Acrodisc® Syringe Filters for Analytical Sample Preparation: Quality Assurance and Certifications

Over thirty years ago, Pall Life Sciences revolutionized sample preparation for analytical chemists with the development of the Acrodisc syringe filter. Today we produce high-quality filters for sample preparation and dissolution testing that meet the unique requirements of every lab we serve. Pall's microporous materials and filtration devices are manufactured under precise, highly controlled conditions. Our global manufacturing operations employ Lean Manufacturing and Six-Sigma principles, and internationally recognized Quality Management Systems to produce products of exceptional quality and value. Pall's device manufacturing facilities utilize the most advanced sealing technologies, vision systems and robotics platforms to ensure optimum lot-to-lot consistency. Read on to learn more about our quality assurance and certifications.

ISO Certification - Speaks to the Quality of Pall

HPLC Certified for Low Extractables

IC Certified for Low Levels of Inorganic Extractables

Automation Certification

Manufacturing Quality Assurance

ISO Certification - Speaks to the Quality of Pall

All Pall manufacturing facilities adhere to uniform manufacturing procedures and have been granted International Standards Organization (ISO) certification to ISO 9001. This ensures that Pall filtration products and systems will perform exactly as specified, no matter where in the world they are purchased. Pall's Quality Management Systems are ISO 9001 registered. This represents the most comprehensive and rigorous standard in the ISO series of standards for quality management and quality assurance.

Pall Life Sciences manufactures a wide range of filtration and separation products at its Ann Arbor site, including medical filters, sterilizing grade filters for aseptic processing, and laboratory filters.

ISO Certificate of Approval

HPLC Certified for Low Extractables

A filter for HPLC applications is designed to increase accuracy by removing unwanted particles. However, the wrong filter can be a source of contaminants in the form of extractables that elute into the sample from the filter device. These undesired artifacts can jeopardize analytical results. Some extractable concerns include coelution, false quantitation, and extraneous peaks.

Pall Life Sciences specifically selects the highest grade of materials and performs rigorous extraction methods on our membrane products to eliminate the occurrence of undesired artifacts.

Pall Life Sciences HPLC certification ensures that analytical results will not be compromised by extractable filter materials. Our membranes have been tested for compatibility with common HPLC solvents (water, acetonitrile and methanol) using established HPLC procedures. In addition, to verify low levels of UV-detectable extractables, samples of the entire HPLC Acrodisc syringe filter line are evaluated prior to release.

IC Certified for Low Levels of Inorganic Extractables

Contact Us: www.pall.com/contact
Pall Life Sciences certifies that Ion Chromatography (IC) Acrodisc syringe filters have been tested using a highly sensitive IC protocol to monitor inorganic extractables. For Ion Chromatography applications, our IC Acrodisc polyethersulfone (PES) syringe filters are certified for low levels of inorganic extractables. Actual background levels of filter extractables are typically less than 20 ppb for chloride, 6 ppb for nitrate, 1 ppb for phosphate, and 10 ppb for sulfate.

**Automation Certification**

Pall Life Sciences has specifically designed and certified our Acrodisc PSF syringe filters to be fully compatible and reliable for use with automated equipment. The following special features make our syringe filters reliable for worry-free performance 24 hours a day:

- Smooth filter-to-filter release
- Consistent turret advancement
- Exceptional housing strength
- Strict “outside filter geometry”

Acrodisc PSF syringe filters from Pall Life Sciences are the only syringe filters to receive Caliper Life Sciences’ Automation Certified guarantee. This certification is granted to syringe filters that meet the stringent requirements for automated dispensing and robotic handling. Pall is manufacturing these products working in close partnership with Caliper Life Sciences Manufacturing and Engineering teams to ensure proper fit, function, and compatibility with Caliper workstations.

Caliper Life Sciences is the manufacturer of the Caliper® TPW™ Workstation, the APW® Workstation, the MultiDose® Workstation, and the Prelude® Workstation. These robotic workstations are uniquely designed to work best with Caliper “Automation Certified” filters for proper operation.

**Manufacturing Quality Assurance**

**Manufacturing Environment**

Pall Life Sciences strictly adheres to cGMPs and cleanroom practices. In addition, we are registered to the ISO 9001 Quality Systems Standards.

**Quality Control**

In addition to the HPLC Certification performed to evaluate UV extractables, Acrodisc syringe filters undergo several other detailed quality control tests. These tests ensure compliance with the product’s specifications. The quality control tests include:

- visual quality tests
- liquid flow rates
- bubble point
- burst test
- liquid UV/IC extractables for certification

**UV Absorbing Extractables**

UV absorbing extractable testing is performed to verify that a product intended for use in HPLC sample preparation will not contribute a significant amount of UV extractable materials to the sample fluid. This test is intended for all filters that are HPLC Certified.

**Bubble Point**

Statistically representative samples from each lot of Acrodisc syringe filters are selected and tested by the bubble point test to confirm pore size and integrity of the membrane seal. A bubble point is the measure of the amount of air pressure required to force an air bubble through a wetted pore and is in inverse

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proportion to the size of the hole. The bubble point rating is determined when the largest pore yields a bubble; the larger the pore, the less pressure required to form the bubble. Bubble point is expressed in units of pounds/square inch (psi), bar or mbar, or kPa for membranes. (ASTM: F216-80)

**Burst/Pressure Test**

Acrodisc syringe filters are tested for resistance to pressure. This test is a quality and safety test to ensure the Acrodisc syringe filter housings will not rupture at their rated operating pressures. The maximum operating pressure listed in the product literature is well below the actual burst pressure. This pressure rating is tested on every lot of filters.

**Visual Examination**

A machine vision system inspects Acrodisc PSF syringe filters throughout the production process for cosmetic defects. Operators and technicians verify the pad printing on the Acrodisc syringe filters. Lettering quality, accuracy, and proper color-coding stamped on each device are inspected. Package labeling is examined for accuracy of label information.

**Ion Chromatography Extractables**

The IC Acrodisc filter is eluted with 18-MOhm water to determine that the quantity of ionic extractable materials are sufficiently low and that the product will yield accurate analytical results when used in Ion Chromatography experiments. This test is applicable to all filters certified for use in IC Chromatography.

**Liquid Flow Rate Test**

Liquid flow-rate tests are performed to ensure that the Acrodisc product meets flow-rate specifications. To perform this procedure the syringe filter is attached to a regulated, pressurized source of test fluid and the flow rate is determined from the volume of fluid processed in a specific time interval.

**HPLC Certified Membranes from Pall Life Sciences (Recommended Uses)**

<table>
<thead>
<tr>
<th>Membrane</th>
<th>Strong Bases</th>
<th>Acids</th>
<th>Aqueous Solutions</th>
<th>Keytones</th>
</tr>
</thead>
<tbody>
<tr>
<td>GHP (hydrophilic polypropylene)</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Fluorodyne® II (hydrophilic PVDF)</td>
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<td>Nylaflo® (Nylon)</td>
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<td>TF (PTFE)</td>
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<tr>
<td>IC Supor® (PES)</td>
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<tr>
<td>Glass (borosilicate glass fiber)</td>
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