ErtelAlsop

The First Name in Liquid Filtration™

# MicroMedia®: Paper

## Filter Paper Media Validation Guide

VGP-08/31

# INTRODUCTION

ErtelAlsop is the result of the merger of Ertel Engineering and Alsop Engineering. Ertel Engineering was founded by Frederick Ertel in 1932 in New York City. He originally manufactured and sold depth filter media for the pharmaceutical industry. In 1938 he moved his company to Kingston, New York, about 100 miles north of New York City, on the Hudson River. In Kingston, Ertel expanded the business to include plate and frame filter presses, pumps, agitators, bottle fillers, and other equipment for liquid processing. In 1943 Ertel developed the first pyrogen retentive media for Bristol Labs to use in the manufacturing of penicillin for World War II. Nineteen seventy nine was the year that Ertel patented the first enclosed horizontal plate and frame filter press, the Vapor-Master®. The design was prompted by Avon's desire to eliminate vapors from its production floor in order to improve working conditions. As usual, Ertel was willing to go the extra mile to provide a solution for its customer's application.

Alsop Engineering was founded by Samuel Alsop in 1920. The Sealed Disc Filter, Alsop's first product, was an enclosed horizontal plate filter. As a matter of fact, Alsop's first filter sheets were manufactured for them by Ertel Engineering. In the 1940's, Alsop invented an accordion shaped filter cartridge, which provided an enclosed filtration environment and much shorter changeover cycles than plate and frame filters. This was the first Zeta-Pak® lenticular cartridge. In addition to the cartridges, Alsop designed the corresponding filter housings. Originally vertical with removable covers, these housings have evolved to include horizontal mounting, ASME code, and sanitary designs. Alsop's product line was not limited to filters alone, it also included tanks and portable mixers. Available in both direct and gear-driven models, the mixers were unique because the same base components were used from 1/4 to 3 horsepower designs. This feature allowed the end user to maintain common parts for various sized agitators.

Today, ErtelAlsop maintains the innovative nature of its founders. ErtelAlsop is a member of the Parenteral Drug Association, Inc. (PDA), American Chapter of the Filtration Society and the International Society of Pharmaceutical Engineers (ISPE). Depth filter pads and paper are provided, precision die cut, for most filter housings and plate and frame filter units. Pharma-Pak® lenticular filter cartridges are available in several cell combinations. Media formulations are available impregnated with filter aids and also of pure cellulose. The BioClean™ sanitary plate design, the 1S PharmaScale™ Filter, the Diamond Series™ Filter Press, the Bio-Pak® Double O-Ring Lenticular Cartridge, and Validation Guides for filter media, filter paper and filtration equipment are the latest additions to the legacy begun by Mr. Ertel and Mr. Alsop.

ErtelAlsop's customer base is filled with clients who have been buying from us for over 80 years. Our commitment to customer service, and willingness to modify our designs to meet customer requirements always has and will continue to make ErtelAlsop stand apart from our competitors.

## Validation

Validation may generally be defined as, "Establishing documented evidence which provides a high degree of assurance that all specific processes used in the manufacture of a drug product will consistently produce a product meeting its pre-determined specifications and quality attributes". (quote from PDA/FDA Joint Conference on Sterilization Process Validation.) By extension, those elements, such as filters, used in the process must also meet these criteria, that is, they must consistently meet pre-determined specifications and quality attributes. Further, there must be corroborating documentation.

## General Information

ErtelAlsop has signed an exclusive agreement with Ahlstrom, of Mt. Holly Springs, Pennsylvania, to serve as their exclusive distributor of pharmaceutical grade filter paper.

This guide was developed to provide information on the methods used to qualify filter paper used in pharmaceutical applications. Included are the filter paper characteristics and the test methods used to qualify the product.

The filter paper grades designated for use in pharmaceutical processing and addressed in this Validation Guide are Grades 6095P, and 7362P. To ensure consistency, these grades are manufactured in accordance to predetermined controlled methods and product specifications outlined by an ISO 9001 Quality Management System. Each lot of material manufactured is tested against predetermined lot release criteria.

These grades are manufactured with raw material comprised of virgin fibers and reverse osmosis process water. Neither remanufactured nor recycled material is used in these grades.

The following sections outline product descriptions, data sheets and test data from independent laboratory testing. The products are designated on the test reports as FC7P with resin and FC7P without resins.

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# Section I

## Product Description

## ErtelAlsop Pharmaceutical Grade Filter Paper

A. Intended Use

Pharmaceutical grade filter paper is manufactured from high purity cellulose fibers using a wet laid process. This filter paper is designed for use in liquid filtration applications.

B. Physical Characteristics

1. Appearance

The filter sheets/pads are white in color. They may have a smooth or slightly cockled surface.

2. Composition

Pharmaceutical filter paper is manufactured using virgin cellulose and with or without a non-formaldehyde wet strength resin. Raw materials used in the manufacturing of this filter paper are recognized by the FDA as "Generally Recognized as Safe" (GRAS) for indirect food contact according to FDA Regulation 21CFR186.1673. Wet strength additives used in the manufacture of the products meet the requirements of 21CFR176.170, Components of Paper and Paperboard in contact with Aqueous and Fatty Foods and 21CFR176.180, Components of Paper and Paperboard in contact with Dry Foods.

3. Shape/Size

Filter paper is manufactured in various shapes and sizes to meet individual customer needs.

