



ERTELALSOP

THE FIRST NAME IN LIQUID FILTRATION

MICRO-MEDIA® L SERIES FILTER MEDIA

THE RIGHT CHOICE FOR CRITICAL PROCESSING

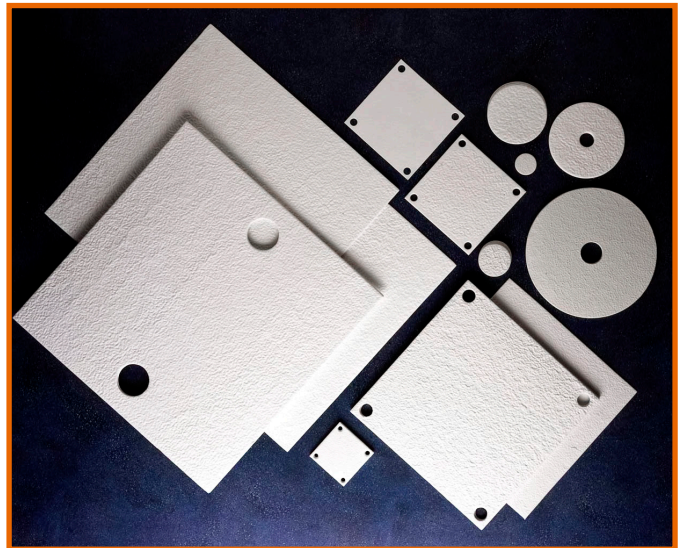
Micro-Media® L Series Depth Filter Media, is specifically designed for use in applications where proteins are present, such as blood fractionation and recombinant DNA derived products. These particular types of applications demand specific controls on pyrogens and extractables. Physical attributes, unique to such applications can lower the surface tension of the media and cause them to release extractables, which can cause problems with the LAL testing used both in process and as a final release. These extractables can cause “false positives” by reacting with a Factor G in the LAL reagent and cellulose components.

A particular source of extractables is 1,3 β D-glucan contamination in the cellulose. Cellulose is a major component of depth filter products. The level of reactivity depends upon the amount of 1,3 β D-glucans released during manufacturing of the filter media and the amount of Factor G present in the LAL reagent, which varies by manufacturer.

Utilizing a unique process, ErtelAlsop minimizes 1,3 β D-glucan levels in cellulose pulp prior to manufacturing the filter media. This minimizes the effects of 1,3 β D-glucans and allows for validation of the LAL test on the product.

COMPOSITION

Micro-Media® L Series Filter Media is available in sheets or Pak® Lenticular Cartridges. Micro-Media® Filter Pads provide enhanced levels of particulate removal due to strong electrokinetic forces, which adsorb particles smaller than the media nominal pore size rating. Pharmaceutical Grad L Series Media is manufactured in accordance with ErtelAlsop’s Drug Master File at CDER.



APPLICATIONS:

- Blood Fractions
- Recombinant DNA Derived Products
- Sera
- Cell Culture Media
- Active Pharmaceutical Ingredients
- Large Volume Parenterals
- Small Volume Parenterals

PRODUCT TESTING

Product testing is always available either at your facility, through our network of distributors, or at our in-house laboratory.

PILOT TESTING - RENTALS

For in-plant testing and scale-up procedures, ErtelAlsop offers a variety of lab filters for rent. A portion of rental fees can be applied to the purchase of your full production filter.

FILTER MEDIA

MICRO-MEDIA® L SERIES

GRADE	RETENTION
M-05L/M-053L/M-054L	15 µm
M-10L/M-103L/M-104L	10 µm
M-40L/M-403L/M-404L	5.0 µm
M-45L/M-453L/M-454L	2.5 µm
M-50L/M-503L/M-504L	1.0 µm
M-50LT/M-503LT/M-504LT	0.8 µm
M-70L/M-703L/M-704L	0.45 µm
M-85L/M853L/M854L	0.3 µm
M-90L/M-953L	0.25 µm

The most accurate way to optimize your process is through laboratory scale testing. Samples of Micro-Media® L or Micro-Clear™ L Series Media are available at no charge. Authorized ErtelAlsop representatives are equipped to run trials on-site, or product samples may be sent directly to ErtelAlsop for testing with prior approval.

Table to the left is for reference only.

