

# FILTRATION SOLUTIONS PHARMACEUTICAL MANUFACTURING



## Delivering quality filtration products...

As one of Europe's leading manufacturers of process filters, Amazon Filters is able to offer solutions for all your filtration needs.

Amazon Filters' understanding and knowledge of Pharmaceutical processes and applications is our strength. We are fully conversant with the US FDA and European regulatory requirements for the design and use of filtration products. This experience enables us to deliver optimum filtration solutions to the Pharmaceutical Industry.

### Industry Focus

Amazon Filters supplies the world's largest Pharmaceutical companies with a wide range of product and utilities filters. We have experience in a range of applications including:

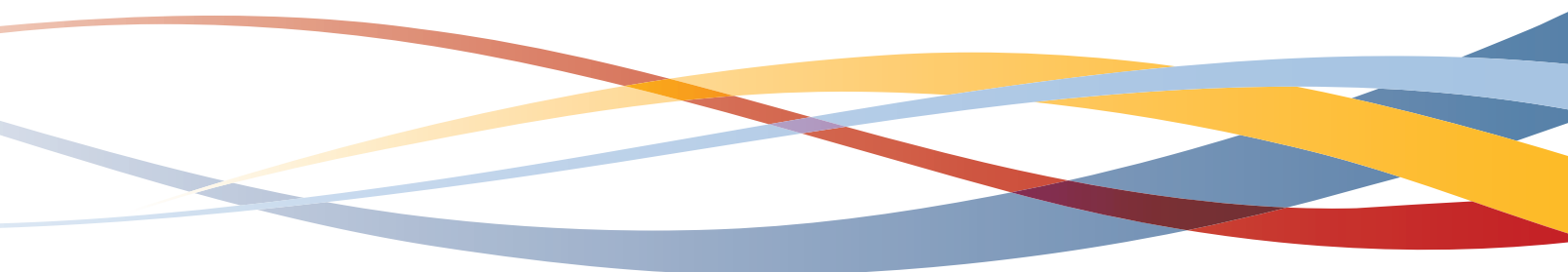
- Product clarification
- Removal of particulates to meet finished goods specification
- Bioburden control
- Sterilising filtration
- Decolourisation
- Carbon and catalyst removal
- Powder traps
- Solvent and chemical transfer filters
- Tank vents
- Bulk and 'point of use' process gas filtration
- Water treatment
- Containment filtration (achieving Operator Exposure Band [OEB] level 4)

Amazon Filters' bespoke filter housing design and manufacturing capabilities enable us to provide filtration systems with improved ergonomics, efficiency and Health & Safety benefits. Filter housings can be designed to International pressure vessel design codes (ASME VIII, EN13445 and PD5500) and are ATEX and Pressure Equipment Directive (PED) 97/23/EC compliant. We are also accredited for self certification to Module H of the PED. Our expertise includes manufacturing vessels using a wide range of stainless steels and exotic alloys.

### Quality Systems

Amazon Filters operates a well established Quality Assurance System which is accredited to ISO9001:2008 by the British Standards Institute with full design and manufacturing approval.

Products supplied to the Pharmaceutical industry are fully traceable and manufactured under clean room conditions. Filters meet the requirements of CFR Title 21 and are USP Class VI Plastics tested.



# Active Pharmaceutical Ingredient (API) Production

Manufacturing high quality API's is critical if the final product is to meet its specification. Amazon Filters has extensive experience in all areas of the API process, from initial filtration of raw chemicals and solvents, through purification of the compound, to particulate control of the finished API.

## Chemical and Solvent Filtration

Amazon manufactures filters using a variety of materials. Therefore we are able to choose the most appropriate filter to offer compatibility with the diverse range of chemicals and solvents used in API manufacturing. Our range of products include depth and pleated filters made from polypropylene, PTFE, halar, nylon and glass fibre. For particularly aggressive or high temperature applications we offer **SupaMesh** filters containing stainless steel media. Filters are available with

