Micro-Cap™ Depth Filter Capsules

For Development, Scale-Up,
Pilot, and Small Batch Studies

ERTEL ALSOP
THE FIRST NAME IN LIQUID FILTRATION™

Micro-Cap™ Disposable Laboratory Filters are perfect for use in product development, small batch processing and intermediate scale-up studies. Micro-Caps™ are available in three sizes and with a broad range of ErtelAlsop's high performance filter media. This provides maximum flexibility in process development and scale-up.

No stainless steel housings are required which eliminates the need for cleaning validation. Connect the Micro-Cap™ directly to the downstream processing components, minimizing operator exposure to the product.

Applications

ErtelAlsop Micro-Caps™ are designed to provide enclosed, disposable depth filtration for

- Small batch fermentation
- Removal of cell debris
- Cell culture clarification
- Serum clarification
- Plasma clarification
- Small Volume Parenteral prefiltration
- Decolorization
- Endotoxin Removal

Performance

The Micro-Cap™ incorporates ErtelAlsop's Micro-Media®, Micro-Media XL, or Micro-Clear™ series of filter media, to provide the optimum balance of dirt holding capacity and throughput. The available media is capable of particle retention from 15 microns to 0.2 microns and all grades exhibit a strong positive zeta-potential allowing for retention of particles smaller than the mechanical pore size of the media. The Micro-Clear™ series is formulated with activated carbon for decolorization.

Scalability

The Micro-Cap™ series offers three choices of surface area to fit your requirements, 22.5 cm^2, 1,100 cm^2 (0.11 m^2), and 2,200 cm^2 (0.22 m^2). With a range of batch sizes from 50 ml to 100 liters, the Micro-Cap™ is ideally sized for laboratory use and scale up for full production is easy. Ask for ErtelAlsop's Filter Sizing Data Spreadsheet to assist you with the scale-up calculations

Reliability

As with all ErtelAlsop depth filter products the Micro-Cap™ provides consistency and lot to lot traceability all in an easy-to-use, self-contained and completely disposable laboratory filter capsule. All Micro-Caps™ must pass a pressure hold test before being released, and the Micro-Cap™ meets all applicable USP requirements including the Class VI Plastic Test.

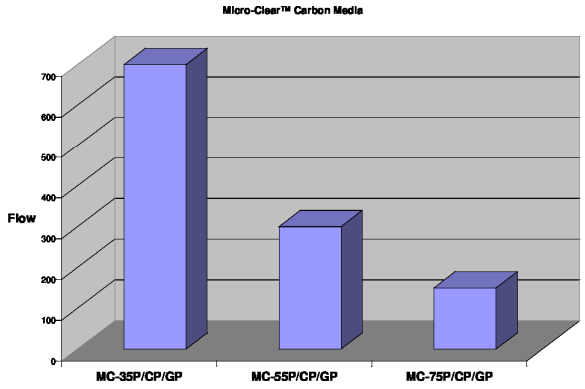
Micro-Cap™ Features & Benefits

Features	Benefits
Disposable	♦ No Housing required ♦ No Cleaning validation ♦ Minimizes operator contact with product ♦ Quick set up and breakdown
Sanitary Design	♦ Simplifies connection to existing process lines ♦ Drain and Vent allow full utilization ♦ Autoclavable
Flexibility	♦ Up to 100 liter batches ♦ Retention from 0.2 to 15 microns ♦ Wide range of Formulations to choose from ♦ Choice of 3 different sizes ♦ Flow Rates from 5 ml/min to 20 liters/min
XL Series Media	♦ Up to 5x throughput over standard media grades ♦ Lowest metal extractables available ♦ Incorporates Celpure® Filter Aid ♦ Exceptional particle retention ♦ Improved Flow Rates
Micro-Clear Carbon Media	♦ Eliminates use of loose carbon ♦ Decolorization ♦ Depyrogenation
Regulatory	♦ Validation Guide ♦ USP Plastics Class VI ♦ Non-Pyrogenic ♦ Every Cartridge Pressure Hold Tested

Micro-Clear™ Carbon Media

Carbon is used as a loose powder in many pharmaceutical applications for decolorization and depyrogenation. ErtelAlsop's Micro-Clear™ series of filter media eliminates the need for loose carbon by incorporating the carbon within the matrix of cellulose fibers in the filter sheet. Micro-Clear sheets eliminates airborne carbon, handling of used carbon, the addition of carbon to the process vessel or precoat tank, and reduces process time due to continuous fluid contact with the carbon as it is passing through the filter sheet.

