Parker domnick hunter Process Filtration

Setting the standard

Parker domnick hunter brings extensive experience through our Scientists, Engineers and sales representatives to the process of offering specific filtration systems to meet the needs of your production process. Support services are available covering a wide range of activities including scale-up advice from laboratory through pilot scales to production systems, validation support, design and manufacturing of custom housings and filtration products and on-site technical support.

Committed to quality

Quality is of paramount importance to Parker domnick hunter. As such we have been certified to ISO9001 since 1987, providing a quality management system that covers the entire organization including R & D, production, warehousing, materials management and customer support. In addition, our manufacturing facilities operate to the principles of cGMP.

This commitment is underlined by our registration to ISO 14001 and certification to current ISO9001.

Validation and product certification

To certify that Parker domnick hunter products meet the required regulatory and quality standards of the industries that we supply, all filters are supplied with a certificate of conformance. These certificates are linked to validation documents for both prefilter and sterilizing grade membrane filter products that define methodologies and data appropriate to each filter type. This information typically includes:

- Technical specifications
- Biological safety testing including current USP <88> Class VI - 121 °C Plastics
- Extractable testing including 21CFR211.72 and 210.3(b), 6 for fibre releasing filters
- Purified water filtration quality including TOC, bacterial endotoxins, conductivity and particle release
- Chemical compatibility information
- Thermal stability
- Correlation of an appropriate non-destructive integrity test to a defined bacterial challenge
- Where appropriate this data is included in Parker domnick hunter’s Drug Master File No. 7564 held at the US Food and Drug Administration repository.

Validation support services

Parker domnick hunter has extensive laboratory facilities and trained personnel capable of providing a range of validation services to support manufacturers in meeting their requirements for process validation relating to the use of filtration products.
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Steam filtration

Steam is an often neglected part of a process, regarded as an add-on to a customer’s liquid or gas filtration needs. It can, however, have large specific applications in its own right.

The quality of steam used within the food and dairy industries has been raised higher on the agenda in an ever increasing number of companies. Minimum accepted standards are now being quoted on a more regular basis with particular reference to ‘culinary grade’ steam.

There is also a growing tendency to install central steam filtration systems that are of high capacity. This requires a specific design of filter to optimize the flow characteristics of the filter medium.

Our range of steam filters is geared to provide a solution for all applications.

Overview of steam quality

The quality of steam can be divided into three distinct categories:

- Process steam
- Culinary steam
- Clean steam

Process steam
This is primarily used in instances where there is no direct contact with the product being manufactured such as indirect heating of products via external steam jackets. In the biotechnology industry applications could include WFI stills, bio waste kill systems, process heating, jacketed autoclaves etc. When adequately filtered it can be used for the sterilization of sterile gas filters.

Culinary steam (3A Standard 609-03)
This is an American standard laid down for the dairy industry and defined as;

“Steam that is free of entrained contaminants, is relatively free of water in liquid form and is suitable for use in direct contact with milk or milk products or product contact surfaces”.

The filtration requirements are, however, applicable to the food and beverage industry as a whole and are being recognized far more outside of the USA. Its growing acceptance is mainly due to a lack of recognized standards for steam outside of the USA.

The Parker domnick hunter range has been specifically developed to target this area.

Clean steam (HTM 2031:1997)*
Clean steam is defined in HTM 2031* as: “Steam whose condensate meets purity requirements of Water for Injection BP [British Pharmacopoeia] (including a limit on pyrogens) with the additional specifications to protect against corrosion of materials used in the construction of sterilizers and medical devices”. The requirements are primarily for the grade of water used to generate the steam. It is, therefore, not possible to produce ‘clean steam’ through filtration.

*Health Technical Memorandum 2031 “Clean Steam for Sterilization”.

General requirements (3A Standard 609-01):
- The steam filter should be capable of removing 95% of particles 2 microns in size and larger in the liquid phase, and should have an associated condensate trap (thermodynamic type).
- The materials of construction of the filter and pipe work should be manufactured from 300 Series stainless steel or above.
- Any additives to the boiler feed water should conform to CFR Title 21, Chapter1, Part 173,Subpart D,Section173.310.
What are the benefits of steam filtration?

Apart from clean steam, when steam is generated in a boiler there are large amounts of contamination from pipe-scale and boiler feed water that need to be fine filtered.