C. Functional Characteristics

Filter paper must depend upon uniformity for quality. For each particular application, the paper must offer the right combination of functional characteristics for its intended use. In liquid filtration applications, the common quality tests applied to the filter paper are liquid flow characteristics (rapidity), wet bursting strength, basis weight, and thickness. Pyrogenicity per USP bacterial endotoxin test (LAL) was determined on the grades addressed within this guide. Pyrogenicity testing of pharmaceutical grades of filter paper on a lot to lot basis may be obtained at customer expense.

D. Test Descriptions

1. Flow Characteristics (Rapidity)

The liquid flow characteristics filter paper are measured by a test called rapidity. Rapidity is defined as a number of milliliters of distilled water passing in one minute through a two-inch diameter test area under a two-inch head.

2. Wet Bursting Strength

Since the majority of filter paper is ultimately wetted with a liquid, the strength of the paper under wetting conditions is important. This property is measured by the force required to rupture or burst a given area of paper under fluid flow conditions. The wet bursting strength is defined as the pressure in inches of water that will just rupture a two-inch diameter test area.

3. Thickness and Basis Weight

The thickness and the basis weight of the sheet are used to determine the uniformity of the sheet. The thickness of a sheet of filter paper can be expressed in mils (1/1000 inch) or mm. The basis weight is the weight per unit area and is defined as the weight in pounds of a 20" x 20" – 500-sheet ream.

4. Bacterial Endotoxins (LAL)

The bacterial endotoxin test is completed by an independent laboratory. The concentration of endotoxins in the filter paper is determined by the LAL chromogenic test method.

This test is conducted by extracting a 55 ml filter in 75 ml (Grade 6095P) and 200 ml (Grade 7362P) of LAL negative water. The extract is then tested at a 1:10 dilution. The acceptance criteria is <0.5 EU/ml.

E. Stability

If filter paper is properly stored, (in original packaging or equivalent and kept dry), stability of the product is not an issue.

A study has been conducted on retainer samples from previous manufacturing lots. Retainer samples from three manufacturing lots from material manufactured one, two and three years ago were tested. The following parameters were measured: Basis Weight, Thickness, Rapidity, and Wet Bursting Strength. This test data was compared to data collected at the time of the manufacture. The results from this study were not noticeably different from the original QA test data.

Pharmaceutical grade filter media will remain stable for a minimum of 3 years assuming the product is properly protected (original packaging or equivalent, and dry).

# Section II

## ErtelAlsop Pharmaceutical Grade Filter Paper

## Specification Sheets

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# SPECIFICATION SHEET

***Grade Designation:*** Grade 6095P Pharmaceutical Grade Filter Paper

***Composition:*** Smooth, bleached white cellulose with non-hazardous wet strength resin

| | Standard | | Metric | |
|---|---|---|---|---|
| ***Basis Weight:*** | (lb/1389 ft²)<br>(oz/yd²) | 25.0<br>2.6 | (gm²) | 87.8 |
| ***Thickness***: | (mils) | 8.00 | (mm) | 0.20 |
| ***Rapidity:*** | | | (mls/min) | 14 |
| ***Wet Bursting Strength:*** | (inches) | 120.0 | (cm) | 304.8 |
| ***Micron Rating:*** | | | (micron) | 2 |

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Micron ratings are based on internal test method where 98% of a particulate size is removed during gravitational filtration. Micron rating values vary from industry to industry depending on the procedure.

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# SPECIFICATION SHEET

***Grade Designation:*** Grade 7362P Pharmaceutical Grade Filter Paper

***Composition:*** Smooth, white cellulose

| | Standard | | Metric | |
|---|---|---|---|---|
| ***Basis Weight:*** | (lb/1389 ft²)<br>(oz/yd²) | 70.0<br>7.3 | (gm²) | 245.7 |
| ***Thickness***: | (mils) | 26.10 | (mm) | 0.66 |
| ***Rapidity:*** | | | (mls/min) | 200 |
| ***Wet Bursting Strength:*** | (inches) | 29.5 | (cm) | 74.9 |
| ***Micron Rating:*** | | | (micron) | 17 |

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# Section III

# ErtelAlsop Pharmaceutical Grade Filter Paper

# Independent Laboratory Test Data

The following test results follow:

**USP XXV Safety Test**

Three lots for each grade were tested according to USP XXV Protocol. All three lots for each grade met the requirements of the safety test.

**USP Plastics Test-Class VI (7 Day Implant)**

One lot for each grade was tested per USP XXV Protocol. Each test included USP Systemic Injection Test, USP Intracutaneous Test and Intramuscular Implant Test are included.

**Bacterial Endotoxins (LAL) – Chromogenic method**

Three lots for each grade code were tested using validation protocol. This test was conducted by extracting a 55 ml filter in 75 ml (Grade 6095P) and 200 ml (Grade 7362P) of LAL negative water. The extract is then tested at a 1:10 dilution. The acceptance criteria is <0.5 EU/ml.

# Typical Extractable Data

| | **Pharmaceutical Grade Filter Paper** |
|---|---|
| **Aluminum, as Al, PPB** | <10 |
| Iron, as Fe, PPB | <10 |
| Magnesium, as Mg, PPB | N/A |
| Calcium, as Ca, PPB | N/A |

***Note: A 5-inch diameter circle of filter media was used in each case. 682 ml of double deionized water was filtered and discarded. 1/5 of above volume was filtered and collected for analysis. The same water supply is used for instrument calibration.***

# *ErtelAlsop is the first name when highly effective depth filtration is critical to the success of your process*

ERTELALSOP
THE FIRST NAME IN LIQUID FILTRATION

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