



# ERTELALSOP

THE FIRST NAME IN LIQUID FILTRATION

## MICRO MEDIA® XL SERIES FILTER MEDIA

### THE RIGHT CHOICE FOR CRITICAL PROCESSING

Micro-Media® XL Series Depth Filter Media, formulated with cellulose, wet strength resin and Celpure® diatomite, an ultra-pure form of Diatomaceous Earth manufactured only by Advanced Minerals Corporation, is specifically designed for use in critical applications. DE can now meet the high quality standards dictated by 21CFR211.160 (b). Traditional “food-grade” forms of DE rarely meet USP-NF standards.

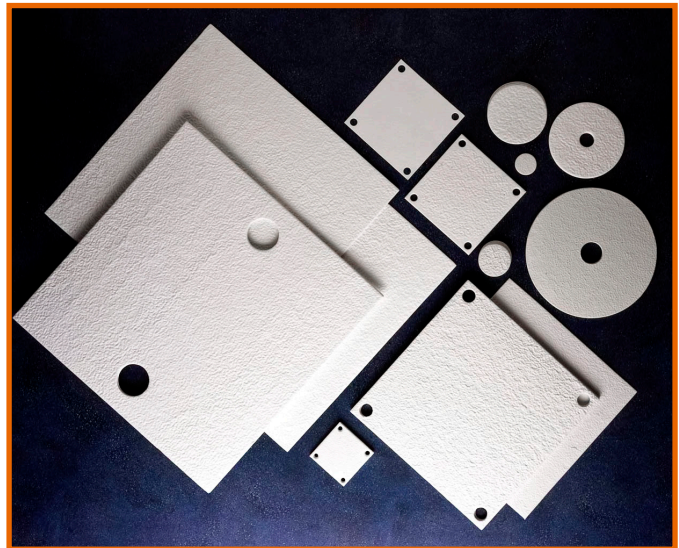
Most filter media manufacturers currently use DE formed to “food-grade” quality standards, NOT pharmaceutical component quality standards, which allows for problems with respect to compendial standards, purity, manufacturing and process control and packaging.

Because the majority of diatomite producers send more than 90% of their products into industrial and food-grade applications, “food-grade” DE is produced to commodity-type standards and economics, which means product specification testing is performed as little as every 10,000 kg of production volume. 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 Micro-Media filter sheets are composed of cellulose pulp, Celpure® Diatomaceous Earth and wet strength resin, which causes the media to exhibit a net 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. The Micro-Clear™ carbon impregnated line of media can also be manufactured using Celpure® diatomite.



#### APPLICATIONS:

- Blood Fractions
- Sera
- Large Volume Parenterals
- Small Volume Parenterals
- Distilled Beverages
- High Fructose Corn Syrup
- Flavors & Fragrances
- Cosmetics

#### 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.

## MICRO-MEDIA® XL

GRADE	NOMINAL RETENTION
M-053	15 µm
M-103	10 µm
M-403	5.0 µm
M-453	2.5 µm
M-503	1.0 µm
M-503T	0.8 µm
M-703	0.45 µm
M-853	0.3 µm
M-953	0.25 µm

The most accurate way to optimize your process is through laboratory scale testing. Samples of Micro-Media® XL 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.

