

ErtelAlsop Micro-Media® XL Series Filters

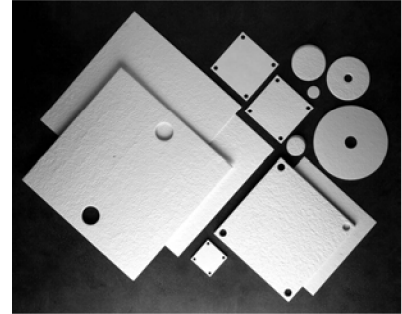


The Right Choice for Critical Processing

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?**



Applications

- Pharmaceutical/Biotech:** Blood Fractions, Sera, Cell Culture Media, Active Pharmaceutical Ingredients, Large Volume Parenterals, and Small Volume Parenterals
- Food & Beverage:** Distilled Beverages, High Fructose Corn Syrup, Flavors
- Personal Care:** Cosmetics, Fragrances

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 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.

Grade Designations

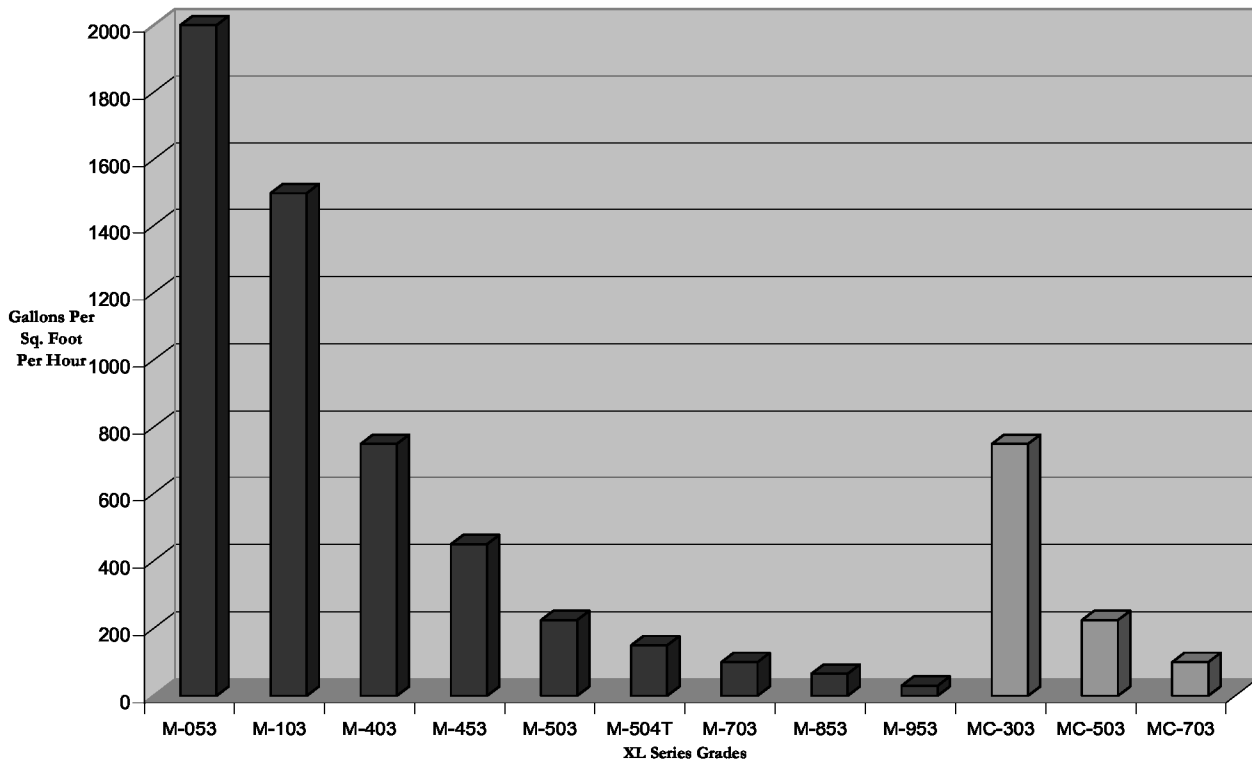
Micro-Media® XL Grade	Retention Rating	Micro-Clear™ XL Grade	Retention Rating
M-053	15 microns	MC-303	5 microns
M-103	10 microns	MC-503	1 micron
M-403	5 microns	MC-703	0.5 micron
M-453	2.5 microns		
M-503	1 micron		
M-503T	0.8 micron		
M-703	0.5 micron		
M-853	0.3 micron		
M-953	0.25 micron		

The table to the left is provided as a reference however, the most accurate way to optimize your process is through laboratory scale testing. Samples of Micro-Media® XL or Micro-Clear™ XL Series Media are available at no charge. All authorized ErtelAlsop representatives are equipped to run trials on-site at your facility or product samples may be sent to ErtelAlsop directly for testing.

Flow Rates

Chart shows flow characteristics of Ertel/Alsop XL Series Micro-Media® at 10 psi with clean water at 70°F

XL Series Media Flow Rates



Extractable Data

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® (solubles in PPB)	Standard DE (solubles in PPB)
Al	nd*	1682
Ca	nd	1050
Mg	124	1010
Fe	56	400
Zn	90	210
Cu	12	16
Sb	nd	12
Mn	4	14

(*nd) Below detectable limit

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.

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. For complete details of the testing, contact ErtelAlsop to request the Applifact entitled Filtration of Human and Animal Sera.

Table III-FinePore Size Comparison (0.25 micron nominal)

Filter Manufacturer	Volume (ml) in 5 minutes	O.D. of Filtrate
ErtelAlsop Grade M-953	141	0.036
Competitor I	29	0.042
Competitor II	16	0.048
Competitor III	27	0.039
Competitor IV	85	0.046

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 ² Rinse	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, visit our web site www.ertelalsop.com or email sales@ertelalsop.com.

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

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