



ERTELALSOP

THE FIRST NAME IN LIQUID FILTRATION™

P-GRADE MICROMEDIA®: XL SERIES

THE RIGHT CHOICE FOR CRITICAL PROCESSING

Pharmaceutical Grade MicroMedia®: XL Series Depth Filter Media, formulated with cellulose, wet strength resin and Celpure® Diatomaceous Earth (DE) diatomite and is specifically designed for use in critical pharmaceutical and biotech applications. Pharmaceutical Grade MicroMedia®: XL Series Depth Filter Media is manufactured in accordance with ErtelAlsop Drug Master File located at the United States Food and Drug Administration Center for Drug Evaluation and Research.

Most filter media manufacturers currently use DE formed to “food-grade” quality standards, NOT pharmaceutical component quality standards, which allows for problems with respect to compendial standards, purity, manufacturing and process control and packaging. Unchecked variations in diatomite result in significant process deviation such as filtrate color, pH and impurity profiles.

DO YOU KNOW HOW PURE THE DE IN YOUR FILTER MEDIA IS?

COMPOSITION

ErtelAlsop XL MicroMedia® are composed of cellulose pulp, Celpure® Diatomaceous Earth and wet strength resin, which causes the media to exhibit a net positive charge zeta potential. This allows for the highly efficient removal of particles smaller than the filter’s nominal rating.



APPLICATIONS:

- Blood Fractions
- Sera
- 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

MICROMEDIA®: XL SERIES

GRADE	NOMINAL RETENTION
M053P	15 µm
M103P	10 µm
M403P	5.0 µm
M453P	2.5 µm
M503P	1.0 µm
M503TP	0.8 µm
M703P	0.45 µm
M853P	0.3 µm
M953P	0.25 µm

The most accurate way to optimize your process is through laboratory scale testing. Samples of MicroMedia®: XL Series 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.

