Validation Guide
EFSTP..STPL
Sterile Filter Elements

Technical specifications are subject to change without notice.
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1. Introduction

Filter elements that are used in high specification filtration applications must conform to strictly defined manufacturing and quality standards.

This guide describes the validation testing of the FST GmbH sterile filter elements EFSTP..STPL, the results from which the product claims and the manufacturing and quality standards have been derived. This information is designed to help the customer select the appropriate filter product for their critical applications.

EFSTP..STPL sterile filter elements feature an epoxy-resin bonded fibre-glass depth media.

EFSTP..STPL sterile filter elements are manufactured using polypropylene hardware and polyester media support and are assembled using the latest thermal welding technology. This results in a robust, durable filter assembly, which will withstand a wide range of chemicals, temperatures and other harsh operating conditions.

EFSTP..STPL sterile filter elements are available to fit into FST process filter housings type FWP while suitable to be used in some filter housings of other manufacturers as well.

The data presented in this guide is a partial representation of the large amount of engineering work required to provide filter users with a high quality sterile filter element. If you require any further information, please contact FST GmbH.

FST GmbH reserves the right to change specification without prior notice as part of their continuous product development program.

It is provided by us, as a guide only, solely for the use of our customers, whose own personnel have the technical skill to interpret the data at their own discretion and risk.

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2. Quality Assurance

FST GmbH EFSTP..STPL sterile filter elements are manufactured applying a well-established Quality Assurance System, which is accredited to ISO 9001:2008.
3. Contamination Control & Cleanliness Standards

All EFSTP..STPL sterile filter elements are manufactured in a controlled clean-room environment using well defined and documented work instructions and quality plans, thus ensuring that the highest quality and cleanliness standards are consistently maintained.

All materials of construction used in the manufacturing of EFSTP..STPL sterile filter elements are certified as silicone free. Furthermore, no silicone is used in the manufacturing process, and all substances used in the manufacturing area are controlled to ensure that they are silicone free.

4. Product Traceability

The Quality Assurance System, accredited to ISO 9001:2008, assures full product traceability. Each sterile filter element is identified by the following methods:

- Part Number - Printed (in alpha-numerical form) on the filter element itself, both the inner and outer packaging labels.
- Batch Number - Printed (in alpha-numerical form) on the filter element itself, both the inner and outer packaging labels.

These identifying numbers allow full product traceability back to raw material lot numbers. The date the sterile filter elements was manufactured and sealed in the bag is shown on the bag label.
5. Product Specification

5.1 Biological Safety

5.1.1 US FDA CFR Title 21 for Food Contact
All the materials used in the construction*1 of EFSTP..STPL sterile filter elements fulfil the requirements on materials used for articles intended to come into contact with food as described in the United States Food and Drug Administration (US FDA) Code of Federal Regulations Title 21 (21CFR), as well as the appropriate European guidelines.

*1 See section 5.5 materials of construction

5.1.2 U.S. Pharmacopoeia (USP) Plastics Class
All the materials used in the construction of EFSTP..STPL sterile filter elements fulfil the requirements on materials used for articles intended to be used for medical purposes as described in the U.S. Pharmacopoeia (USP) Plastics Class VI (Approved Medical Grade Plastic Materials).

5.1.3 European Regulation (EC) Number 1935/2004
EFSTP..STPL sterile filter modules meet the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:
EFSTP..STPL sterile filter modules have been assessed by an external laboratory under the Plastics Materials and Articles in Contact with Foodstuffs Regulations laid out in EC Directive 2002/72/EC, its amendments (EC Directives 2004/1/EC, 2004/19/EC, 2005/79/EC & 2007/19/EC) and its successor EU Regulation No 10/2011 (depth glass fibre media excluded).

5.1.4 Statement on Polymer Additives & BSE
EFSTP..STPL sterile filter elements are considered highly unlikely to present a risk of TSE/BSE transmission. The products are considered to be in compliance with the European ‘Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMEA/410/01 REV. 2 - October 2003)’ adopted by the Committee for Proprietary Medicinal Products (CPMP) and by the Committee for Proprietary Veterinary Products (CPVP).

In addition we certify that they are unlikely to pose a risk for TSE infectivity according to the USP Perspective to Minimize the Potential Risk of TSE Infectivity in Bovine-Derived Articles Used in the Manufacture of Medicinal Products, USP Pharmacopeial Forum, Vol. 30(5), Sept-October 2004.

