[0010] In addition to filter loading, when considering testing of ePTFE filters with the conventional use of PAO as a challenge aerosol, bleed through was also identified as a potential issue. The issue of bleed through may occur when using thermally generated PAO to test ePTFE filters. This is due to the thermally generated aerosol having a 0.10-0.45 mass mean diameter which is closer to the MPPS of the filter. This creates an issue with a photometer measuring a concentration and looking for leaks at or above 0.01%. The bleed through could erroneously manifest itself as an artificially large leak or in some cases a continuous leak across the filter measuring a 0.025% or less leak rate.

[0011] It is therefore desirable to provide a fully functional HEPA filtration media which meets all requirements, is relatively durable, may be challenged appropriately to determine filtering effectiveness and leakage and which further meets all required aseptic filtration standards. It is further desirable to provide such filtration media without additional pre-filter requirements and with appropriate methodology to determine full functionality of the media and determine possible leakage points without causing fouling of the in-situ filters.

[0012] Thus, there is a need in the art to provide a fully functional aseptic pharmaceutical filter media which has associated full testing methodology, is durable, maintains HEPA filtration efficiencies and which has a long in place filtration life.

Summary

[0013] It should be appreciated that all combinations of the foregoing concepts and additional concepts discussed in greater detail below (provided such concepts are not mutually inconsistent) are contemplated as being part of the inventive subject matter disclosed herein. In particular, all combinations of claimed subject matter appearing at the end of this disclosure are contemplated as being part of the inventive subject matter disclosed. It should also be appreciated that terminology explicitly employed herein that also may appear in any disclosure incorporated by reference should be accorded a meaning most consistent with the particular concepts disclosed herein.

[0013A] According to one aspect, there is provided a challenge testing apparatus for an in-situ pharmaceutical installation of an ePTFE filtering media, comprising: 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 bicomponent 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 aerosol generator combined with an aerosol diluter providing less than 0.3 μg aerosol/L air down to 0.01 μg aerosol/L air and below of aerosol concentrations into said air stream of said air handling unit; an upstream scanner for detection of the aerosol concentrations 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 the aerosol concentrations passing through said downstream support scrim of down to 0.01 percent of the aerosol concentrations detected at said upstream scanner.

[0013B] According to another aspect, there is provided a method for 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 upstream of said filtration media an ultra-low concentration of oil based aerosol of below .05 μg aerosol/L air; diluting said aerosol with an aerosol reducer to a dilution factor of between 750 to 1000; creating an ultra-low filter challenge concentration of 20 million particles at greater than or equal to 0.3 micron and 7 million particles at greater than or equal to 0.5 micron per cubic foot of air; measuring an upstream concentration of said oil based aerosol at said upstream spun bond scrim material; allowing said oil based aerosol to penetrate through said ePTFE membrane; measuring a downstream concentration of said oil based 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 concentration at said upstream spun bond scrim material; calculating a leakage detection of said oil based aerosol.

[0014] ~~It is therefore one aspect~~In one embodiment of the present ~~invention~~ disclosure,~~to~~ there is provided a replacement material and certification testing for leak size and detection of aseptic clean room filtering media which utilizes a significantly lower resistant media, thereby substantially reducing energy costs.

[0015] It is further desirable to provide a method for certification and testing of media in such conditions using ultra-low concentrations of PAO and a means for detection of said ultra-low concentrations downstream of the filter to determine leak size and filter condition.

[0016] In another ~~aspect~~ embodiment of the present ~~invention~~disclosure, it is desirable to provide a more efficient alternative to micro-fiber glass filtering media in such an environment.

[0017] ~~It is t~~Therefore one ~~aspect~~ embodiment of the present ~~invention~~ disclosure ~~to~~ integrates ultra-low level PAO testing and challenging of ePTFE HEPA filtration media in an aseptic cleanroom environment. ~~It is a~~A further ~~aspect~~ embodiment of the present ~~invention~~ disclosure ~~to~~ provides an ePTFE bi-component filtration media which may be appropriately tested and certified on a regular basis for efficiency and leakage with an aerosol without fouling of the ePTFE membrane or filter media.

