



finetech Finetech Research and Innovation Corp.

Sterile Filter Test Report

Project Management Unit: China Productivity Center
Project Execution Unit: Xuntai Research Innovation Co., Ltd.



Test Type	Time	Goals	Tasks Carried Out	Results
Physical	2 Months	<p><i>(According to Millipore)</i></p> <ol style="list-style-type: none"> Appearance inspection after sterilization: No defects, visible debris or foreign body. Flow after sterilization: water flow reaches ≥ 150 mL/min @ 2.1 kg/cm². Residual volume before sterilization: ≤ 0.1 mL. Outer ring burst test before sterilization: ≥ 5 kg/cm² pressure. Bubble point of water after sterilization: Bubble point value ≥ 2 kg/cm² pressure. Integrity test of outer ring after sterilization: 3 kg/cm² with no leakage or bubbles after 1 minute. Luer pressure test after sterilization: No breakage with 3 kg/cm² pressure. Dimensions of Luer fixture before sterilization: Can withstand the use of ≤ 5N. Sterilization paper packaging integrity test after sterilization : Sterilize paper before foaming point is reached. No air bubbles are generated at the seal. 	<ol style="list-style-type: none"> No defects, debris, or foreign body in product appearance inspection. Product water flow after sterilization: ≥ 150 mL/min @ 2.1 bar. Single and double layer membrane filter before sterilization residual volume reaches ≤ 0.1 mL. Burst test of outer ring reaches ≥ 5 kg/cm² pressure. Test bubble point after sterilization: ≥ 2 kg/cm² pressure. Test the outer ring with 3 kg/cm² pressure. Luer pressure test after sterilization: no cracking. Meets Luer standard size before sterilization. Integrity test of sterilized paper packaging after sterilization test. 	<ol style="list-style-type: none"> Inspection confirms completeness, with no defects or foreign bodies. The average flow rate for PES membrane: 150mL/min. Residual Volume Results: 0.06~0.09 mL, Reaches ≤ 0.1 mL residual volume. Product first raised to 3 kg pressure test. After, the pressure was raised to 5 kg and more to reach the testing standard. Bubble point of PES, PVDF and PP nonwoven fabric is 3.3~3.9 kg/cm². Results confirmed no leaks or bubbles generation for 1 minute. Female connector (Luer) shows no cracks after the pressure test. The torque meter shows it can withstand a force of ≤ 5 N. Integrity test of sterilized paper before reaching the bubble point, No air bubbles are generated at the shell seal.
Chemical and Biological	3 Months	<p><i>(According to Millipore)</i></p> <ol style="list-style-type: none"> Sterility: No living microorganisms detected in the filter. <ol style="list-style-type: none"> The sterilized filter is tested for EO carryover. Bacterial Retention after Sterilization: No bacteria are generated after filtration. 	<ol style="list-style-type: none"> Entrust Taiwan AST for sterilization. <ol style="list-style-type: none"> Entrust Taiwan and the United States to inspect the EO residue test. Commissioned China Medical University to test the bacterial residue. 	<ol style="list-style-type: none"> Test report of biological indicator: verification of the EO process, the effect of complete sterilization was achieved. <ol style="list-style-type: none"> Results: EO residues were not detected. Results: The PES+PP and PVDF filters can effectively filter the bacterium.