The suppliers state that the polymers used in the manufacture of EFSTP..STPL sterile filter elements may incorporate small amounts of tallow based additives, stearates or other materials that are derived from fatty acids and during processing, a re-esterification or hydrolysis process is used with a minimum temperature of 200°C and an appropriate pressure for at least 20 minutes. Subsequent processing at the granulation & fibre production stages take place at temperatures in excess of 200°C for several minutes. This fulfils the requirements laid down in the Notes For Guidance, EMEA.410/01 Rev.2.

Animal derived materials are not intentionally used during the manufacture of the raw material that gets used in the seals fitted to EFSTP..STPL sterile filter elements.
5.2 Integrity Testing

A representative sample of EFSTP..STPL sterile filter modules are integrity tested during manufacture as part of the manufacturing quality control programme.

5.3 Retention Characteristics

Tests by an independent test laboratory on representative samples have shown that the EFSTP..STPL sterile filter element is fully retentive to aerosolised Brevundimonas diminuta (NCIMB 11091, ATCC 19146) bacteria when challenged with a total of >10⁷ CFU per cm².

No penetration was detected which is equivalent to a log reduction value (LRV) of >10⁷ CFU per cm² of effective filtration area.

A schematic diagram of the apparatus used in the filter tests is shown in Figure 1.

A suspension of micro-organisms in aqueous solution was nebulised by a Collison spray forming a fine aerosol containing viable micro-organisms. The generated aerosols were injected into an air stream flowing into a long, stainless steel tube connected to the test filter. The efficiency of the filter was calculated by determining the airborne concentration of viable micro-organisms upstream and downstream of the test filter using suitable aerosol sampling techniques and microbial assay methods.

Brevundimonas diminuta was used for this testing because it is generally recognised as the most appropriate micro-organism for challenge testing of 0.2µm rated filters.

**FIGURE 1:** Apparatus for challenging filters with microbiological aerosols
5.4 Flow Characteristics

EFSTP140STPL sterile filter elements were tested using filtered air at 20°C and 0 bar gauge. Typical pressure drop values obtained from the tests, with the housing pressure drop deducted, are shown below:

![Graph showing flow rate vs. differential pressure for EFSTP140STPL sterile filter elements.]

5.5 Materials of Construction

All raw materials used in the construction of EFSTP..STPL sterile filter elements meet the requirements for food contact use as laid down in the United States Food and Drug Administration (US FDA) Code of Federal Regulations Title 21 (21CFR), as listed below:

<table>
<thead>
<tr>
<th>Component</th>
<th>Material</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter media</td>
<td>Fiberglas with Epoxy Resin binder</td>
<td>21CFR175.105,300</td>
</tr>
<tr>
<td></td>
<td></td>
<td>21CFR176.170,180</td>
</tr>
<tr>
<td></td>
<td></td>
<td>21CFR177.1520</td>
</tr>
<tr>
<td></td>
<td></td>
<td>21CFR174.5</td>
</tr>
<tr>
<td>Media support</td>
<td>Polyester</td>
<td>21CFR177.1630</td>
</tr>
<tr>
<td>Inner cylinder (Core)</td>
<td>Polypropylene</td>
<td>21CFR177.1520</td>
</tr>
<tr>
<td>Outside cylinder (Cage)</td>
<td>Polypropylene</td>
<td>21CFR177.1520</td>
</tr>
<tr>
<td>End caps</td>
<td>(Glass-filled) Polypropylene</td>
<td>21CFR177.1520</td>
</tr>
<tr>
<td>Seals</td>
<td>Ethylene Propylene (EPDM)</td>
<td>21CFR177.2600</td>
</tr>
</tbody>
</table>
5.6 Nominal Dimensions

![Diagram of filter element]