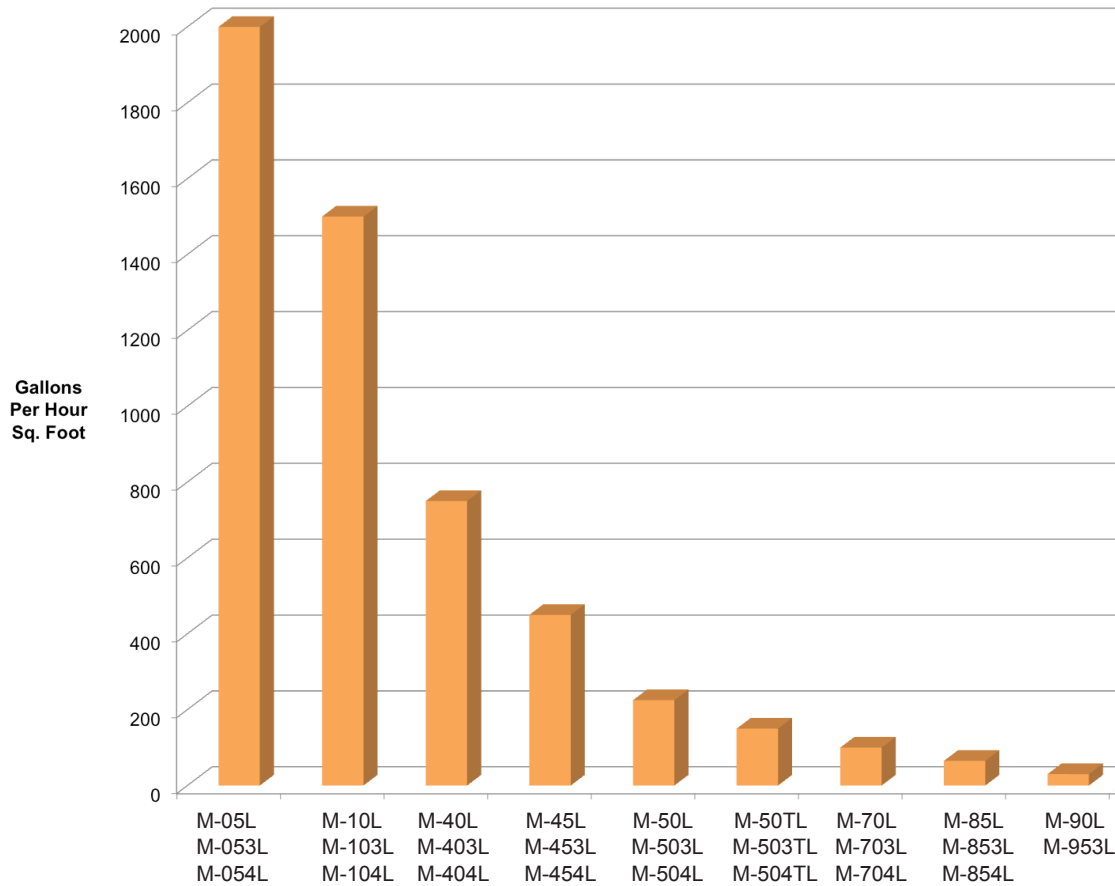


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FLOW RATES

The chart below shows flow characteristics of ErtelAlsop L Series Micro-Media® at 10 psi with clean water at 70°F



EXTRACTABLE DATA

ErtelAlsop has performed extractions on Micro-Media® L Series Filter Media using WFI (Water for Injection) and HSA (Human Serum Albumin) and tested for LAL content:

WFI RESULTS - EU/ML	HSA RESULTS - EU/ML
<0.03	<0.125

Micro-Media® L Series Filter Media is released by Quality Control based upon water extractions. However, it is also important to perform studies using Human Serum Albumin due to its ability to extract 1,3 β D-glucans from cellulose. In performing these studies, ErtelAlsop can provide customers with the highest level of assurance that 1,3 β D-glucan contamination will be maintained at acceptable levels.

THE FORMAT TO FIT YOUR NEEDS

All ErtelAlsop media formulations can be manufactured in formats to fit your application. Filter sheets, discs and Pak® Lenticular Cartridges are all available to provide you with product to optimize your application. ErtelAlsop also manufactures a complete line of filter machinery, from Small Batch and Pilot Scale Lab Filters to Plate and Frame Filters, Sealed Disc Filters and Pak® Lenticular Cartridge Housings.

For over 80 years, ErtelAlsop has been proactively solving the depth filtration problems of industry. We originated and patented the Pak® Lenticular Cartridge concept. We created the BioClean™ Sanitary Filter Plate Assembly to accommodate the stringent cleaning standards of the pharmaceutical industry. We designed the 1S PharmaScale™ Filter at the request of a customer who needed to duplicate results at the one-inch square level. Most recently, we took the traditional plate and frame concept and literally turned it on its ear. The Diamond Series™ line of Plate and Frame Filter Presses combines weld-free technology for the ultimate in cleanliness with a diamond shape, which allows for complete drainage and venting. Constant innovation has positioned us at the forefront of the industry.

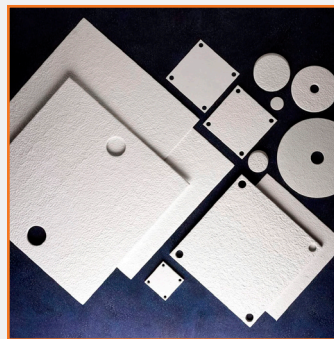
For more detailed information on the products we manufacture, contact us by phone at 800.533.7835 or visit our web site www.ertelalsop.com.

FILTER MEDIA

ErtelAlsop filter media is available for any application and/or operating condition, and is chosen based on your specific operating conditions, the performance required by the filtering media, and criteria given to us by you and/or by sample processing we do in our lab.

ErtelAlsop offers the widest varieties of filter media including 100% cellulose pads, cellulose and diatomaceous earth pads, cellulose and Celpure® diatomaceous earth pads, cellulose and perlite pads, and cellulose and activated carbon pads.

All filter pads are manufactured to very high standards for a wide range of applications in the pharmaceutical, chemical, cosmetic, electric utility and food and beverage markets. ErtelAlsop also offers a Validation Guide to assist in the validation of its filter pads in your process. The Validation Guide contains information regarding raw materials, extractables, and general information about the product. The combination of ErtelAlsop “P” grade filter pads and ErtelAlsop’s BioClean™ plate and frame filter press design, can help to simplify your depth filtration validation now more than ever.



For additional
product information visit
ErtelAlsop.com

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