CLAIMS

1. 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 ~~low volume~~ 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 ~~for ultra-low volumes~~ of aerosol concentrations into said air stream of said air handling unit;

an upstream scanner for detection of the 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 the aerosol concentrations ~~for ultra-low volumes~~ passing through said downstream support scrim of down to 0.01 percent of said the aerosol concentrations for ultra-low volumes detected at said upstream scanner.

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

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

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

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

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

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

8. 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 ~~with~~ 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;