[0018] In some embodiments, the filter system and media of the system described herein includes a dual layer bi-component media of spun-bond material, the bi-component material being a combination of PET and PE with a total weight of about 80 GSM for both layers and a combined stiffness of about at least 400 Gurley.

[0019] In various embodiments, the dual layer of bi-component material may include a density of about 8 PPI with an average pleat height of about 25 to about 55 mm. Optimally, in may embodiments, the pleat height will be about 35 mm.

[0020] In some filters, the pleat separators can be a clear poly-alpha olefin separator bead applied in between each pleat to assure pleat separation and spacing. In other filters and embodiments, the pleats can be formed by embossing a pattern in the media that assures pleat separation and spacing.

[0021] In other ~~aspects~~embodiments, the specially formulated ePTFE membrane may be about 8 to about 15 microns and preferably about 10 microns.

[0022] In some ~~aspects~~embodiments, the bi-component filter material may be laminated with the ePTFE membrane at about 160 degrees C.

[0023] In various ~~aspects~~embodiments, the resulting material can be rolled and then later pleated as set forth for insertion into air filter assemblies which can include metal gel seal, neoprene or knife edge frame types.

[0024] Upon insertion of the ePTFE HEPA filter at an installation, some ~~aspects~~ embodiments set forth herein can include regular certification and leakage testing by use of ultra-low PAO challenging aerosol at down to about 0.010 μg PAO/L of air and up to about 6.0 μg/L. More particularly and alternatively, an ultra low concentration of about 0.3ug/L PAO to about 0.5 ug/L with a combination of particle sizes of about 0.3um to about 0.5 um particle count sizing. Correspondingly, a discrete particle counter can be combined with the aerosol generator for challenging and leakage testing, in various embodiments, which can include a counter able to test at 0.5 um to about 0.3 μm or smaller μm channel size.

[0025] In other embodiments, microspheres (polystyrene latex) may be generated as a challenging material and read on the downstream side of the filtering membrane using a particle counter to similarly determine leakage and filter efficacy. In various examples, microspheres sized from 0.12 and up to 0.30 μm can be utilized. Similar testing and challenging concentrations can as well include challenging measurements of $20x10^6 \geq 0.3$ um particles per ft^3 PAO to about $7x10^6 \geq 0.5$um particles per ft^3 PAO.

[0026] Generally, in the various examples and embodiments provided, a filter and testing methodology is provided wherein a specialized ePTFE HEPA filter may be utilized and appropriately challenged for certification purposes while maintaining the efficiency and efficacy of the filtering media. Usage of the various embodiments described herein provides alternative testing and certification methodology for clean room application of ePTFE filtering media without the significant drawbacks of high volume PAO aerosol testing previously seen in the art.

[0027] ~~It is t~~Therefore one ~~aspect~~ embodiment of the present ~~invention~~ disclosure ~~to~~ provides a system for installation and testing of ultra-low concentration challenging PAO or other type of aerosol upstream of an ePTFE HEPA filter for use in aseptic pharmaceutical clean rooms wherein the challenging concentrations of the PAO or other aerosol is less than about 1.0 μg/L air challenge aerosol with an associated low or ultra-low concentration upstream scanner, in conjunction with a downstream ultra-low concentration particle detector or other scanner for determination of downstream concentration of the challenging aerosol. To measure a 0.01% leakage rate based on a 1.0 μg /L down to about 0.3 ug/L and further down to about 0.1ug/L and lower upstream challenge aerosol concentration, a photometer or detector downstream must be sensitive and accurate for measuring a leakage rate of 0.01% upstream PAO challenge concentrations, or a downstream concentration of less than 0.001, 0.00003 and