This will ensure that:
• There is no fouling of critical orifices [pressure regulation valves / injectors etc. on filling machines].
• There is no contamination / discolouration of sterile equipment.
• There is no contamination of products.
• There is an increase in process efficiencies [e.g. bulk contamination can lead to an increase in pressure drops in distribution pipelines].
• There is adequate protection to downstream filters. For both liquid and gas filters this can ensure that the filter will not block prematurely or be damaged in service because of the presence of large particulate.

Filter media types

The type of filters used for steam filtration can be divided into three main groups:

Sintered

- Tight pore structure
- Low surface area
- Low flow rates
- Relatively low cost

This product is produced by forming tubes from metal powder under high temperatures and pressures.

Pleated mesh

- High surface area
- High flow rates
- Relatively expensive
- More open structure

The filtration media in this product is made from weaving metal wires to create a mesh.

Pleated sintered metal fibre [pleated microfibre]

- Tight pore structure
- High surface area
- High flow rates
- Higher cost than pleated mesh

This filtration media is produced by sintering together [high temperature and pressure] small metal fibres, to produce a material that is essentially a metal version of glass microfibre media.

Micron range can be as low as 3 micron absolute but as the micron rating drops the costs rise substantially. The grade used by Parker domnick hunter is the 5 micron product.

The Parker domnick hunter range consists of all three types. The grade used depends on the application.
Filter micron ratings

The effect of condensate

The rating of a filter is dependent on whether it is being rated in gas or liquid. For example, a filter which has an absolute rating of 40 micron in liquid and a nominal rating of 25 micron, will remove particles from a gas stream down to approx 5 micron.

The available range of steam filters with quoted rating is as follows:

<table>
<thead>
<tr>
<th>Micron rating in steam</th>
<th>General (Sintered)</th>
<th>General (Pleated Mesh)</th>
<th>Culinary (Sintered)</th>
<th>Culinary (Pleated microfibre)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>25 µm</td>
<td>5 µm</td>
<td>1 µm</td>
<td>1 µm</td>
</tr>
</tbody>
</table>

A nominal rating is given for steam as the true rating is dependant on the water content. Even though most steam is dry saturated, it is not completely free from entrained water. Typically dry saturated steam has a dryness fraction of around 95%. Rather than trying to complicate the whole subject by quoting the rating as a function of dryness fraction the above general ratings have been adopted.

If large quantities of condensate are present within the system then the filter efficiency will be reduced from a gas rating to a liquid rating in direct proportion to the amount of liquid present. Therefore, to maximize the efficiency and throughput of the filter, the design of the steam distribution system and housing is extremely important.

For example, a 5 micron pleated mesh filter in a well designed and drained distribution system could provide better quality steam than a 1 micron culinary filter in a poorly designed system with high condensate loads.

True efficiencies can be determined for the worst-case (liquid phase) as in culinary steam standard. Other methods have been adopted such as using titanium oxide powder in an air challenge but this is not representative of the application.

The efficiency in the liquid phase for the pleated metal fibre product is shown below:

![Efficiency graph for culinary grade pleated steam filter](image-url)

Cumulative efficiencies for ZCHS-001 Pleated metal fibre culinary grade steam filters
The steam filter range can be split into two product types: SINTERED and PLEATED. Both types are available in both a general grade and a culinary grade. The filters are housed in the HBACE and VISCE housing range.

Sintered tube
These are available in two micron ratings; 25 micron (general) and 1 micron (culinary).

Pleated mesh and microfibre
These are also available in two micron ratings; 5 micron (general: mesh) and 1 micron (culinary: microfibre)

Jumbo (J) and Multi Jumbo (3J).
The Jumbo cartridge is specifically designed to maximize the flow performance of the filter media by maximizing the bore of the endcap and hence reducing the differential pressure. The area of pleated media has been optimized to match the capacity of the housing connections with respect to steam flow.

For example, a steam system requiring a 5 round 10¨ housing can now be replaced with the 4¨ Jumbo product.

The introduction of the Jumbo filter has also allowed a more cost-effective solution for the pleated range of culinary steam filters for high capacity systems. These systems in the past have all used multiple 10¨ filters. The above new range also gives a great advantage in size over a sintered system for culinary steam. A diagram highlighting the relative size of both solutions is shown below.

Note: For efficient steam distribution it is recommended that steam velocities are restricted to 25 m/sec⁻¹. For more information on the HBA range, please contact Parker domnick hunter.
Which product for which application?