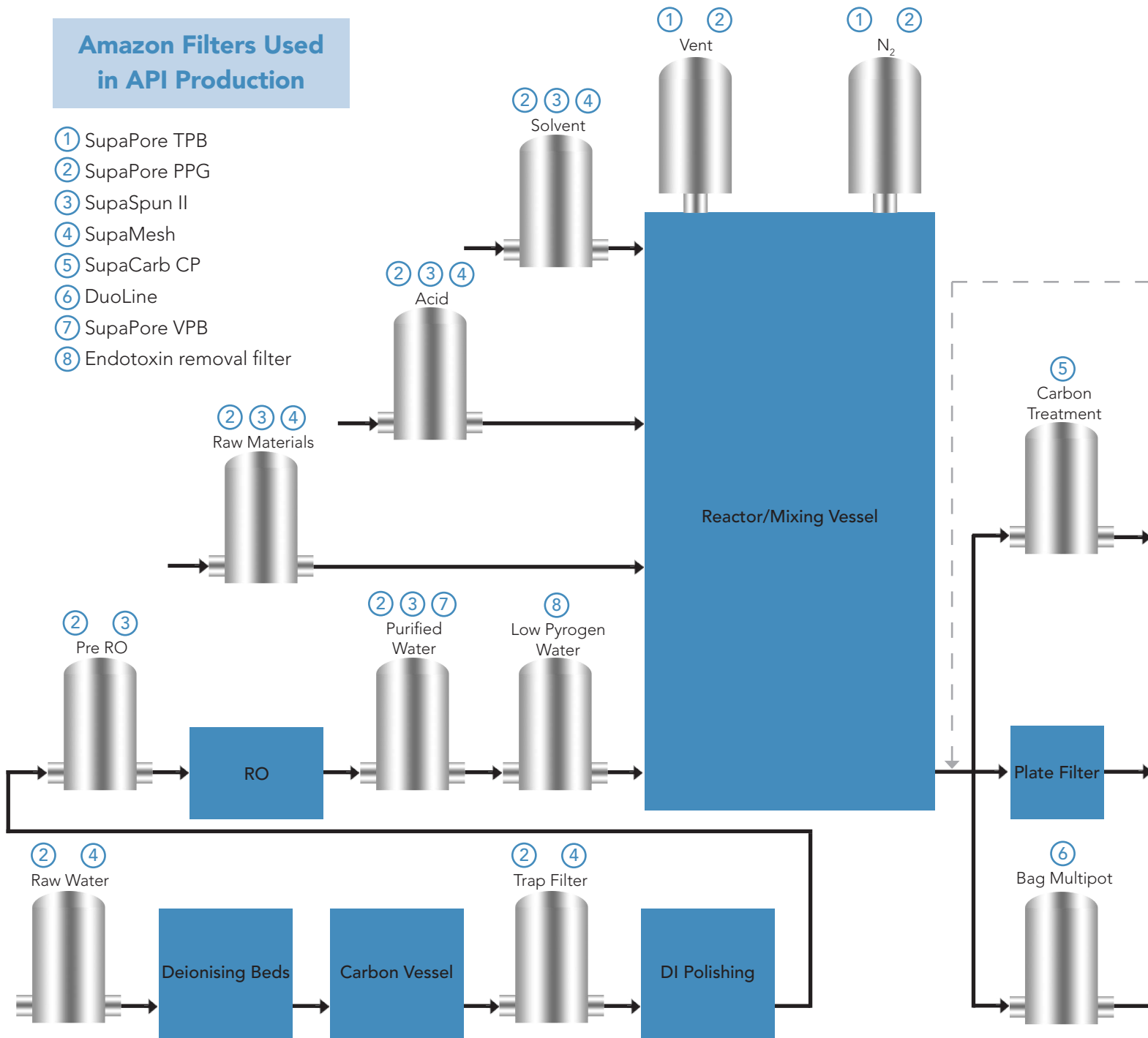
ratings as fine as 0.1  $\mu\text{m}$  to over 100  $\mu\text{m}$ , so are suitable for all particle control applications. Filters typically used are Amazon **SupaSpun II**, **SupaPore TP**, **SupaPore Halar** and **SupaPore PPG** cartridges.

## Solids Removal

During the compound purification process there will typically be a requirement to separate solids formed in the reactor. This can be achieved by build up of 'cake' on the surface of cartridge filters such as **SupaPore PPG** or by utilising **DuoLine** bag filters.

## Amazon Filters Used in API Production

- ① SupaPore TPB
- ② SupaPore PPG
- ③ SupaSpun II
- ④ SupaMesh
- ⑤ SupaCarb CP
- ⑥ DuoLine
- ⑦ SupaPore VPB
- ⑧ Endotoxin removal filter



