of even minute particles of PAO by the particle counter may indicate damage to the filter which may then be correspondingly repaired or replaced as needed. By utilizing a pairing of an ePTFE filter with an ultra- low concentration PAO challenge and a particle detector, use of HEPA ePTFE without fouling of the membrane by the PAO is accomplished.

[0053] As shown in Figure 1 , an exemplary machine for combining the bi-component layers 10 and 30 which are moved by belts 11 and 31 with the ePTFE membrane 20 is shown. Belt 21 feeds the specially formed membrane ~~21~~ 20 sandwiched between two 40 gsm spunbond bi-component non-woven layers 10 and 30. The upper and lower layers ~~10~~ 30 and ~~30~~ 10, respectively, can be of various types of filtering media for lamination with ePTFE membranes that are known in the industry and the specific types of media utilized herein are not to be deemed limiting. A HEPA ePTFE bi-component filter as described herein may exhibit an initial air flow resistance value which is 50% less than a standard HEPA glass media filter typically used in such environment. Such filter may be tested for certification in some embodiments using the methodology described herein utilizing ultra- low concentrations of PAO or microspheres along with a discrete particle counter to determine leak size and leakage indicative of damage to the filtering media.

[0054] The two spunbond layers 10 and 30 may be selected to provide a total weight of about 80 gsm combined such that each individual layer may be more or less than the exemplary 40 gsm layer as needed for the specific application and to provide a good laminating surface for bonding with the ePTFE membrane 20. The bi-component layers may also be selected to provide a combined stiffness of at least about 400 Gurley. These bi-component materials may be selected from many known members but, in various
embodiments, polyethylene and PET may be combined to form the spunbond bi-component material. As indicated, an exemplary specification for the scrim may be a PE/PET bi-component spunbond scrim for lamination purposes. In various embodiments, each layer may have a basis weight of 40+3 g/m2 and a thickness of 0.25± 0.05 mm. An exemplary air permeability is greater than about 350 cfm with a tensile strength of MD> 100 N/5cm and CD > 30.

[0055] Returning to Figure 1, bi-component layers 10 and 30 are fed by belts 11 and 31 to a laminating station or combination area 45 wherein ePTFE membrane 20 is fed by belt 21. Combined filtering media layer 50, shown in Figures 1, 2, 3, and 5A, depicts the bi-component layers laminated to the ePTFE membrane 20. As seen in Figure 1, laminating station ~~50~~ 45 bonds the membrane to the

layers 10 and 30 at a temperature of about 165 C to about 175 C at a speed of about 20 to 30 m/min. Pressure rollers 52 are also provided to ensure proper laminating of the two layers 10, 30 with the membrane 20 after application of the laminating heat. Similarly, Figure 2, while not shown to scale, depicts the membrane layer 20, which is fed from a roll after being previously mixed and formed, in between the lower and upper scrim layers 10 and 30, respectively. Once heat treated and properly laminated by the laminating station 45 and rollers ~~50,~~ 52, the combined ePTFE filtering media 50 is depicted in Figure 3 with upper and lower layers ~~30/10~~30,10 positioned opposite each other and heat ~~laminated / bonded~~laminated/bonded with the membrane 20.

[0056] In the present embodiment, the combined filtering media 50 is a HEPA filter mat having fiber diameters of between 0.5 and 2.0 micrometers. As is known, HEPA filters remove at least 99.97% of the airborne particles 0.3 μm (micrometers) in diameter. While the spunbond scrim layers do not provide membrane-like entrapment filtration, they are combined with an actual membrane layer 20 where particles are actually trapped by the tendrils of the ePTFE membrane material. The ePTFE membrane 20, depicted herein, provides unique characteristics in combination with the scrim layers as well as the specific testing and challenging methodology using ultra-low PAO concentrations preventing fouling of the membrane by the PAO and maintaining filter efficiency even after multiple certification challenges.

[0057] The specialized ePTFE membrane 20 utilized herein is created from a fine powder PTFE material, for example a powder from Daikin called Polyflon PTFE F-135. The fine powder utilized has a standard specific gravity of about 2.149 to about 2.165 and a bulk density of about 0.42 to about 0.54 g/ml. The fine powder further has a particle size distribution of 400-650 μm.

[0058] The fine PTFE fine powder is then mixed with an oil at a ratio of about 33% into a doughy billet. The mixing oil may be IP Solvent 2028 with a viscosity of 3.01 m.Pa.s/at 20 degrees C and a density of 213 to about 262 g/cm3 at about 15 degrees C. This mixture is brought to a boiling point at about 213 to about 262 C with a mixing time of about 10 minutes. Once the material is thoroughly mixed, it can be stretched into a membrane or film through both TDO and MDO stretching. Initially, an MDO stretch is accomplished at a 5:1 ratio and at a temperature of about 50 degrees C. Three rollers are utilized in MDO stretching, each roller heated to about 250 degrees C. After completion of the MDO stretch, a TDO stretch is accomplished at a ratio of about 30-50 to 1. The membrane is preheated at

a temperature of about 200/200 degree C, a stretching temperature of 300/300 degree C and a heat set temperature of about 370/500 degrees C. Once the membrane is formed, it can be rolled for later use and combination within a scrim layer for formation of an ePTFE filter material.