Process steam
This requires basic prefiltration to render the steam suitable for the sterilization of membrane and glass microfibre cartridges. The cartridges used are either the 5 micron PLEATED or the 25 micron SINTERED. Flow rates through both the SINTERED and PLEATED mesh products are high. For accurate details on capacities to allow selection refer to the Parker domnick hunter sizing program.

Culinary steam
The choice of a culinary grade steam filter (PLEATED or SINTERED) is governed primarily by the flow rates required. It is important to note that a sintered culinary grade filter will give the same quality of steam as the pleated metal fibre. The main difference is in the flow capacity. If pipework is old or prone to release of pipescale etc., it is advised that a 5 micron or a 25 micron filter is used as a prefilter.

The table below gives an approximate guide to selecting when a sintered product should be specified over a pleated variant. For each pipe size a maximum flow rate is given, above which a pleated product should be used.

<table>
<thead>
<tr>
<th>Connection Size (inches)</th>
<th>Flow Rate (kg / hr @ 1 barg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5&quot;</td>
<td>All</td>
</tr>
<tr>
<td>1&quot;</td>
<td>&lt; 30</td>
</tr>
<tr>
<td>2&quot;</td>
<td>&lt; 150</td>
</tr>
</tbody>
</table>

To put the difference in flow rates between SINTERED and PLEATED for culinary grade filtration into perspective a 10" pleated filter will flow the same as three 20" sintered filters.

Clean steam
High purity water has been demonstrated to be chemically aggressive, the purer the steam, the more aggressive it can be. It is possible to generate clean steam within a standard distribution system rather than using new stainless steel but corrosion issues are more important to consider. Reaction with the pipework and valves can lead to a hard protective oxide layer (magnetite Fe₃O₄) on the inside of pipes. If the steam is acidic (pH < 7) the layer can be broken down and particulate shedding results. This contamination is usually identified as black or reddish discoloration of products.

To guarantee this particulate does not contaminate, it is recommended (HTM2031) that a 5 micron filter is positioned at the point of use. Parker domnick hunter would install the culinary grade filter or a HIGH FLOW TETPOR II product if particulate free steam had to be guaranteed.

A summary is shown on the flow chart following to aid the selection process.
### Process Steam
- Direct from boiler
- No direct contact with product being manufactured

### Culinary Steam (3A Standard 609-03)
- 95% retention of >2 micron particles in the liquid phase
- Manufactured from 300 series stainless steel
- Any additives to the boiler feed should conform to CFR Title 21, Chapter 1, Part 173, Section 173.310

### Clean Steam (HTM 2031:1997)*
- Condensate to WFI standards

### Applications
- General heating
- Steam jackets
- Bio-waste kill systems

### Applications
- Used in direct contact with food
- Direct contact with food processing equipment and HVAC systems

### Applications
- Pharmaceutical products
- Pharmaceutical plant HVAC systems

### Cartridges
- Required if steam is used to sterilize liquid and gas cartridge filters
- Selection dependant on flow parameters

### Cartridges
- Selection dependant on flow parameters

### Cartridges
- For removal of magnetite particles generated from stainless steel pipes due to corrosive purity of steam

### SINTERED 25 µm
(Selection Criteria)
- Use for relatively low flow rates

### SINTERED 1 µm
(Selection Criteria)
- Use for relatively low flow rates

### JUMBO Filters
(Selection Criteria)
- Highest available capacity

### Pleated 5 µm
(Selection Criteria)
- High flow rate and dirt holding capacity

### Culinary 1 µm
(Selection Criteria)
- Used to maximize steam capacity of pipe

### Culinary 1 µm
(Selection Criteria)
- To conform to HTM 2031 Point of Use filter rated at <5 µm

### HIGH FLOW TETPOR II
(Selection Criteria)
- PTFE membrane 100% removal of magnetite particles generated from stainless steel pipes
Installation of steam filtration systems

General
It is normal in steam distribution systems to limit the velocity of the steam to a maximum of 40 m/sec and in most cases the velocity will be in the region of 25 m/sec. The higher velocities can be used on short branch lines where higher pressure drops may be acceptable.

As a guide the pressure drop through pipes at various line pressures is given below. This is given for a worst case of 40 m/sec and purely intended to give an appreciation of the magnitude of pressure drops involved.

