



Technology Services
For Total Fluid Management

Qualification Of Integrity Test Equipment

Introduction

Filter integrity testing can be one of the most critical procedures in a filtration process and may be an essential requirement for batch release of a product. The increasing requirement for accuracy and documentation has resulted in a wider use of automated integrity test equipment.

Such equipment must be qualified to ensure that it satisfies both process and regulatory requirements.

How Can Pall Assist?

Expertise

We have over twenty years experience in the design, manufacture, and qualification of PALLTRONIC® integrity test equipment.

Time and cost saving

Our approach to instrument qualification minimizes time and costs.

Quite simply, we make instrument qualification easier for you.

Qualification Tests

Installation Qualification IQ

We check all the equipment components and documentation. The suitability of the testing environment and services are also checked if the instrument is qualified on your site.

Operational Qualification OQ

We offer two options.

1. GAMP* guidelines state that the OQ of standard instruments such as integrity test units can be divided into two parts.



A completed OQ₁ containing extensive qualification studies on a reference instrument. A shorter OQ₂ protocol on your specific instrument is then performed, saving both time and cost.

2. Alternatively, all OQ tests in the form of a standard system acceptance test (SAT) can be performed on your specific instrument. A customized SAT protocol can also be prepared for you if required.

Performance Qualification PQ

We can also assist in generating customized PQ protocols and if required, perform the tests.

Benefits

- Pall's experience and expertise ensures instrument qualification of the highest standard meeting the latest industry and regulatory requirements
- All materials, measuring equipment and labor supplied by Pall for trouble-free testing
- Completed OQ₁ document on reference instruments saves time and costs
- Tests can be performed on site or off-site for maximum flexibility
- The ultimate benefit to you is a faster and more secure qualification process to meet regulatory requirements

* Good Automated Manufacturing Practice guidelines issued by the ISPE

Where are Tests Performed?

At a Pall site

We perform the tests in our purpose-designed laboratories. If required, you can view the testing.

On your site

We set up and perform the tests at your location.

Equipment and Materials

We have all the necessary equipment to ensure that qualification tests are performed accurately and reliably. We also supply materials such as filters. This capability means that we can offer a fast, professional and cost-effective service.

Range of Qualification Service

The service covers the Palltronic FLOWSTART™ and Palltronic AquaWIT™ instruments. Specialized versions of these instruments can also be qualified as appropriate.

Documentation

Standard Qualification & Validation Documents

Standard protocols for IQ/OQ₂ or SAT can be purchased from Pall. Completed OQ₁ documents are also available together with validation support documentation based on GAMP guidelines.

Customized Protocols

We work closely with your specialists to ensure that the format and content of customized protocols meet your requirements.

Reports

On completion of the tests, the final reports are reviewed, approved and signed by a competent Pall specialist. The full documentation is then submitted to you for approval.

Charges

Wherever possible, we provide a fixed price in advance. Where this is not possible, we will provide an estimate to assist you in budgeting and cost control.



Pall Corporation

2200 Northern Boulevard
East Hills, New York 11548-1289

888.873.7255 toll free
516.484.5400 phone
516.484.0364 fax

Visit us on the Web at www.pall.com

Pall Corporation has offices and plants throughout the world in locations including: Argentina, Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, Hong Kong, India, Indonesia, Ireland, Italy, Japan, Korea, Malaysia, Mexico, the Netherlands, New Zealand, Norway, Poland, Puerto Rico, Russia, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan, Thailand, United Kingdom, United States, and Venezuela. Distributors are located in all major industrial areas of the world.