 10% | <0.0005 | <0.0001 | <0.005 | |
| Ethanol 50% | <0.0005 | <0.0001 | <0.005 | |
| Acetic Acid | 0.170 | <0.0001 | <0.005 | |
| n-Heptane | <0.0005 | <0.0001 | <0.005 | |
| Zeta Plus C(P) Series extractables (mg/g of media) | | | | |
| Solvents | Na | K | Ca | Mg |
| Water | 0.175 | 0.042 | 0.045 | 0.008 |
| Ethanol 10% | 0.210 | 0.065 | 0.080 | 0.014 |
| Ethanol 50% | 0.165 | 0.025 | 0.063 | 0.010 |
| Acetic Acid | 0.255 | 0.130 | 0.115 | 0.019 |
| n-Heptane | 0.007 | 0.003 | 0.012 | 0.002 |
| Solvents | Fe | Heavy metals | Organics | |
| Water | <0.0005 | <0.0001 | 0.031 | |
| Ethanol 10% | 0.0011 | <0.0001 | 0.014 | |
| Ethanol 50% | 0.0008 | <0.0001 | 0.009 | |
| Acetic Acid | 0.0050 | <0.0001 | 0.067 | |
| n-Heptane | <0.0005 | <0.0001 | 0.002 | |

< = limits of detection
 NOTE : Extractable levels will vary from sample to sample as the raw materials are natural products.

Zeta Plus C, CP, S and SP Series Ordering Guide

1. Cartridges

| Zeta Plus | Diameter (inch) | Cartridge Design | Gasket Type | Grade | Formulation | |
|-----------|-----------------|--|---|----------------------|--------------------|---------|
| Z | 08 | P = Plug-in 7 cells (0.23 m ²) P2 = Plug-in 2 cells (0.065 m ²) P4 = Plug-in 4 cells (0.13 m ²) | Standard A = Silicone (MVQ)* | 05 | S SP | |
| | | D = Standard 8 cells (0.26 m ²) | Standard D = Nitrile (NBR)* | 10 30 50 60 | S SP C CP | |
| | 12 | C = 9 cells / small (0.85 m ²) B = Special precoat 12 cells (1.1 m ²) D = Standard 16 cells (1.5 m ²) S = Special 7 cells (0.7 m ²) | Options A = Silicone (MVQ)* B = Fluorocarbon (FPM)* C = EPR (EPDM)* | 70 | C CP | |
| | | 16 | M = Standard diffusion netting 14 cells (3.2 m ²) D = Standard 15 cells (3.4 m ²) S = Special precoat 9 cells (2.1 m ²) | *ISO Designation | 90 | S SP |

2. Zeta Plus BC Capsules

| Catalogue Number | Grade and Formulation |
|---|---|
| BC 0025L (Luer) - 25 cm ² area BC 0025S (Sanitary) - 25 cm ² area BC 1000A (single pack) - 650 cm ² area BC 2000A (single pack) - 1300 cm ² area | 10 C 10 CP 05 S 05 SP 30 C 30 CP 10 S 10 SP 50 C 50 CP 30 S 30 SP 60 C 60 CP 50 S 50 SP 70 C 70 CP 60 S 60 SP 90 S 90 SP |

3. Sheets

By request, Zeta Plus media can also be supplied in sheet format. Please contact your local 3M Purification representative for further details on how to order.

Important Notice

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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 sold 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.

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