Your Partner in Ophthalmics
Adding value to your business
Whether it is processing viscous products, maintaining preservative levels or preventing specific contamination issues, Parker domnick hunter understands the problems faced by manufacturers of ophthalmic products. Our innovative new product range has been specially developed to reduce your processing costs and ensure product quality and consumer safety.

Products designed with you in mind
Focused on Adding Value to your Business

The foundations of process improvement

Supported by innovative products, state-of-the-art technical facilities and a specialized international team, Parker domnick hunter’s capability is based on understanding the specific needs of your business.

Global support
Part of the $12 billion turnover Parker Hannifin Corporation, we have subsidiaries in 25 countries worldwide, so we can offer you truly global support with a local perspective.

World class facilities
A major global investment programme has created first-class R&D, manufacturing and support facilities across the world. In addition, product and service quality is assured through:

- Commitment to training and education programmes
- Active use of ISO 9001:2000 as a key business management system

Innovation at the core of a dedicated product range
Winovation™, Parker domnick hunter’s class-leading product development programme, has delivered a dedicated application based product range. Our customers are an integral part of our development process and our multi-disciplinary team is focused on developing solutions to meet our customers’ present and future business needs.

This collaboration has led to a comprehensive range of filter formats to satisfy your requirements from R&D through to full-scale production.
Dedicated Support when you need it
Matching resource to your requirements

Parker domnick hunter’s fundamental approach is to integrate our team into yours to accelerate your business growth. You gain direct access to our teams from New Product Development, Laboratory Services, Technical Support, Manufacturing and Quality to provide the right solution delivered on time, every time.

Committed to process improvement
Our goal is to continually improve your productivity, reduce your process costs and ensure the safety of your final product. Our Technical Support Group (TSG) Scientists and Engineers work with your team to define the process needs and produce optimized solutions.

A process audit is an excellent way of identifying and addressing the main risks that may compromise the quality of your production process. From utilities through to your aseptic filling line, we can help identify improvements and advise on areas such as applicable products, system layouts, steam sterilization and integrity testing.

Scaleable solutions
Parker domnick hunter offers a wide range of filter formats to ensure that transition from pilot scale through to production is as smooth as possible with minimal revalidation.

Complete validation support
Parker domnick hunter’s Laboratory Support Group (LSG) can provide full validation services in support of filings with agencies responsible for the regulation of cGMP manufacturing organizations.

Adding value through training
Specialists from across our business can provide training at our state-of-the-art facilities or at your own site.
Typical training courses include:
- Filtration Theory and Practice
- Integrity Testing and Validation
- SIP, CIP and Compatibility Testing

Our training courses make use of e-learning, presentations and experiential learning and can be tailored to your specific needs.
Adding Value to your Production Process

Addressing your targets and goals

Our focus on understanding the unique processing issues faced in the ophthalmics industry ensures we can continue to deliver innovative ways to help you improve your production process.

Parker domnick hunter works with you to:

- Design cost-effective filtration systems, even for difficult to filter products.
- Minimize product losses due to preservative binding onto filter membranes.
- Implement process improvements by streamlining the validation process.
- Deliver high-quality and economical solutions for utilities and sterile gas.

Choosing the right product

The choice for your sterile filtration application will depend upon your manufacturing process and the final composition of your ophthalmic solution. Parker domnick hunter has a range of fully validated sterile filtration products that can address your specific production issues and economize your process.

<table>
<thead>
<tr>
<th>Product</th>
<th>Membrane</th>
<th>Main Feature</th>
<th>Cost Saving Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>TETPOR HP</td>
<td>Hydrophilic PTFE</td>
<td>Zero binding of preservatives</td>
<td>Filling can begin immediately without preconditioning of filters to eliminate product wastage.</td>
</tr>
<tr>
<td>PROPOR SG</td>
<td>PES</td>
<td>Very high flow rates</td>
<td>Faster processing for minimal batch turnaround times.</td>
</tr>
<tr>
<td>PROPOR HC</td>
<td>PES plus PES prefiltor layer</td>
<td>Increased capacity</td>
<td>Economical filtration of difficult to filter solutions with a high concentration of viscosity enhancer.</td>
</tr>
</tbody>
</table>

N.B. This table is for guidance only. Filterability can vary from one solution to the next and Parker domnick hunter recommends that filterability studies are conducted on an individual basis to ascertain the optimal filtration system.
Delivering Cost Effective Filtration
For difficult to filter solutions

Parker domnick hunter has extensive experience in overcoming processing problems associated with viscous and difficult to filter ophthalmic solutions. We can help you to significantly reduce your processing costs by optimizing your system to maximize throughputs, eliminate time delays and minimize filter system size.