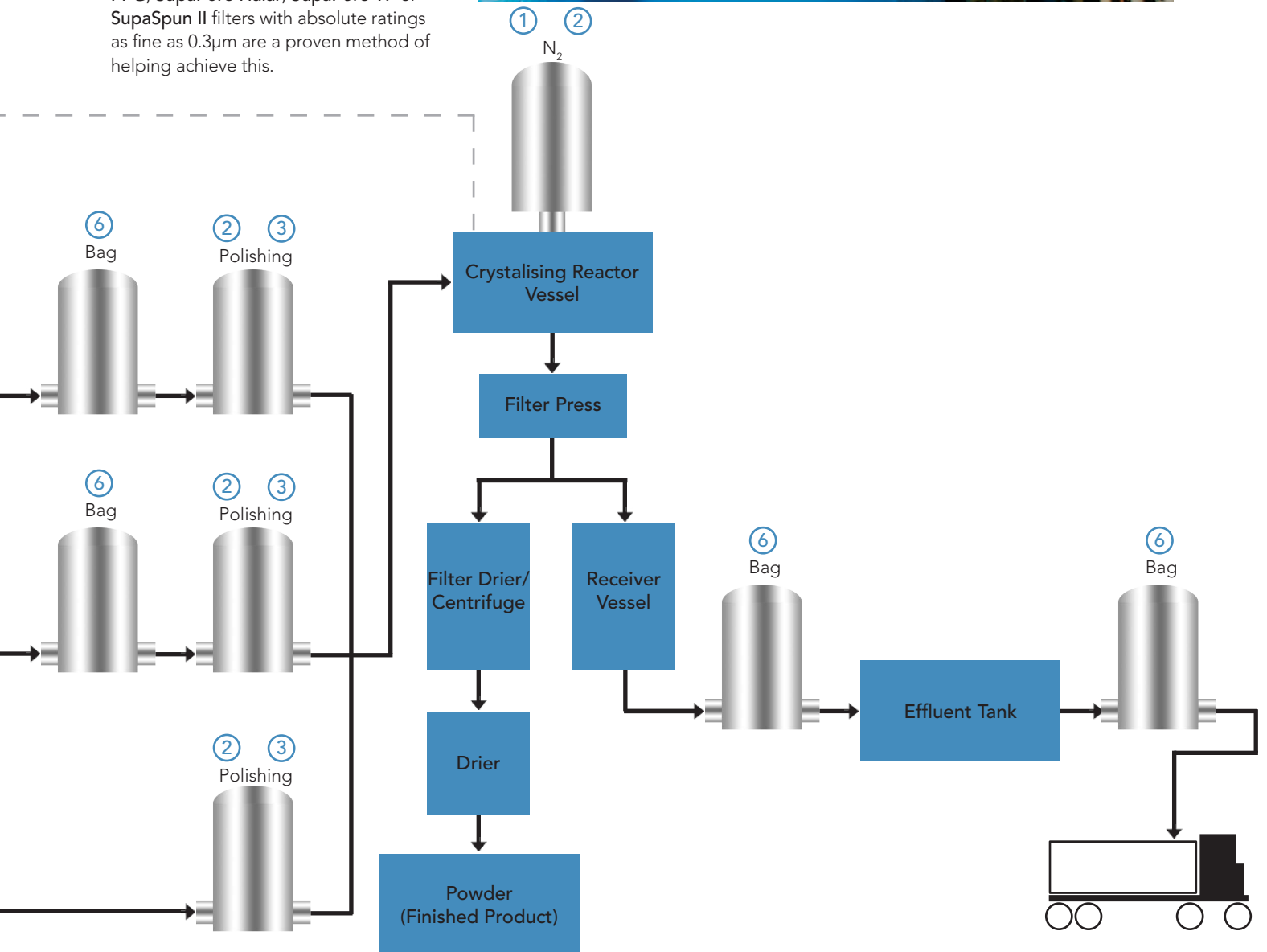
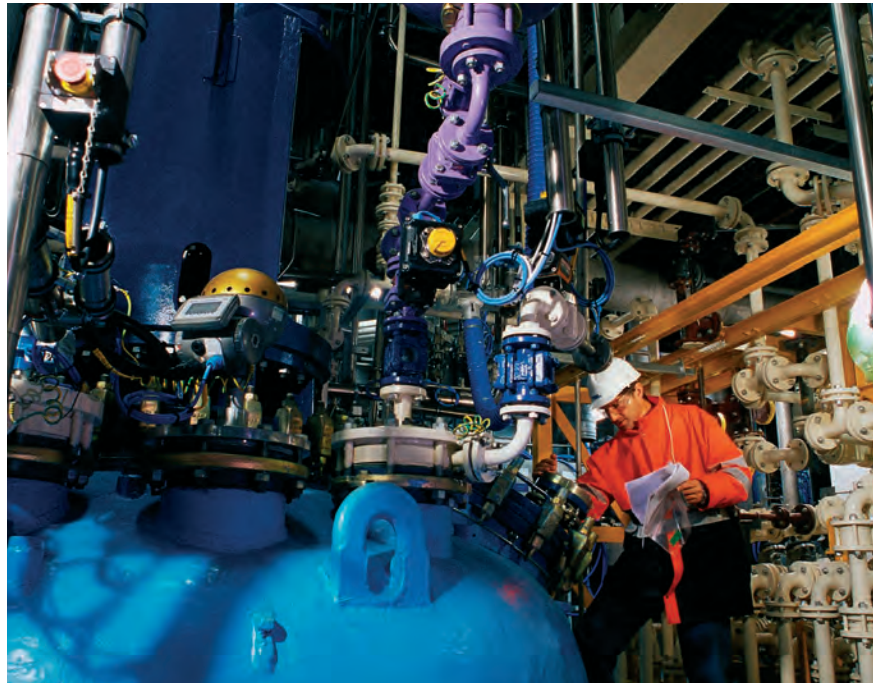
**Carbon Treatment**

