CRITICAL PROCESS FILTRATION, INC.

Filter Validation Support

Filter validation for pharmaceutical production requires extensive testing and documentation. Proving the safety and consistent performance of the filter is critical to assuring both regulatory compliance and high quality pharmaceutical production.

Critical Process Filtration partners with users and third party experts to develop cost-effective filtration systems and perform application-specific tests for filter performance and safety. We provide complete documentation suitable for validation reviews by regulatory authorities.

Review proposed filter system to assure optimal performance

Test the effects of the fluid and process on the filter

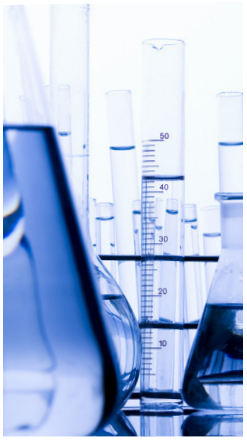
Assure that the filter does not adversely affect the fluid or process

Test filter performance under the conditions of the application

Document test results in a format suitable for regulatory review

System Consulting

The validation process doesn't begin until the filter system has been designed and tested under application conditions to optimize filter life and system cost-effectiveness. Critical Process Filtration's laboratory staff will test designs using disc filters or small capsule filters and a few milliliters or liters of liquid. We strive to get the best life from the filter system using the least amount of filter media at the lowest cost and highest performance levels possible under the operating conditions. We partner with end user personnel to create and execute a test program to find the ideal filter combination.



Filter Pre-Qualification

Critical Process Filtration filters are proven to remove bacteria according to the standard test from ASTM International (ASTM F838-05). We can provide a detailed validation guide showing product specifications and the results of bacteria retention and other tests used to pre-qualify filters for consideration in pharmaceutical applications.

Our validation guides include:

Performance and Safety Data

- Bacteria Retention (ASTM F838-05)
- Sensitization (ISO 10993-10)
- Hemocompatibility (ISO 10993-4)
- Biocompatibility "USP Class VI" (USP <88>)
- Cytotoxicity (ISO 10993-5)
- Gravimetric Extractables (USP<661> NVR)
- Extractables Identification and Quantification (testing based on ISO 10993-18, FDA, EMEA and other guideline documents)
- TOC (USP <643>)
- Conductivity (USP <645>)
- USP Oxidizable Substances
- Bacterial Endotoxins (USP <85>)
- Non-Fiber Release (USP <788>)
- Particle Release (USP <788>)

Filter Specifications

- Water and Air Flow Rates
- Integrity Test Specification
- Operating Limits –
  - Differential Pressure
  - Operating Pressure
  - Operating Temperature
- Heat Sanitization Tolerance –
  - Hot Water
  - Autoclave
  - Inline Steam
- Chemical Compatibility
- Certification of Compliance with 21 CFR (FDA Food Contact)
- Silicone Free Materials Statement
- No Animal Products Statement

Critical Process Filtration supplies users with the results of all of these tests for pharmaceutical and biopharmaceutical grade filters.

Supplier Pre-Qualification

In addition to the documentation of filter performance and safety, pharmaceutical end users should qualify the filter supplier. The supplier should have documentation of a quality system, be willing to provide quality certification with each filter and have the manufacturing and testing facilities appropriate for the industry.

Critical Process Filtration uses state of the art computer controlled equipment to consistently produce high quality products as well as significantly reduce hand operations that can compromise quality. All manufacturing and testing is continuously monitored in real time so that data can be quickly and easily analyzed to maintain high quality and improve cost.

The Critical Process Filtration manufacturing and quality systems meet rigorous ISO 9001:2008 standards. Each operation, including assembly, testing, cleaning, drying and packaging, is done in an appropriately rated clean room. Manufacturing is controlled using a sophisticated system that networks work stations, manufacturing centers and inspection points. During the manufacturing and inspection processes, data is collected in real time to allow continuous quality monitoring and full traceability of all materials and processes. Filter assemblies are integrity tested before release.

Critical Process Filtration invites customers to perform quality and compliance audits at their facilities.

Validation Testing for Specific Applications

Regulatory bodies require that filter performance be tested in conditions that closely resemble the actual application. That is because some pharmaceutical intermediates and ingredients may affect the performance of the filter. Liquids such as solvents and oils can affect flow rates and may affect the retention characteristics of the filters. Some materials may also cause high levels of leachables. To document that the filter will perform under actual operating conditions and will not affect the product, Critical Process Filtration will jointly conduct testing with customers in actual process fluids. Tests are conducted to determine if the filters will perform as required under the "worst case" operating conditions of the application. Those tests include:

- Material Compatibility
  - Filter performance is not adversely affected by the fluid
  - The fluid is not adversely affected by the filter and remains within specifications
- Leachable Identification and Quantification - Provided with a Report Including:
  - Description of analytical techniques carried out on the material, including sample preparation, extraction conditions, and instrumentation settings
  - A list of all identified compounds, per analytical technique.
  - Quantitative and semi-quantitative (Screenings) results of the compounds found in the test article.
- Prove Bacteria Retention in Customer Fluid (ASTM F838-05)
- Establish Fluid-Based Integrity Test Specifications

We work with our customers to perform additional tests, if warranted by operating conditions or specific regulations.

This practice closely follows the recommendations of the Parenteral Drug Association's Technical Report 26 - "Sterilizing Filtration of Liquids". The guidelines in TR26 are followed by most manufacturers of pharmaceutical products as a means to validate their sterile filtration processes and assure compliance with guidelines.

Critical Process Filtration coordinates all testing and offers these services with no additional cost to the user. Our goal is to provide the user with the most cost-effective filtration systems and services possible with the most efficient support possible.

Total Performance

Critical Process Filtration, Inc. is a vertically integrated manufacturer of filtration products for industries in which filtration is considered a critical part of the manufacturing process. We supply a complete line of products and services to help you cost effectively satisfy all your filtration requirements from a single source.

Contact our Technical Service Department to learn more about these and other services we offer.

CRITICAL PROCESS FILTRATION, INC.

Critical Process Filtration, Inc.
One Chestnut Street • Nashua, NH 03060
Tel: 603.880.4420 • Fax: 603.880.4536

criticalprocess.com • sales@criticalprocess.com