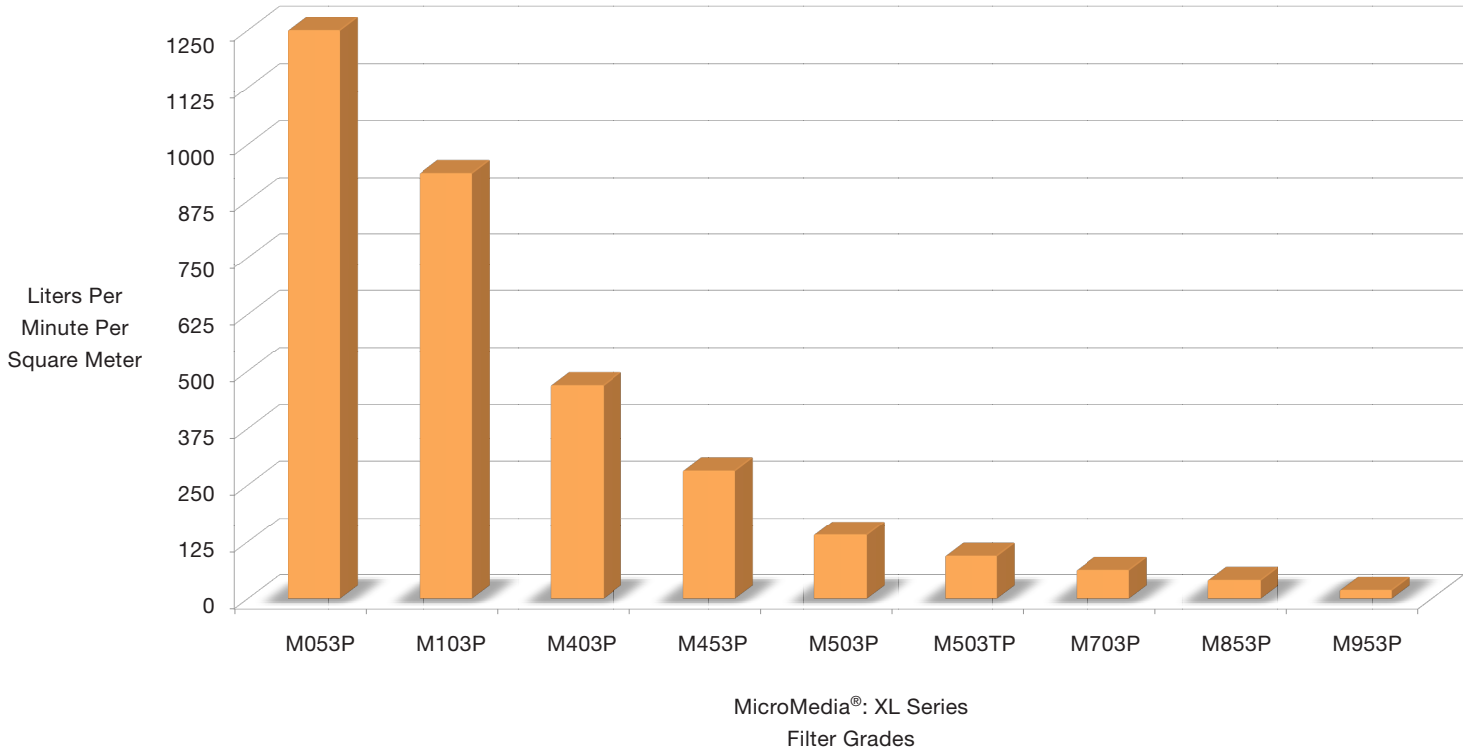


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FLOW RATES

The chart below shows flow characteristics of MicroMedia®: XL Series at 0.7 bar with clean water at 21°C



EXTRACTABLE DATA

The use of Celpure® Diatomaceous Earth in the manufacture of ErtelAlsop MicroMedia®: XL Series Media provides superior quality and lower extractable levels when compared to standard “food grade” DE as well as increased particle retention and product throughput.

Diatomite filter aids were originally developed for the beverage industry, when the beverage and pharmaceutical industries used similar quality standards. As a direct result, both industries relied extensively upon standard “food grade” diatomite. Even the advent of pharmaceutical GMPs did little to alter this practice.

Quality standards for this “food grade” DE were often not in keeping with the critical standards of the pharmaceutical industry. In particular, problems surfaced with regard to compendial standards, purity, manufacturing and process control and packaging.

Hence, the advent of ErtelAlsop MicroMedia®: XL Series Media for the Pharmaceutical Industry.



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ERTELALSOP VS. COMPETITORS

In tests done by an independent facility on ErtelAlsop MicroMedia®: XL Series against four other grades, XL Series Media consistently outperformed its competitors. Test results follow, including run data, typical extractables and Endotoxin data.

TESTING PROCEDURE:

- Original Serum E, Lot No. S4103, O.D. 710 nm=1.340
- Membrane Size: 3.5-inch diameter
- Filtration Time: 5 minutes
- Pressure: 0.7 bar

One batch of unfiltered serum was used as a challenge against 15 samples of depth filter media from 5 different manufacturers. Measurements were taken for optical density of the unfiltered sera and then of actual filtrate after the 5 minute challenge.

XL Grade M953P test results are shown below.*

FINE PORE SIZE COMPARISON (0.25 MICRON NOMINAL)

FILTER MANUFACTURER	VOLUME IN 5 MINUTES	O.D. OF FILTRATE
ErtelAlsop Grade M953P	141 ml	0.036
Competitor 1	29 ml	0.042
Competitor 2	16 ml	0.048
Competitor 3	27 ml	0.039
Competitor 4	85 ml	0.046

*For complete details of the testing, contact ErtelAlsop to request the applifact entitled Filtration of Human & Animal Sera.

WATER FOR INJECTION EXTRACTABLE TEST

Note: ErtelAlsop's Pharmaceutical Grade MicroMedia®: XL Series allows for a 40% reduction in Flush Volume requirements.

FILTER MANUFACTURER	FLUSH VOLUME	EXTRACTABLES (PPB)								
		Al	As	Cu	Fe	Pb	Ni	Cr	Ca	Mg
ErtelAlsop	30 L/m ²	<1	<10	<3	10	<10	<3	<3	228	13
Competitor #1	50 L/m ²	<50	<10	<100	<100	<10	<10	<10	<50	<100
Competitor #2	54 L/m ²	27	<16.7	0.58	20	0.22	<.027	0.08	55	23

- Results based on laboratory testing
- We recommend that customers run their own testing to determine appropriate level of acceptable extractables

ENDOTOXIN TESTING

EU/ML	TEST PROCEDURE	TEST METHOD	TEST FREQUENCY
<0.06	5L/ft ² Rinse	Turbidimetric	Lot

THE FORMAT TO FIT YOUR NEEDS

All ErtelAlsop media formulations can be manufactured in formats to fit your application. Filter sheets, discs, Pak® Lenticular Cartridges, and MicroCap Pro™ single use capsules 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, Pak® Lenticular Cartridge Housings, and MicroCap Pro™ Single Use System Chassis.

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. 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. We designed our [MicroCap Pro™ Single Use System](#) with its large chassis rotatable from a vertical to horizontal position, making it convenient and ergonomic for switching the capsules out. 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.

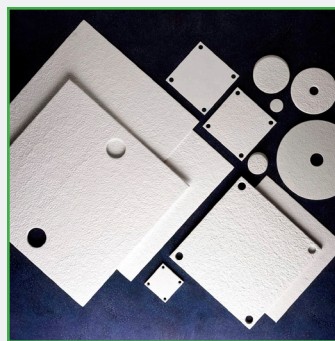
Celpure® is a registered trademark of Advanced Minerals, Inc.

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.



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