Coloured impurities produced during the reaction steps are typically removed by utilising activated carbon. If loose carbon is used filtration will be required to remove the bulk carbon post decolourisation. This can be achieved by using cartridge filters such as **SupaPore PPG** or by utilising **DuoLine** bag filters.

A better alternative is to use Amazon **SupaCarb CP** activated carbon cartridges in single pass or recirculating mode. **SupaCarb CP** cartridges utilise a Pharmaceutical grade activated carbon and offer a more compact, cleaner, easier to handle and cost effective carbon treatment solution.

**Purified API Filtration**

Typically the finished API will need to meet demanding particulate specifications. Amazon **SupaPore PPG**, **SupaPore Halar**, **SupaPore TP** or **SupaSpun II** filters with absolute ratings as fine as 0.3µm are a proven method of helping achieve this.





## Secondary Manufacturing

### Liquids Creams and Ointments

Finished liquids, creams and ointments are expected to be free from visible particles. Filtration is a simple method to help achieve this. Where single batch usage of filters is required, we recommend either Amazon **SupaSpun II** or **SupaPore PPG** filters. Where systems are operated at high pressures or where reuse is preferred we recommend stainless steel media **SupaMesh** filters.

### Sterile Liquids and Parenterals

#### Product Formulation

Amazon Filters is able to offer a wide range of particulate and bioburden reduction cartridges to provide the optimum solution for the filtration of the various liquids used in product

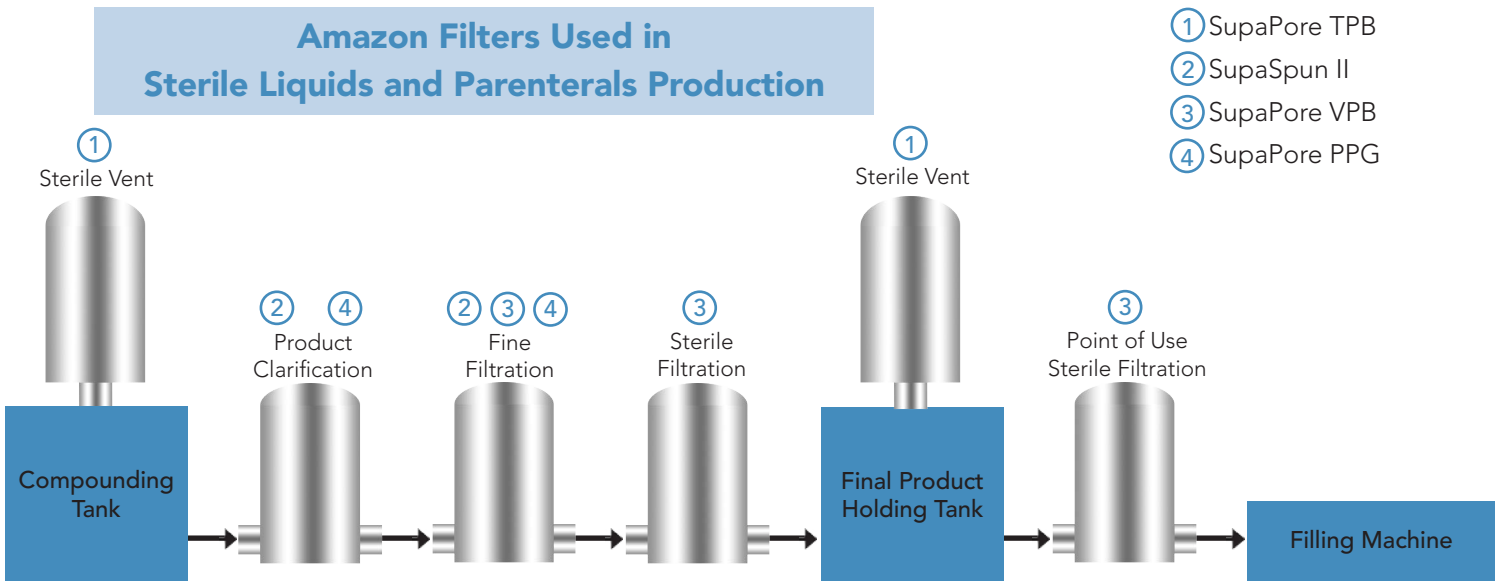
formulation. **SupaSpun II** depth filters (available in absolute ratings from 0.3 - 180 µm) and **SupaPore PPG** pleated cartridges (available in absolute ratings from 0.5 - 100 µm) are ideal for many of the filtration applications found in primary and final formulation areas.