Processing steam at higher velocities has a number of disadvantages such as:
- Noise
- Pipework erosion
- Water hammer
- Required operating pressure not achievable at point of use

<table>
<thead>
<tr>
<th>Filter Type</th>
<th>Pressure drop (mbar) / 10 meters @ 40 m/sec Line Pressure (barg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
</tr>
<tr>
<td>0.5&quot;</td>
<td>100</td>
</tr>
<tr>
<td>1&quot;</td>
<td>60</td>
</tr>
<tr>
<td>2&quot;</td>
<td>30</td>
</tr>
<tr>
<td>3&quot;</td>
<td>15</td>
</tr>
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<td>4&quot;</td>
<td>10</td>
</tr>
<tr>
<td>6&quot;</td>
<td>10</td>
</tr>
<tr>
<td>8&quot;</td>
<td>10</td>
</tr>
</tbody>
</table>

Condensate drainage
The key to an efficient steam distribution system is that of condensate removal. Steam mains can produce a large amount of condensate especially on start up from cold. Even a well lagged line can produce quantities of condensate which, if not properly managed, will cause problems.

For example, a 100 mm diameter pipe 30 meters long carrying steam at 7 barg will produce 16 litres of condensate per hour.

Measures to aid condensate removal can be found in the steam-in-place guide. Contact Parker domnick hunter for further information.

Inadequate drainage of condensate leads to a number of problems, namely:
- Lowering of filter efficiency (gas to liquid)
- Much higher pressure drops
- Difficulty in obtaining the necessary sterilization temperatures at the process
- Premature blockage of filters

Premature blockage of filters
If a large amount of condensate is allowed to build up in distribution lines, debris from the bottom of the pipe will be picked up and carried onto the filter. This could block a culinary grade steam filter extremely quickly. By eliminating condensate the chance of picking up this contamination from the pipes is significantly reduced.

Cleaning of steam filters
Parker domnick hunter can assist with recommendations for cleaning of stainless steel steam filters. Please contact Parker domnick hunter Technical Services Group for further details if required.
Steam filter sizing

A steam filter sizing program is available. This requires the input of steam flow and pressure to generate the differential pressures for each filter size. A pre-selection is performed as part of the program as it omits differential pressure values that are either below 15 mbar or above 250 mbar.

Saturated steam pipeline capacities at specific velocities (schedule 80 pipe)

<table>
<thead>
<tr>
<th>Pressure bar</th>
<th>Velocity m/s</th>
<th>kg/h 15 mm</th>
<th>20 mm</th>
<th>25 mm</th>
<th>32 mm</th>
<th>40 mm</th>
<th>50 mm</th>
<th>65 mm</th>
<th>80 mm</th>
<th>100 mm</th>
<th>125 mm</th>
<th>150 mm</th>
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<tbody>
<tr>
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<td>7</td>
<td>14</td>
<td>24</td>
<td>37</td>
<td>52</td>
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<td>394</td>
<td>648</td>
<td>917</td>
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<td>0.7</td>
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<td>8</td>
<td>17</td>
<td>29</td>
<td>43</td>
<td>65</td>
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<td>182</td>
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<td>430</td>
<td>716</td>
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<td>15</td>
<td>12</td>
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<td>48</td>
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<td>25</td>
<td>45</td>
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<td>100</td>
<td>182</td>
<td>280</td>
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<td>15</td>
<td>19</td>
<td>40</td>
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<td>205</td>
<td>310</td>
<td>465</td>
<td>810</td>
<td>1270</td>
<td>1870</td>
<td>3220</td>
<td>5215</td>
<td>7390</td>
</tr>
<tr>
<td></td>
<td>25</td>
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<td>331</td>
<td>520</td>
<td>740</td>
<td>1375</td>
<td>2080</td>
<td>3120</td>
<td>5200</td>
<td>8500</td>
<td>12560</td>
</tr>
</tbody>
</table>
Technical Support Group activities

Parker domnick hunter have a trained team of Scientists and Engineers available to answer questions regarding the technical capabilities of our products, to assist in the selection and design of appropriate filtration systems and to provide user training programs. The following services can be delivered both on-site and in-house:

- Filterability testing to optimize filter system design
- Advice on the development of integrity testing, steam sterilization and clean-in-place procedures
- Development of validation protocols
- Troubleshooting
- Facility audits to ensure continued optimization of filter use
- Operator training including filtration theory, filter system design and management, validation, etc.

For more information on any of the above support services please contact your local Parker domnick hunter representative.

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