The problem
Viscosity enhancers added to ophthalmic solutions, such as cellulose derivatives or hyaluronic acid, can be variable in supply quality producing an ophthalmic product which varies from batch to batch and over time. Even with careful optimization of the mixing process, problems associated with premature filter blockage are still common. This can result in frequent filter changeouts mid-batch, product loss and increased processing time.

The solution
The PROPOR HC has been developed by Parker domnick hunter as a specific solution to this type of processing problem. The optimized membrane configuration, incorporating a high capacity membrane prefiltre layer, ensures maximum throughput of viscous solutions. In combination with our new range of PROCLEAR prefilters this provides the fastest and most cost-effective batch processing available.
Minimizing Product Losses
By eliminating preservative binding

Your choice of filter membrane for sterilizing ophthalmic products can have a major impact on the economy of your system. Parker domnick hunter can offer filtration products that not only guarantee product sterility but are also designed to minimize preservative binding for reduced product loss.

The problem
Product loss due to preservative binding during filtration stages is a major concern in ophthalmic solution production. Membrane chemistry can have a significant effect on preservative binding properties. The choice of filtration membrane is critical in reducing the amount of product wastage through binding and therefore total processing costs.

The solution
The hydrophilic PTFE membrane used in our innovative TETPOR HP filter product consistently outperforms other membrane materials when it comes to low preservative adsorption. Tests conducted using common preservatives benzalkonium chloride (BAK) and polyhexamethylene biguanide (PHMB) have shown this to be true even when compared to PES or PVDF, which are well known for their low binding characteristics. The TETPOR HP can completely eliminate preservative binding, minimizing product loss and ensuring cost-effective processing.

Comparison of product loss due to preservative binding on different filter membranes for a 0.001% solution of benzalkonium chloride (BAK)

* The relative volume of product loss represents the volume at which the concentration of BAK in the filtrate recovers back to 95% of the original concentration, which is typically the point at which the filling operation can begin.
Streamlining the Validation Process
Supporting filter qualification

From solutions for ‘dry eye’ through to invasive cataract surgery, any change to the production process has to be thoroughly assessed and validated to comply with regulatory requirements. Parker domnick hunter can help to remove this potential barrier and ensure re-validation does not stand in the way of improving the economics, robustness and quality of your production process.

How can we help?
• Working with you to develop process specific validation protocols in line with the recommendations of PDA Technical Report 26 (Revised 2008), Sterilizing filtration of liquids.
• Managing and executing validation studies in our dedicated laboratories.
• Providing final reports that can be used in support of your submission of post approval changes [PAC] to your NDA if required.

Our experience
We have conducted comprehensive validation work on a wide range of ophthalmic product ingredients from simple saline solutions to viscosity enhancers, preservatives and APIs:
• Sodium hyaluronate
• Chloramphenicol
• Pilocarpine hydrochloride
• Timolol maleate
• Taufon
• Benzalkonium chloride
• Polyvinyl alcohol
• EDTA [edetate disodium]
• Polyhexamethylene biguanide
• Hydroxypropyl methyl cellulose [HPMC]
Utilities
Underpinning your process

The utilities area is often forgotten but, if not managed correctly, can be the beginning of quality problems within production. Parker domnick hunter has many years’ experience in providing high quality and cost effective solutions into utilities.

Protecting water systems
Due to the nutrient-poor environment of purified water systems, diminutive organisms have been frequently reported to pass through standard 0.2 micron sterilizing grade membranes. The higher retention of the PROPOR LR is directly correlated to one of the more commonly found waterborne organisms (*Ralstonia pickettii*) while maintaining flowrates comparable to existing systems and allowing direct retrofitting.

Ensuring gas quality
Air and nitrogen come into direct contact with your final product and as such their quality is paramount. Efficient sterilization is dependent not only on the performance of the sterilizing grade filter but also on how the gas is supplied and preconditioned.