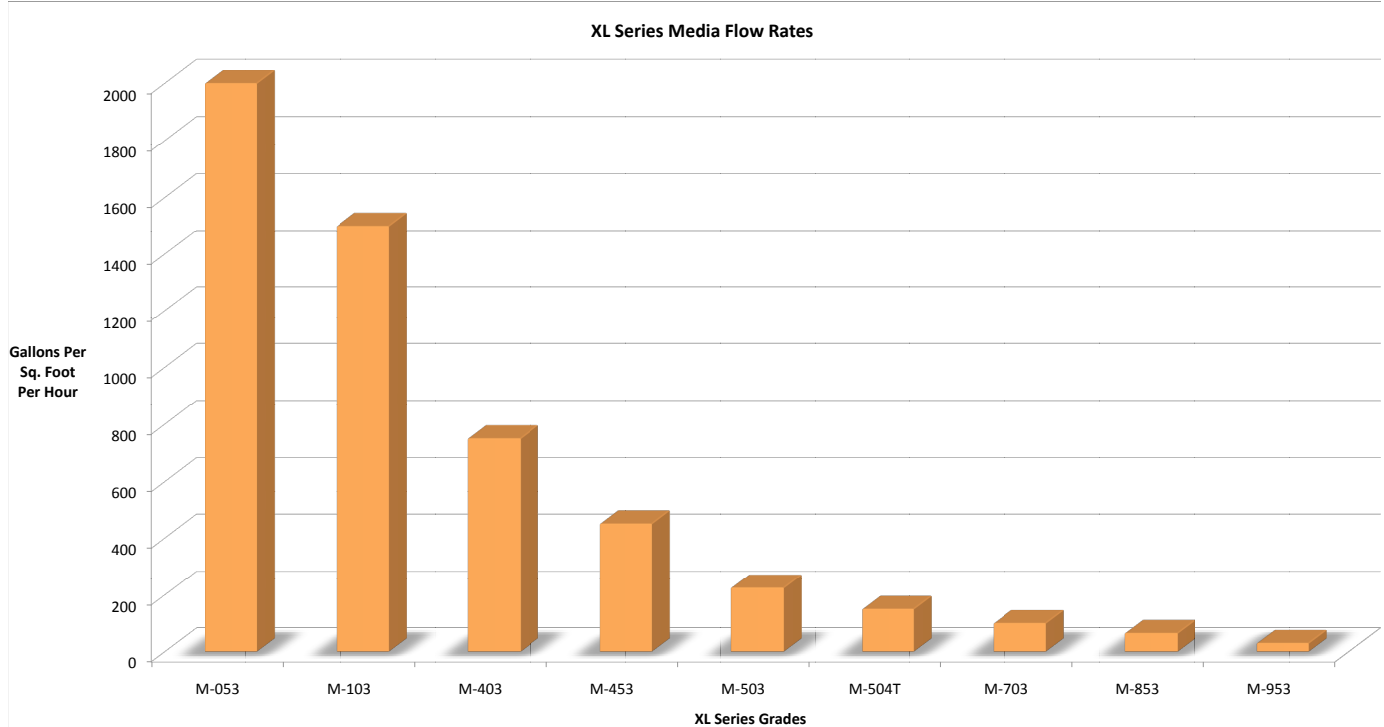


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## FLOW RATES

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



## EXTRACTABLE DATA

The use of Celpure® Diatomaceous Earth in the manufacture of ErtelAlsop 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.

		CELPURE®	STANDARD DE
Aluminum	Al	Below detectable limit	1682
Calcium	Ca	Below detectable limit	1050
Magnesium	Mg	124	1010
Iron	Fe	56	400
Zinc	Zn	90	210
Copper	Cu	12	16
Antimony	Sb	Below detectable limit	12
Maganese	Mn	4	14

\*Solubles in PPB



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## ERTELALSOP VS. COMPETITORS

In tests done by an independent facility on ErtelAlsop XL Series Media against four other grades, XL Series Media consistently outperformed its competitors. Test results follow, including run data, typical extractables and LAL 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: 10 psi

One batch of dirty 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 M-953 test results are shown below.\*

### TABLE III-FINEPORE SIZE COMPARISON (0.25 MICRON NOMINAL)

FILTER MANUFACTURER	VOLUME IN 5 MINUTES	O.D. OF FILTRATE
ErtelAlsop Grade M-593	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 apilfact entitled Filtration of Human and Animal Sera.

### WATER FOR INJECTION EXTRACTABLE TEST/OXFORD LABS

ALUMINUM (PPB)	CALCIUM (PPB)	IRON (PPB)	MAGNESIUM (PPB)
<10	200	<5	25

### LAL TESTING/ASSOCIATES OF CAPE COD

EU/ML	TEST PROCEDURE	TEST METHOD	TEST DATE
<0.06	Cape Cod 5L/ft <sup>2</sup> Rise	Gel Clot	12/01

## 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](http://www.ertelalsop.com).

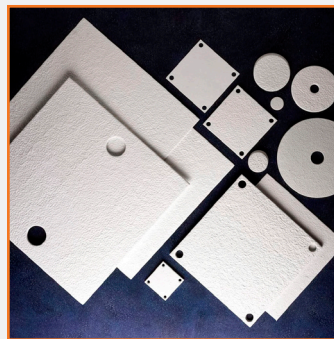
Celpure® is a registered trademark of Advanced Minerals, Inc.

## 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.



For additional  
product information visit  
**ErtelAlsop.com**

**Technical Bulletin XL-11**

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