#### Product Sterilisation

Sterility of critical products is achieved typically by autoclaving or by using 0.2 µm rated sterilising grade filters. 0.2 µm absolute rated **SupaPore VPB** filters contain a low absorption polyethersulphone membrane and are fully validated to confirm compliance with the requirements of sterilising grade filters. Filters can be sterilised and integrity tested in-situ and are available in a range of cartridges, capsules, sizes and styles.

Effective prefiltration is vital to ensure sterilising filters do not block mid-process and cause significant operational problems. Therefore Amazon Filters has developed a range of high efficiency prefilters to complement the 0.2 µm rated filter. Absolute rated **SupaPore VPB** prefilters, **SupaSpun II** depth filters and **SupaPore PPG** pleated filters have high removal efficiencies for particulates and bioburden and minimise the risk of premature blockage of the final filter.

### Amazon Filters Used in Sterile Liquids and Parenterals Production



- ① SupaPore TPB
- ② SupaSpun II
- ③ SupaPore VPB
- ④ SupaPore PPG

## Product Support Filters

### Water Treatment

Amazon Filters has years of experience in all areas of Water Treatment processes and our products are an essential resource to this important utility.

Incoming mains water, post Carbon bed traps, pre and post UV and pre-RO filters are just a few of the applications where Amazon products can be relied upon. Typically **SupaSpun II** filters rated from 0.3 - 180 µm absolute, are used for particulate removal and **SupaPore VPB**, rated from 0.2 – 1.0 µm absolute, are used for bioburden control.

### Vent and Gas Filtration

Gases that come into contact with the product should be filtered to prevent contamination. Critical gas applications include blanketing gases, fermenter inlet and outlet, tank venting and filtration of gases used in critical areas.

For these applications we recommend Amazon **SupaPleat Plus** or **SupaPore PPG** cartridges for general particulate control and **SupaPore TP** PTFE sterilizing grade filters for sterile filtration duties.



Amazon is able to offer a range of jacketed housings for vent applications where heating of the filter is required e.g. WFI tank vent.

### Steam

Pipework, tanks and equipment used in manufacturing are often steam sterilised in-situ. Steam used for this should be particulate free to prevent contamination and damage to process filters. For this application we recommend Amazon **SupaMesh** stainless steel mesh cartridges.

### Filter Housings

Amazon Filters standard product range and its bespoke filter housing design and manufacturing capabilities enable the provision of filtration systems with improved ergonomics, efficiency and Health & Safety benefits. We ensure the housings have a high standard of surface finish, are fully draining and suitable for CIP (Clean In Place) and SIP (Steam In Place). The Amazon **70 Series** sanitary housings are ideal for meeting these requirements.

Filter housings can be designed to International pressure vessel design codes (ASME VIII, EN13445 and PD5500) and are ATEX and Pressure Equipment Directive (PED) 97/23/EC compliant. We are also accredited for self certifying to Module H of the PED. Our expertise includes manufacturing vessels using a wide range of stainless steels and exotic alloys.

Where there is a requirement to filter highly corrosive fluids Amazon Filters is able to offer two purpose designed ranges of filter housings – **Tantaline** housings and **18 Series** PTFE housings. These exhibit exceptional resistance to chemical damage.



### Tantaline Corrosion Resistant Housings

A selection of housings from Amazon Filters' range can be modified to provide a surface that is composed of pure Tantalum metal. This produces a product that has far greater resistance to many corrosive chemicals than nickel alloys such as Hastelloy and a significantly more robust surface finish than coated housings.

### 18 Series PTFE Housings

The **18 Series** housings are manufactured from PTFE so exhibit exceptional resistance to the widest range of chemicals. This range consists of two variants, one made from pure unfilled PTFE and one made from carbon filled PTFE. The carbon filled PTFE housing is conductive so reduces the risk of static build-up and discharge and therefore is particularly attractive for processes operated in potentially explosive atmospheres.

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