[0059] An exemplary process for creation of the ePTFE membrane for use in the filter media and method steps discussed herein is shown in Figure 12. As can be seen, the fine powder solvent is mixed with mixing oil and finely mixed. The paste is then pre-formed and then extruded through an extruder for calendaring to a roll of membrane at about 220 μm. Once it is calendered, a roll of ePTFE membrane is formed which may then be sent to a dryer for adequate drying so that the membrane may be stretched as necessary to prepare for lamination at an appropriate thickness. Variant TDO/MDO stretching may be imparted onto the ePTFE membrane such that after lamination to the scrim material, including in the varying embodiments of a bi-component scrim discussed herein, the combined media exhibits the necessary and desired pressure drop and efficiency appropriate for the desired application.

[0060] After completion of the TD stretching as depicted in Figure 12, the membrane 20 has a thickness of between about 6 to 10 μm prior to combining with the upper and lower bi-component scrim layers 10, 30 as shown. The combined HEPA ePTFE media exhibits a total thickness of about 0.40 mm with a range of between 0.25 and 0.55 mm. Further, the basis weight, in varying embodiments, is shown to be about 81 g/m^2 with a range of between about 76 and about 86 g/m^2. Further, the average pressure drop of the combined media produced with the ePTFE membrane made and applied as set forth herein is about 11.73mm H_20 with a range of about 10.20 to about 13.26 mm H_20.

[0061] ~~Shown in~~Referring again to Figure 1 there is shown an example of an alternative embodiment and machine designed for combination of the dual scrim layers and the ePTFE membrane 20. After combining the multiple layers together, the combined filtering material 50 may be fed into a laminating machine ~~50~~ 45 as discussed herein. The lamination speed for bonding of the membrane to the bi-component layers 10, 30 is approximately 20-30 m./min. and results in a combined HEPA ePTFE filtering media having a pressure drop of about 100-150 Pa. and a related efficiency of greater than 99.94%. Such ratings are exhibited with a testing condition of air stream velocity of 0.053 m/s with a silica aerosol.

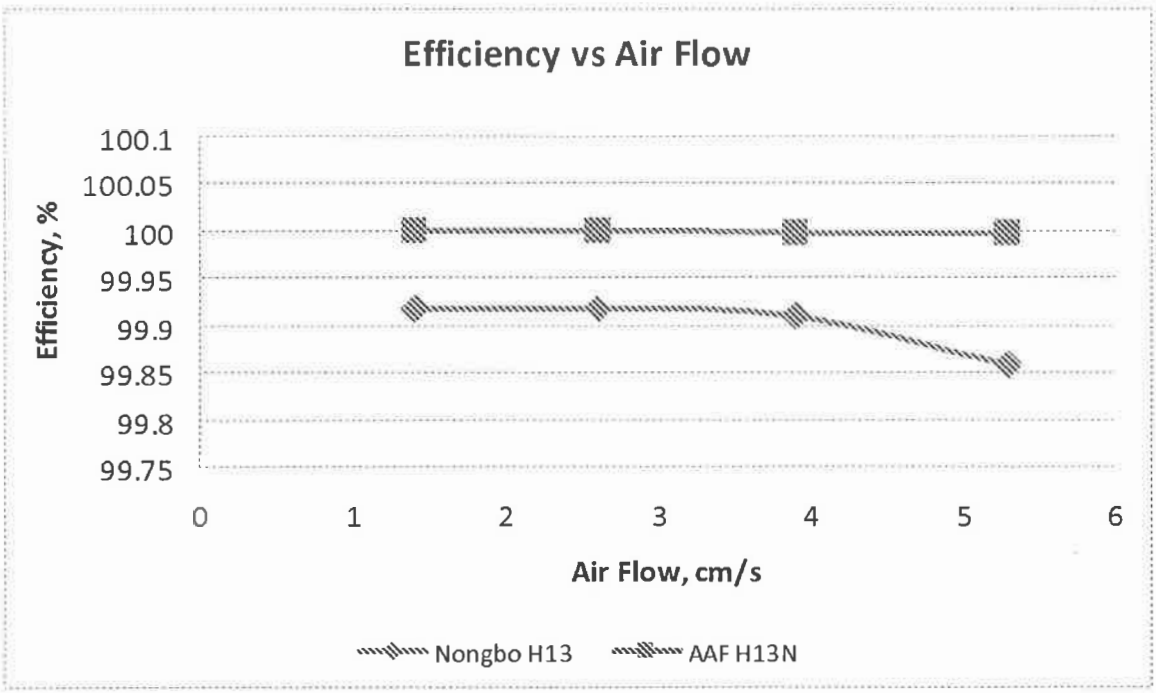


CHART 2

Wherein the triangular dotted line represents a prior art Ningbo (Chinese manufacturer) HI 3 HEPA filtering media and the square dotted line represents the presently described embodiment of the HEPA ePTFE dual layer scrim material described herein.