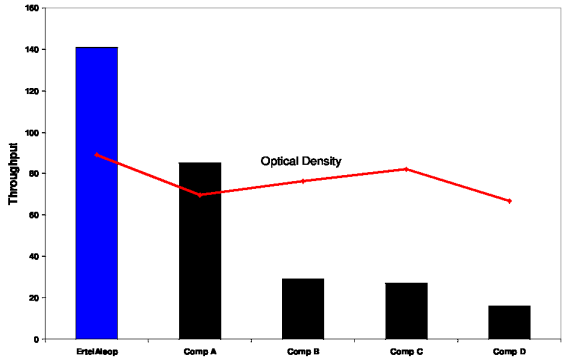
Micro-Clear media is available in three grade structures and three standard types of activated carbons, providing nine standard grades. ErtelAlsop manufactures all carbon media in a dedicated production facility.



XL Series Media – Unparalleled Performance

ErtelAlsop's Micro-Media® XL Series combines 75 years of experience with the highest performing filter aid available on the market, Celpure® to provide optimal filter performance. This series of media exhibits 2-5 times the throughput of competitive media while maintaining equivalent or better product clarity (See Figure 1).

Incorporation of XL Series media in the Micro-Cap™ allows for the use of this media through the entire process development and scale-up cycle.

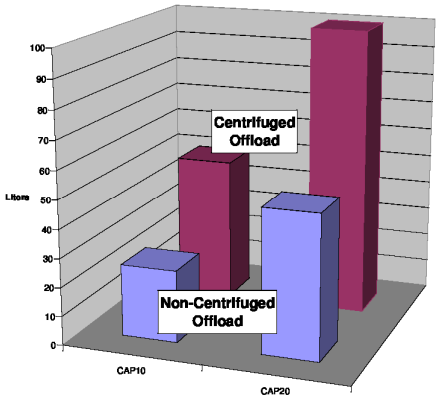


ErtelAlsop XL Series Micro-Media® vs. Competitive Media
Testing performed on 1% Bovine Serum Albumin

Figure 1

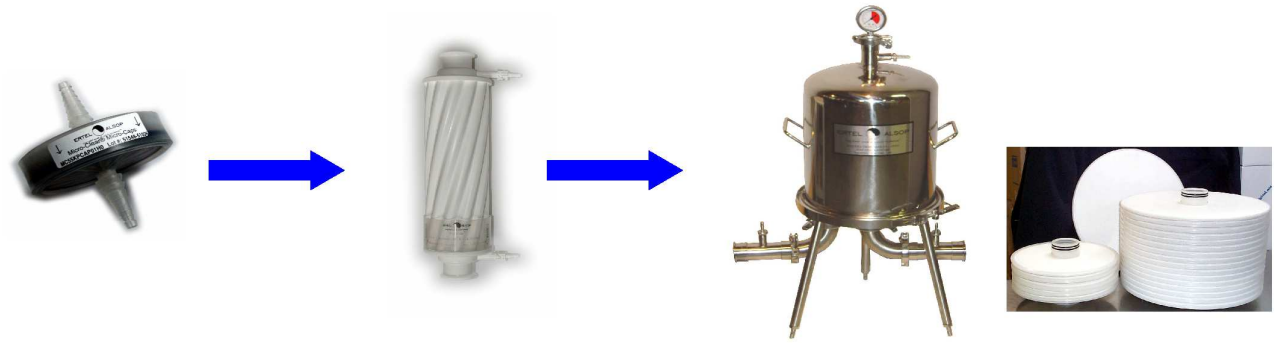
Filtration of Cell Debris

ErtelAlsop Micro-Caps™ are ideal for post fermentation clarifying applications and protection of chromatography columns. The graph to the left shows the typical capacities of the 10 and 20-inch capsules for centrifuged and non-centrifuged bioreactor offloads. 10-inch Micro-Caps™ should be used for up to 50 liter batches while the 20-inch capsules can be used on batches up to 100 liters. For non-centrifuged offloads a two stage filtration process is usually necessary due to the broad range of particle sizes present in the fluid.



Typical capacity of 10" and 20" Micro-Caps™ for centrifuged and non-centrifuged bioreactor offloads

Scale-Up Simplified



ErtelAlsop offers a broad array of filtration products to allow for full scalability. For product development or early stage feasibility studies, the Micro-Cap 01 series with only 22.5 cm^2 of filtration area allows for small volume trials.