<table>
<thead>
<tr>
<th>Model</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>Connection</th>
</tr>
</thead>
<tbody>
<tr>
<td>EFSTP90</td>
<td>55.5 mm</td>
<td>69 mm</td>
<td>88 mm</td>
<td>T-Code</td>
</tr>
<tr>
<td>EFSTP120</td>
<td>55.5 mm</td>
<td>127 mm</td>
<td>146 mm</td>
<td>T-Code</td>
</tr>
<tr>
<td>EFSTP140</td>
<td>68.5 mm</td>
<td>253 mm</td>
<td>307 mm</td>
<td>Code 7</td>
</tr>
<tr>
<td>EFSTP180</td>
<td>68.5 mm</td>
<td>492 mm</td>
<td>556 mm</td>
<td>Code 7</td>
</tr>
<tr>
<td>EFSTP190</td>
<td>68.5 mm</td>
<td>737 mm</td>
<td>801 mm</td>
<td>Code 7</td>
</tr>
</tbody>
</table>

Please note: The information shown above is for guidance only and may be subject to change in line with FST GmbH ongoing product development program.
5.7 Maximum Operating Temperatures and Differential Pressure

The maximum recommended operating temperature for the EFSTP..STPL sterile filter elements is 80°C.

The maximum allowable Differential Pressure (DP) across EFSTP..STPL sterile filter elements in either a forward (flow outside to inside) or reverse direction (flow inside to outside) is dependent upon the operating temperature:

<table>
<thead>
<tr>
<th>Temperature (°C)</th>
<th>Maximum differential pressure forward flow (bar)</th>
<th>Maximum differential pressure reverse flow (bar)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>4.0</td>
<td>3.5</td>
</tr>
<tr>
<td>30</td>
<td>4.0</td>
<td>2.5</td>
</tr>
<tr>
<td>40</td>
<td>4.0</td>
<td>1.5</td>
</tr>
<tr>
<td>50</td>
<td>3.0</td>
<td>1.0</td>
</tr>
<tr>
<td>70</td>
<td>2.0</td>
<td>0.5</td>
</tr>
<tr>
<td>80</td>
<td>1.0</td>
<td>0.5</td>
</tr>
</tbody>
</table>

From available collapse testing data of cores at elevated temperatures, typical collapse pressures were 8.0 bar at 40°C and 5.0 bar at 60°C. This far exceeds the maximum differential pressures set for the EFSTP..STPL sterile filter elements, and therefore allows a substantial safety margin.

From burst testing carried out on outer cages, typical differential pressures reached without the cage bursting were 4.9 bar at 24°C and 2.5 bar at 50°C. This far exceeds the maximum reverse-flow differential pressures set for the EFSTP..STPL sterile filter elements, and therefore allows a substantial safety margin.

FST GmbH recommends that EFSTP..STPL sterile filter elements are changed at a differential pressure like shown in the following table in normal service, latest after one year - the operating conditions above should be treated as maximum differential pressures for short term use without causing sterile filter element collapse problems.

<table>
<thead>
<tr>
<th>Working pressure (bar)</th>
<th>Element change depending on differential pressure (bar)</th>
<th>Element change depending on working conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 4</td>
<td>0.05</td>
<td>Latest after one year or 40 sterilisation cycles, depending on type of sterilisation (hard/soft) possibly earlier</td>
</tr>
<tr>
<td>5 - 16</td>
<td>0.35</td>
<td></td>
</tr>
<tr>
<td>17 - 50</td>
<td>0.5</td>
<td></td>
</tr>
</tbody>
</table>

The maximum differential pressure allowable may also be limited by the design specification for the filter housing.
5.8 Sanitisation

5.8.1 Steaming and Autoclaving

EFSTP..STPL sterile filter elements can be repeatedly steam sterilised in situ or autoclaved at 121°C for up to 40 cycles of 15 minutes each cycle without losing their filtration integrity.

5.8.2 Hot Water Sanitisation

EFSTP..STPL sterile filter elements can be sanitised with hot water at up to 90°C for 30 minutes without losing their filtration integrity.

5.8.3 Chemical Sanitisation

EFSTP..STPL sterile filter elements will withstand repeated sanitisation cycles with common agents used at industry standard concentrations. Typical sanitising agents include low concentrations of:

- Peroxyacetic acid
- Hydrogen peroxide
- Sodium hypochlorite
- Peracetic acid

Sanitisation protocols are contained in the technical publication ‘Sterilising and Sanitising Filter Assemblies’, available on request.

Note:
Autoclaving, in situ steam sterilisation, hot water and chemical sanitisation can be extremely demanding on the construction of a sterile filter element. To ensure maximum filter life these procedures must be carried out with care. Recommended protocols are contained in the technical publication ‘Sterilising and Sanitising Filter Assemblies’, available on request.