We can provide a comprehensive range of technologies and services to guarantee the efficient and trouble free operation of your compressed air system. Our qualified service team are able to certify your system to the relevant quality class for your process in accordance with ISO 8573.1:2001. Class 1.1.1. We can also provide tailored nitrogen gas generation solutions if required.

With over 40 years’ experience in the provision of sterile gas to the pharmaceutical industry, we have an extensive range of solutions encompassing filters, integrity test methodologies and system designs to ensure the quality of your final product.
# Pharmaceutical Products

## Sterile liquid filtration

<table>
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<tr>
<th>Product</th>
<th>Micron</th>
<th>Material</th>
<th>Features</th>
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<tbody>
<tr>
<td>PROPOR SG</td>
<td>0.2</td>
<td>Polyethersulfone</td>
<td>High flow, Low preservative binding</td>
</tr>
<tr>
<td>PROPOR HC</td>
<td>0.2</td>
<td>Polyethersulfone</td>
<td>High capacity, Low preservative binding</td>
</tr>
<tr>
<td>PROPOR LR</td>
<td>0.1</td>
<td>Polyethersulfone</td>
<td>Retentive to diminutive organisms, High flow rates</td>
</tr>
</tbody>
</table>

## TETPOR HP
0.2 micron
- Hydrophilic PTFE
- Elimination of preservative binding

## PORECHECK IV
- Integrity Testing
- Bubble point testing
- Diffusional flow / pressure decay testing
- Water intrusion testing

## TETPOR AIR
0.2 micron
- Validated by liquid and aerosol challenge

## TETPOR PLUS
0.2 micron
- Resistant to chemical attack
- Ideal for venting of ozonated water tanks

## HIGH FLOW TETPOR II
0.2 micron
- Unrivaled flow rates
- Validated by liquid and aerosol challenge

## HIGH FLOW TETPOR HT
0.2 micron
- Continuous use at high temperatures
- Validated by liquid and aerosol challenge

## Liquid filtration

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<th>Product</th>
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<th>Material</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROPOR BR</td>
<td>0.2</td>
<td>Polyethersulfone</td>
<td>Bioburden reduction, Maximum throughput</td>
</tr>
</tbody>
</table>

## PROCLEAR PP
0.6 - 100 micron
- Polypropylene
- Particulate removal
- Robust to withstand aggressive chemicals

## PROCLEAR GF
0.6 - 10 micron
- Glass Fibre
- High capacity
- Maximum throughput

## Sterile gas filtration

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<th>Features</th>
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<tbody>
<tr>
<td>TETPOR AIR</td>
<td>0.2</td>
<td>PTFE</td>
<td>Validated by liquid and aerosol challenge</td>
</tr>
</tbody>
</table>

## TETPOR PLUS
0.2 micron
- PTFE
- Resistant to chemical attack
- Ideal for venting of ozonated water tanks

## HIGH FLOW TETPOR II
0.2 micron
- PTFE
- Unrivaled flow rates
- Validated by liquid and aerosol challenge

## HIGH FLOW TETPOR HT
0.2 micron
- PTFE
- Continuous use at high temperatures
- Validated by liquid and aerosol challenge

## Utilities

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<th>Product</th>
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<tr>
<td>OIL-X EVOLUTION</td>
<td>Preconditioning of compressed air</td>
</tr>
<tr>
<td>CRD</td>
<td>Refrigeration dryers, Dewpoints of 3°C [37°F] and 10°C [50°F]</td>
</tr>
<tr>
<td>MAXIGAS</td>
<td>Nitrogen generators, 95-99.999% purity</td>
</tr>
<tr>
<td>PNEUDRI</td>
<td>High efficiency adsorption dryers, Dewpoints of -20°C [-4°F] to 70°C [158°F]</td>
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</table>

## MAXIGAS
- Nitrogen generators
- 95-99.999% purity

## HSA
- Single element sanitary liquid housing
- ATEX, CE and high pressure versions

## HIL
- Pharmaceutical finish single element liquid housings
- Ideal for water treatment and chemical applications

## PNEUDRI
- High efficiency adsorption dryers
- Dewpoints of -20°C [-4°F] to 70°C [158°F]