For small batches and process development trials the Micro-Cap 10 and 20 will allow for up to 100 liters of product to be filtered and allow for quick scale-up calculations to determine the required filtration area for full scale production utilizing

ErtelAlsop's line of Zeta-Pak® lenticular cartridge housings. These fully enclosed filter housings are available in 12" and 16" diameters with filtration areas from 0.55 m^2 (6 ft^2) to 14.8 m^2 (160 ft^2). These housings are supplied to fit ErtelAlsop double o-ring Bio-Paks® in either vertical or horizontal configurations. ErtelAlsop also offers a complete range of latest technology plate and frame filters from 4" (10 cm) square up to 36" (91 cm) square, for those applications more suited to plate and frame filtration.

Scaling Data

Filtration Area

Model 01 capsule 22.5 cm^2
Model 10 capsule 1,100 cm^2/0.11 m^2
Model 20 capsule 2,200 cm^2/0.22 m^2

Filtration Volumes

50 ml to 100 liters

Flow Rates

01	3-50 ml/min
10"	50ml-10 l/min
20"	100ml – 20 l/min

Pressure

3.75 bar (55 psig) max operating
2 bar (30 psid) max differential

Sterilization

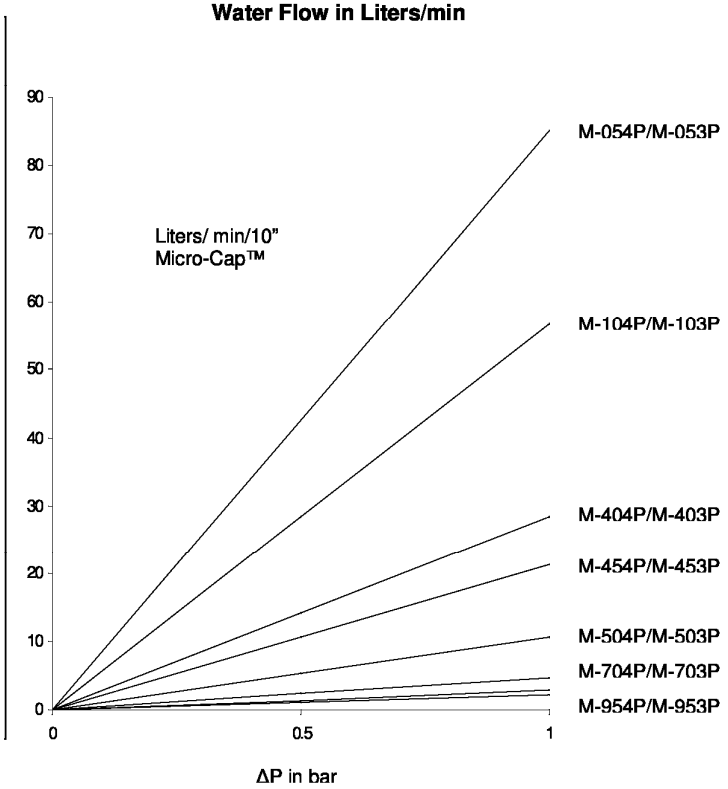
1 cycle of wet autoclaving 121ºC at
1 bar for 30 min

Extractables

(Following a 5 l/ft^2 flush with WFI)

Al	< 10 ppb
Fe	< 5 ppb
Ca	<200 ppb

Water Flow in Liters/min



Design Specifications

Model	01	10	20
Enclosure	Polypropylene	Polypropylene	Polypropylene
Filter Area	22.5 cm^2	1,100 cm^2	2,200 cm^2
Connections	1/4"-3/8" stepped Hose Barb with female slip leur	1-1/2" Sanitary Clamp	1-1/2" Sanitary Clamp
Drain & Vent Seals	N/A	Silicone	Silicone
Vent	Luer Loc with Cap	Hose Barb	Hose Barb

Micro-Cap™ Ordering Information

M-853P CAP 01 H 0

Media Grade(See Table)

Micro-Cap™ Filter Type

Configuration

01= 22.5 cm² Filtration Area
10= 1.100 cm² Filtration Area
20= 2.200 cm² Filtration Area

Inlet/Outlet Fitting

H= Hose Barb (60 mm model only)
T= Tri-Clamp (10" and 20" capsules)

Gasket

0= None
6= Silicone

Filter Media Table

Micro-Media XL™ Series

M-053P	15	microns
M-103P	10	microns
M-403P	5	microns
M-453P	2.5	microns
M-503P	1	micron
M-703P	0.45	micron
M-853P	0.3	microns
M-953P	0.2	microns

Micro-Media®

M-054P	15	microns
M-104P	10	microns
M-404P	5	microns
M-454P	2.5	microns
M-504P	1	micron
M-704P	0.45	micron
M-854P	0.3	microns
M-954P	0.2	microns

Micro-Clear™ Carbon Media

MC-35P/CP/GP	5	microns
MC-55P/CP/GP	1.0	micron
MC-75P/CP/GP	0.5	micron

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