[0064] Returning to the figures, as depicted in Figure 4, the combined laminated media 50 is prepared for pleating by initially unrolling the combined media and feeding to a belt for conveyance to a pleating apparatus 60. As is understood, pleating is accomplished through many processes and the one depicted is only provided as a means to describe one of a number of processes for pleating, crimping and folding the ePTFE pleated filter media. Further, the depiction shown in the figures is for descriptive and explanatory purposes. Prior to pleating of the media 50, an injector nozzle 53 provides separator material beads 51 on the filter media which are used to ensure proper separation of adjacent pleats formed from the media by the pleating machine. Failure to sufficiently separate the pleats can cause the pleats to collapse under the pressure of active airflow. By providing spaced separators, maintenance of the pleat structure is assured to allow for adequate surface area of the filtering media, pleat positioning and efficacy.

[0065] Separators 51 , depicted in several embodiments of Figures 4, 5B, 5C, 6A and 6B, may be of many types of construction. This includes simple beads, sections, bow tie structures, elongated lines 54 or other configurations. Many variations of separator construction

[0076] As indicated, it is significantly desirable to use the various embodiments of filtering media disclosed herein as compared to traditional micro-glass. As a result, such methodology using ultra-low concentration generators of aerosol must be used in combination with detection equipment of such concentrations at both the upstream and downstream side of the media 210. An upstream scanner 208 may be combined with the downstream scanner 209 as shown. Automated systems including a microprocessor and software may be utilized to read the measurements of the two scanning devices in order to quickly and accurately determine downstream concentrations. Such microprocessor may be incorporated with said upstream scanner, downstream scanner, or in some embodiments, may combine both structures and functionality to calculate the downstream leakage percentage. Alternatively, in other embodiments, downstream measurements may be made and determinations of downstream ultra-low concentrations then determined.

[0077] Upstream concentrations, even when at ultra-low values as specified herein, may be so large that an upstream discrete particle counter may be over overwhelmed. Thus, in some embodiments, a combination of an upstream photometric scanner with a downstream discrete particle counter may be utilized in order to calculate the appropriate downstream penetration percentage concentration of the challenging aerosol. In general, an upstream aerosol photometer with an associated filter scanning head 208 may be used to determine ultra-low upstream concentrations. Associated with the upstream aerosol photometer and scanning head 208 may be a modified Laskin nozzle 202 which generates the ultra-low concentrations of the challenge PAO for the filter test and certification. Such Laskin nozzle generator may be used in combination with an aerosol reducer such as an oil mist eliminator with a 18 guage capillary bypass. This dilution factor may be between about 750 to about 1000, or for example about 960. The modified Laskin aerosol generator may be modified such that finite control and output of the challenge PAO concentrations may be maintained at such low concentrations as to not substantially affect the efficiency and effectiveness of the HEP A ePTFE filtration media 210 depicted. Such concentrations include controllable emissions of from about 1.0 ug/L down to about 0.01 µg PAO/L or lower which may include determination of concentrations down to about 0.3 **µm**/ cubic foot or about 6 million particles per cubic foot or lower. Of course, the upstream detector 208 may be any type of ultra-low concentration detectors capable of accurately measuring the PAO concentrations on the upstream airflow and filter face such that an accurate calculation of the downstream concentration percentage may be made.

CLAIMS

1. ~~An ePTFE filtering media and~~A challenge testing ~~configuration~~ apparatus for an in-situ pharmaceutical installation of ~~the~~ an ePTFE filtering media, comprising:

~~the~~ a pleated filtering media positioned within an air stream of an air handling unit in an aseptic pharmaceutical airstream handling system, said filtering media including an upstream support scrim and a downstream support scrim and an ePTFE membrane interposed between said upstream support scrim and said downstream support scrim;

wherein said upstream support scrim and said downstream support scrim are a bi-component material and said ePTFE membrane is laminated there between;

a poly-alpha olefin separator between of each of said plurality of pleats of said pleated filtering media;

an upstream low volume aerosol generator combined with an aerosol diluter providing less than ~~about~~ 0.3 µg aerosol/L air ~~for low volume~~ down to ~~about~~ 0.01 µg aerosol/L air and below for ultra-low volumes of ~~challenging~~ aerosol concentrations into said ~~airstream~~air stream of said air handling unit;

an upstream scanner for detection of ~~said ultra- low~~the ~~challenging~~ aerosol concentrations for ultra-low volumes at said upstream support scrim of said filtering media;

a downstream scanner with a scanning probe inserted into said air handling unit downstream of said pleated filtering media and facing said downstream support scrim, said scanning probe inserted through an access port in said air handling unit of said pharmaceutical airstream handling system for detection of ~~ultra-low~~the aerosol concentrations ~~of said challenging aerosol~~for ultra-low volumes passing through said downstream support scrim of down to ~~about~~ 0.01 percent of said ~~upstream~~ the aerosol concentrations ~~of said challenging aerosol~~for ultra-low volumes detected at said upstream scanner.

2. The ~~configuration~~ apparatus of claim 1 wherein said downstream scanner is operable to detect ~~downstream~~ the aerosol concentrations ~~of said challenging aerosol~~for ultra-low volumes passing through said downstream support scrim as low as .000001 µg aerosol/L air.

3. The ~~configuration~~ apparatus of claim 2 wherein said downstream scanner is a discrete particle scanner.

4. The ~~configuration~~ apparatus of claim 1 wherein said upstream low volume ~~emitter~~ aerosol generator is a modified laskin nozzle generator in combination with said aerosol ~~reducer~~ diluter being an oil mist eliminator having an 18 gauge capillary bypass creating a dilution factor of ~~about~~ 960.

5. The ~~configuration~~ apparatus of claim 1 further comprising an electrical communication between said upstream scanner and said downstream scanner.

6. The ~~configuration~~ apparatus of claim 5 further including a microprocessor in communication relationship with both said upstream scanner and said downstream scanner.

7. The ~~configuration~~ apparatus of claim 1 wherein said pleated filter media is a HEPA filter.

8. A method for ~~installation and~~ leakage testing of ePTFE filtration media in an aseptic pharmaceutical filtration environment, comprising:

installing a filtration media having an upstream spun bond scrim material and a downstream spun bond scrim material;
interposing an ePTFE membrane between said upstream spun bond scrim material and said downstream spun bond scrim material;
injecting ~~into said~~ upstream ~~air~~ of said filtration media an ultra-low concentration of oil based ~~challenging~~ aerosol of below .05 μg aerosol/L air;
diluting said aerosol with an aerosol reducer with to a dilution factor of between ~~about~~ 750 to ~~about~~ 1000;
creating an ultra-low filter challenge concentration of ~~about~~ 20 million particles at greater than or equal to ~~about~~ 0.3 micron and ~~about~~ 7 million particles at greater than or equal to 0.5 micron per cubic foot of air;
measuring ~~the~~ an upstream concentration of said oil based ~~challenging~~ aerosol at said upstream spun bond scrim material;

allowing said oil based ~~challenging~~ aerosol to penetrate through said ePTFE membrane;

measuring ~~the~~ a downstream concentration of said oil based ~~challenging~~ aerosol by particle detection at said downstream spun bond scrim material to a value at least as low as 0.01 percent of said upstream ~~challenging aerosol~~ concentration at said upstream spun bond scrim material;

calculating a leakage detection of said ~~challenging~~ oil based aerosol.

9. The method for ~~installation and~~ leakage testing of ePTFE filtration media of claim 8 wherein said method further comprises installing an upstream scanner for said measuring said upstream concentration of said oil based aerosol at said upstream spun bond scrim material; installing a downstream particle scanner for said ~~measure~~ measuring said downstream concentrations of said oil based aerosol at said downstream spun bond scrim material.

10. The method for ~~installation and~~ leakage testing of ePTFE filtration media of claim 9 further comprising transmitting said upstream concentration measurements of said upstream scanner to a computer; transmitting said downstream concentration of measurements of said downstream scanner to a computer; calculating a leakage percentage of said oil based ~~challenging~~ aerosol through said ePTFE filtration media over a predetermined period of time.

11. The method for ~~installation and~~ leakage testing of ePTFE filtration media of claim 8 further comprising:

installing a communication link between an upstream scanner and a downstream scanner;

transmitting said upstream concentration measurements of said upstream scanner to a reading device;

transmitting said downstream concentration of measurements of said downstream scanner to said reading device;

calculating a leakage percentage of said oil based ~~challenging~~ aerosol through said ePTFE media by a processor;

reporting said calculated percentage to a user.

12. The method for ~~installation and~~ leakage testing of ePTFE filtration media of claim 8 wherein said method further comprises installing an upstream photometric scanner for measuring said upstream concentration of said oil based aerosol at said upstream spun bond

scrim material and installing a downstream particle detection scanner for measuring said downstream concentration of said oil based aerosol at said downstream spun bond scrim material.